INFECTED BLOOD INQUIRY – WRITTEN SUBMISSIONS ON BEHALF OF THE CORE PARTICIPANT CLIENTS REPRESENTED BY THOMPSONS SCOTLAND

A. THE SCOPE OF THE SUBMISSION

1. The identity of the clients on whose behalf this submission is drafted

1.1 This submission is presented on behalf of the 293 individual clients and the charities Haemophilia Scotland and the Scottish Infected Blood Forum, all of whom are represented by Thompsons Scotland who are core participants in the Inquiry. The clients on whose behalf the submission is presented are referred to collectively in this submission as "the Thompsons clients". It should be observed

at the outset that our representation of a small number of these clients is more limited in scope than others. For those whose infections clearly occurred beyond Scotland, for example, the instructions received are limited to the matters falling within the ambit of the Scottish elements of the Inquiry which affect them.

1.2 The focus of the work done on behalf of the Thompsons clients and hence the focus of this submission is on the occurrence and effects of the blood contamination disaster in Scotland. Almost all of the Thompsons clients are core participants in the Inquiry due to the fact that they or their loved ones were infected in Scotland.

1.3 Numerous written statements by Thompsons clients have been presented to the Inquiry on behalf of their clients. In addition, five "campaign" client statements were presented to the Inquiry by Thompsons clients. A number of the Thompsons clients also gave oral evidence to the Inquiry. Three "campaigner" clients gave oral evidence as well.

1.4 As a result, the body of written and oral which has been heard by the Inquiry forms a unique and valuable representative sample of the infected and affected community from Scotland, their experiences and the circumstances and effects of the disaster. This evidence taken together represents a comprehensive body of largely unchallenged evidence which should generally be accepted as a clear account at least of the clinical care (or lack thereof) received by patients in Scotland in the blood contamination disaster and the considerable effects and impact of the disaster on the infected and affected community in Scotland.

1.5 There are a number of distinctive features of the Scottish infected and affected community and the impact on it of the disaster:

(a) Responsibility for policies/ decision-making in Scotland was vested in a number of entities which were distinctly Scottish, reflecting the fact that over the whole of the period with which the Inquiry is concerned, Scotland had its own, separate health and transfusion services as well as health being a matter which was either part of the administrative devolution arrangements (and was hence within the exclusive competence of the Scottish Office) or part of the more formal devolution settlement after the Scotland Act 1998. The independence of the Scottish National Health Service is reflected in the fact that Scotland had its own

legislation governing this area. The NHS in Scotland was constituted by the National Health Service (Scotland) Act 1947, which imposed a duty on the Secretary of State for Scotland to promote the establishment in Scotland of a comprehensive health service designed to secure improvement in the physical and mental health of the people of Scotland.[1] Of interest to this Inquiry that Act also imposed a duty on the Secretary of State (in effect for Scotland) to establish a system for the prevention, diagnosis and treatment of illness.[2] The Act also provided for the Secretary of State to appoint and receive advice from a national Health Services Council and a standing advisory committee in the operation of the NHS in Scotland.[3] Under the terms of the Act, where the Secretary of State had, in providing hospital and specialist services, acquired supplies of human blood for the purpose of carrying out blood transfusion, or supplies any other substances or preparations not readily obtainable (including presumably blood products, he was empowered to make arrangements to make such supplies available to local health authorities and medical practitioners who required them on such terms, including terms as to the payment of charges, and on such conditions as he determined.[4] By the time of the national Health Service (Scotland) Act 1972, the Secretary of State had an obligation to constitute health boards for the administration of health services to be provided by him.[5] That Act created the Common Services Agency ("CSA") which *inter alia* was responsible for the system of blood transfusion.[6]

The fact that Scotland had its own independent National Health Service and own blood transfusion service (SNBTS) meant that it also had its own transfusion directors and haemophilia directors who met as separate groups or together, often along with representatives of government in Scotland to develop blood

---

[1] National Health Service (Scotland) Act 1947, section 1(1); and National Health Service (Scotland) Act 1972, section 1(1)
[2] Ibid.
[3] 1947 Act, section 1(2) et seq.
[4] 1947 Act, section 19
[5] 1972 Act, section 13(1)
[6] 1972 Act, section 19 and schedule 3

collection, screening, transfusion and associated treatment policies with which the inquiry is concerned. It also had its own fractionation facility at the Protein Fractionation Centre at Liberton, though as the evidence available to this Inquiry has shown products were also made there for use in Northern Ireland and (in times of excess supply) in other parts of the UK. At government level, the Scottish Home and Health Department ("SHHD") within the Scottish Office and then the devolved Scottish Executive post-1999 (subsequently known as the Scottish Government) was charged with the day to day exercise of these responsibilities in relation to health.

However, it must be borne in mind that these arrangements and responsibilities for the administration of matters relating to health in Scotland also occurred within a UK context. As will be demonstrated in a number of areas with which this submission is concerned, this apparently confused structural arrangement led to practical consequences for the people of Scotland which need not have occurred. The apparent freedom and autonomy of the administrative arrangements relating to health thus need to be seen within the more restrictive UK context at both governmental and health service levels. In this context it is also important to note the influences on the decision-making of bodies charged with the administration of the health service in Scotland from national organisations which did not have the Scottish patients at the forefront of their considerations and did not have direct responsibility for Scotland. These included UKHCDO, Royal Colleges nationally, the DHSS, MRC and others, the roles of which are considered below. These arrangements gave rise to issues about the extent to which the bodies with responsibility for Scotland and knowledge of the Scottish considerations did so effectively, given the influential role of these national bodies which exerted direct and indirect control over the Scottish health service;

(b) In the treatment of patients with bleeding disorders, there was a relative lack of use of imported concentrates in the treatment of bleeding disorders, but these still caused infection, as is discussed in detail below. The fact that Scotland was so near self-sufficiency in the crucial periods makes the use of these products

and the consequent infections all the more culpable. The reasons for their continued use despite the advantages from which Scotland benefitted in light of the SNBTS having control over the PFC were not fully realised. The safety of patients was compromised as a result;

(c) Though a smaller number of HIV infections occurred in Scotland as a result of the limited use of US products, in the production of which the plasma used contained more HTLV-III virus, infections from the domestic blood supply occurred which ought not to have done. As far as HCV was concerned the products were 100% infective on first infusion. Given this background, the significance of HCV has achieved greater prominence in Scotland as there are a disproportionately higher number of individuals who are infected with HCV and not HIV in the bleeding disorder community in Scotland. This statistical position influenced political activity and the relative success of campaign groups in Scotland in having HCV recognised as a serious consequence of the blood contamination disaster, viewed independently of the equally tragic consequences of HIV infection;

(d) The widespread use of domestically produced factor concentrates (in some places in Scotland exclusively) meant that the failings in the collection and screening of blood resulted in infections for both the transfusion and the bleeding disorder community. Particular issues in the Scottish experience included the continued reliance on the collection of blood from sources known to be at a greater risk of the transmission of disease when such practices had fallen away elsewhere, including the collection of blood from prisons and military institutions (including US military institutions in Scotland). The Scottish system of blood collection was relatively unsafe. The commitment to the production of domestic factor VIII concentrate was a laudable aim but was only so if done safely. It was not, as the relatively high numbers of HIV infections in both the transfusion and bleeding disorder communities tragically demonstrates;

(e) The reliance on the domestic blood supply for both red cells and plasma for fractionation created the ability for lessons to be learned about diseases emerging in other countries (in particular AIDS) such that they could have been

avoided in Scottish blood and blood products due to the later emergence of diseases in the Scottish donor population. The opportunity to learn those lessons and take appropriate action was not taken and infections were caused unnecessarily as a result;

(f) In Scotland, the collection of blood was characterised over key periods with which the Inquiry was concerned by the drive for plasma for the production of plasma derived blood products, in particular factor VIII concentrate. The result of the constant need for more plasma to feed to apparently insatiable desire amongst the haematologists responsible for the care of those with bleeding disorders in Scotland, coupled with the resistance to using red cell concentrates as opposed to whole blood for transfusion was that unsafe collection practices required to continue, putting both the recipients of blood products but also blood transfusions at unnecessary risk;

(g) In Scotland, there was a late introduction of a domestically produced HCV safe factor VIII concentrate which was not routinely available until April 1987, as opposed to April 1985 in the rest of the UK (8Y). This resulted in HCV infections in the period between December 1984 and April 1987 which were not a feature of the infections which were evident elsewhere in the UK. There was a failure in the way in which the risk assessment undertaken over that period was conducted such that those at risk of infection were not adequately protected. This is addressed as a distinct period below;

(h) As noted above, there was statistically less infection with HIV in the bleeding disorder community then elsewhere in the UK. The infections with HIV within this community and indeed in the transfusion recipient community are no less shocking and tragic. The result of this, however, is more patients whose lives have been blighted by HCV infection. It is important to realise that the concept of "mono-infection" to describe these individuals is, however, inappropriate as (a) those infected in the bleeding disorder community were exposed to multiple pathogens from their pooled products, the precise consequences of which remain poorly understood (as is explored in more detail below) (b) this definition tends to underplay the multiplicity of the harms perpetrated on the infected more generally, in particular the consequences of treatment and the more

subtly presenting consequences, such as psychological consequences of infection;

(i) The failed opportunities to take advantage of the autonomous system of blood collection and transfusion in Scotland along with its undoubted scientific prowess as a result of the overriding drive to ensure consistency across the UK meant that opportunities were missed which would have increased the safety of blood and to an extent blood products in Scotland. These failed opportunities resulted in similar outcomes as elsewhere in the UK which need not have occurred, had Scotland's autonomous system been allowed to operate as it could have done, in particular in the areas of antibody and surrogate testing for infection; and

(j) On a political level, engagement with the Scottish Executive/ Government since devolution in 1999 has meant that the infected and affected community have had a different experience of the outcome of/ response to the disaster. Though many of the features of the disaster which have compounded the harms of the infected and affected have remained the same (such as the inadequate financial support schemes which for many years were run nationally, the inadequate response of the UK government, the lack of proper Inquiry into the circumstances of the disaster), the experience of the infected and affected community in the aftermath of the infections has been somewhat different, though also harmful to them.

1.6 There are, however, other important themes which emerge from the evidence relating to the Scottish experience of the blood contamination disaster which indicates that issues arose in similar ways throughout the United Kingdom, including:

a) The lack of clear decision-making structures involving government and the medical profession to enable decisions to be made, including an unnecessary deference to "clinical freedom" which in effect represented a form of chaos. Though ultimate decision-making power lay with government, the tendency for the government to make advice from the medical profession which did not

consider itself ultimately to accountable created a system whereby nobody took responsibility much to the detriment of patients;

b) The lack of strategic oversight of the way that the system for the provision of blood and blood products was administered, including (but not limited to) the short term nature of the funding practices and the lack of foresight in financial planning;

c) The inherent inertia within the system relating to the use of blood and blood products based on an apparent desire to avoid taking action until "conclusive proof" was available to justify it, despite the inherent dangers of blood and blood-derived products which required a forward thinking and reactive system to be able to operate in the best interests of patients;

d) The investment of decision-making power in autonomous individuals with little apparent accountability to their peers, government or the patients (for example haemophilia directors, regional transfusion directors);

e) The lack of engagement by the medical profession with the patients for whom their efforts were designed, including in the clinical care of patients with bleeding disorders or in receipt of blood transfusions but also amongst those regional transfusion directors who were responsible of the collection of blood and the safety of domestically produced blood products. This element of the disaster is of particular relevance (as it the case nationally) in lack of adequate patient involvement/ informed consent in treatment decisions, failure to inform patients about testing and research conducted on them without their knowledge or consent, the failure to inform patients about their positive tests or to inform them adequately about how they had become infected, the risks to others or the consequences of infection; and

f) The cumulative compounding effects of years of absent or inadequate government action in connection with the disaster which exponentially increased the harm suffered by the infected and affected community, including the failure to recognise the genuine need for a public inquiry to provide answers as to what had happened, the dehumanisation of victims and their relatives by inadequate financial and emotional/ psychological support, their stigmatisation as a result. Though there are particularly Scottish elements to this important

part of the Inquiry's remit, many of the experiences emanate from the UK government or patterns replicated throughout the UK-wide health service and so are common UK-wide.

1.7 The structure of this submission should not be taken as a rigid proposal as to how the subject matter of the Inquiry should be approached – quite the contrary. Though the structure of this submission has been arrived at in order to provide some manageable way of presenting the submissions of the Thompsons clients on the vast array of material available to them, the Inquiry should be careful to take account of the fact that elements dealt with in different sections of the submission were, in reality, happening at the same time. Indeed, it will be submitted that the allocation of issues arising from the dangers of blood and blood products into hermetically sealed topics at the time of the infections with which the Inquiry is concerned was a contributory factor in itself to the outcome of the disaster. For example, it will be submitted that the way in which HIV was viewed by clinicians and the government as a new problem and one which needed to be handled in isolation was a mistake. Instead, it needed to be viewed in the context of the existing known risks of viral transmission by blood and blood products and not as a threat in isolation but a threat in addition to the existing ones. Similarly, the decision to regard the threat of viral transmission by blood products as a threat as a matter for haematologists responsible for the administration of the end products, and not for virologists or infectious diseases doctors aware of the threat or transfusionists aware of the risks of them materialising in the blood supply, was a mistake at the time. The Inquiry is urged not to repeat this mistake and to ensure that it is borne in mind that matters happened in real time differently than the way in which these submissions are presented.

2. <u>The resultant ambit of the submission</u>

2.1 The focus of this submission will be on the blood contamination disaster in Scotland. This is not to say that the evidence which has been amassed by the Inquiry and which relates more directly to the disaster in other parts of the United Kingdom are not relevant to it, as is highlighted in a general sense above. Indeed, the position of those on whose behalf this submission has been prepared is that evidence is of significance insofar as it demonstrates either similarities between events which took place in Scotland, leading at times to the conclusion that efforts to respond to events appear to have been co-ordinated nationally to a certain extent, or differences between what happened in Scotland and what happened elsewhere, the significance of which varies from occurrence to occurrence. Further, there are areas in which the experience in Scotland was influenced or directed by national bodies such that the outcome and experience was the same in Scotland as elsewhere. That was at times done directly and at times indirectly. Therefore, though focussed on the Scottish blood contamination disaster, this submission draws on the national experience as well.

2.2 Where the evidence available to the Inquiry which emanates from beyond Scotland is of relevance to the findings and conclusions which the Inquiry is invited to make relating to Scotland, the relevance of that evidence is highlighted below.

3. The standards to be applied/ approach to limitations in the evidence

(a) Evidence from the infected and affected community in Scotland

3.1 The Inquiry has heard an overwhelming body of evidence in favour of general conclusions which the Thompsons clients would have the Inquiry draw. It is important that the Inquiry hears and attaches due weight to the evidence heard from the infected and affected community and not rely overly on evidence from individuals whose acts or omissions are the subject of potential criticism. It has already been submitted to this inquiry that that was a flaw of the way in which the Penrose Inquiry was conducted which should not be repeated here. It is a feature

of the evidence which the Inquiry has heard that decisions were taken by politicians, clinicians and others for the infected and affected community, without that community being consulted as to its views and priorities. It is fundamentally important in the context of this Inquiry that the same mistake is not repeated, both for the catharsis which the victims of the disaster are entitled to experience from the Inquiry but also in the search for truth. The evidence of those whose acts and omissions is subject to challenge and potential criticism must be viewed sceptically as it was given with that vested interest behind it. This is precisely why the Inquiry has seen fit to spell out in its procedural documentation that the evidence of clinicians will not be treated as if it were independent expert evidence.[7]

3.2 The evidence from the infected and affected community was largely unchallenged orally. It should be taken as a coherent account of what happened as a matter of fact. This is particularly so because of:

(a) The volume of the evidence submitted (in both oral and written form) to the Inquiry coupled with the consistency of the themes which emerge from the evidence of the infected and affected witnesses on matters arising from their own experience;

(b) The honesty and dignity which characterise the evidence given by those infected and affected which, it is submitted adds to its credibility;

(c) The willingness of witnesses to the Inquiry to recognise actions on the part of the medical profession which benefitted them and which they were prepared to recognise as such, which, it is submitted, should have the same effect;

(d) The importance of the subject-matter of the testimony of the infected and affected community to them, which has the effect of rendering it more reliable, especially when compared with any apparently contradictory evidence emanating from clinicians or others. This is particularly the case as much of such contradictory evidence has emanated from clinicians or others who have limited and at times selective memory of events. As regards the circumstances of

[7] Statement of Approach – Questioning of witnesses (updated to 9 February 2022), para 4(a)

individual clinical care, the fact that the system has so often failed to retain contemporaneous medical records or failed to generate accurate records of what happened, which ought otherwise to have been useful evidence about what happened should render the oral testimony of these contradictory witnesses generally to be deemed to be unreliable. They operated in a system in which they never expected to have to remember things which ought to have been recorded in medical notes. That the system has failed to retain accurate notes means that these recollections are generally unreliable. That is not the case for the infected and affected for whom the events being described are generally etched on their memories, such is the impact of them on their lives; and

(e) On more technical matters or matters outwith the witnesses' direct experience, the Inquiry has heard from a number of witnesses from within the infected and affected community whose evidence is persuasive, based as it is on years of detailed research and investigation into the events with which the Inquiry is concerned.

3.3 Clearly, the Inquiry is not charged within its terms of reference with the examination of all of the individual cases of the infected and affected about which it has heard. However, there is an equally clear need to look at individual cases as a basis for drawing conclusions about the systemic issues with which the Inquiry has been charged with examining in its terms of reference. This submission does this where it is considered necessary. There is a need for the Inquiry to strike a similar balance between the need to consider things at a general, systemic or community level and the need to consider the detail of certain, important individual cases, many of which are representative of a wider cohort of patients, as illustrative of the reality of the systemic position. The Inquiry's close attention to the evidence of the infected and affected across the board is significant in this regard. Therefore, the Inquiry will be urged in the submission below to consider (a) certain individual cases which it is submitted and illustrative of the systemic causes of the blood contamination disaster and (b) general themes which arise from the totality of the infected and affected evidence.

3.4 In numerous cases, the issue of missing medical or inaccurate medical records has played a part. The fact that those who were responsible for the retention of records have failed to retain them should not mean that those parties should gain a forensic advantage from their disappearance or inaccuracy. The result of the records being missing in most cases is that the testimony of the patients and their relatives stands unchallenged. In addition, that so many medical records are missing appears to be an issue in itself. The issue is addressed below, where relevant and appropriate. It was also the general position of the Scottish evidence that in many cases contemporaneous medical notes or letters which were invariably not shown to the patients at the time conflict with the patient or affected person's recollection of events. Medical notes might on occasion have been taken to be more a reflection of what the doctor would have liked to have happened as opposed to what actually did. It is submitted below that one recommendation which ought to be made by this Inquiry involved more patient participation in the recording of medical records and the distribution of letters, such as to GPs. This recommendation seeks to encourage patient participation on the process of medical treatment and avoid the issues of inaccuracy which appears to have been prevalent in medical notes and letters which the Inquiry has considered. In general terms, the frequency with which these evidential conflicts arose should result in the Inquiry looking at notes and letters of this nature with a degree of suspicion.

3.5 It is important that the infected and affected analysis of the underlying issues is given due weight and that their evidence is not just viewed presentation as a about their own personal experiences. Their evidence is illustrative of important material and those who have been affected by the disaster are well placed to draw legitimate conclusions about the causes of the disaster. In particular, due regard should be paid to the "campaign" evidence in this regard in both written and oral form. Even where the conclusions which have been drawn by the infected and affected are not accepted as reasonably drawn by the Inquiry, account should still be taken of these conclusions as illustrative of the inevitable and reasonable consequence of the combination of their legitimate and justified need for answers as to what happened to them, the complete lack of explanation and accountability

on the part of those responsible and their own researches. The fact that those who were so consistently kept in the dark have been forced to devote their lives to seeking their own answers and the fact that they have been driven to at times shocking conclusions are in themselves illustrative of a form of harm which has been caused by the disaster and the state's response to it.

(b) <u>The aims of this public Inquiry</u>

3.6 For the Thompsons clients, the Inquiry is an exercise:

(a) in establishing the truth of what happened;

(b) in bringing past and on-going wrongs to light;

(c) in learning the lessons from the disaster to protect all patients who reply on the NHS for safe treatment;

(d) in calling those responsible for past failings to account; and

(e) in providing the opportunity for those who were responsible (i) to acknowledge and accept responsibility for the wrongs that were done by them and on their watch, and (ii) to apologise fully and unequivocally for the harms they caused.

3.7 Thus, the final report of the Inquiry must fulfil the following elements of its remit[8]:

- Fact finding – the Inquiry is charged with establishing the truth of what happened and with bringing past and ongoing wrongs to light. The Inquiry must draw firm conclusions as to why the blood contamination disaster occurred. The language used in the final report must be clear and unequivocal. Suggesting that certain events were "unfortunate" for example where they

[8] See House of Commons Briefing Paper entitled Statutory commissions of Inquiry: the Inquiries Act 2005 (30 January 2018, number SN06410)

were caused by wrongdoing, culpable and/ or were avoidable would serve little benefit to the infected and affected community or the wider public in whose interests the Inquiry has been ordered to take place.

- Responsibility/ accountability – the Inquiry is required by its terms of reference to call those responsible for the failings which led to the blood contamination disaster to account, both at an organisational and individual level.[9] It is extremely important to the victims of the disaster and to the wider public interest that the Inquiry is clear in its final report about what went wrong and about who or what organisations were responsible for those failures. This will assist with the cathartic healing process of those who have been so badly affected and will also provide a strong foundation for useful recommendations to be made and hopefully implemented.
- Victims being respected and listened to is very important in the context of this Inquiry, where over many years the harm experienced by the infected and affected community has been multiplied and compounded, in part by lack of attention being paid to their voices, needs and concerns. By approaching their evidence and their interpretation of the facts in a respectful and compassionate way in the final report, there is a greater chance that the Inquiry will provide the opportunity for catharsis that the infected and affected have cried out for for so many years.
- Recommendations - for the infected and affected community and in the public interest more widely, things must work better in the future if the multiple and consistent failings which have been identified by the evidence are to be avoided. This comprises the necessity for their loss and their needs to be recognised as well as the State's moral duty to look after them but also the public interest in the operation of the health service and government more generally requires to be served by robust and evidence-based recommendations being made.

[9] Infected Blood Inquiry, term of reference 10

(c) The standards to be applied to the issues arising for this Inquiry

3.8 In order that the Inquiry maximises the opportunity for its objectives to be met, it is of fundamental importance that it scrutinises the actions of those who have caused the disaster as a matter of fact with a critical eye. The standard which must be applied to the Inquiry's analysis of decision making/ action or indeed inaction must be whether the actions, decisions, policies or practices were reasonable and in the best interests of patients. This must be the standard to be applied given that the aspiration of the NHS is to be patient focussed and to provide an excellent service to its end users. It is submitted below that in connection with the disaster the State repeatedly acted in breach of its moral duty to the patients and their families. Its moral duty was founded upon a duty to do what was right by those patients for whom it was responsible. In the context of medical care, the State's moral duty to do what is right involves doing what is in the best interests of those patients under its care. It is in the pursuit of the fulfilment of that moral duty that the rules of medical ethics exist, which are the specific manifestations of what the State and those who act as its agents require to do in furtherance of that aim.[10] Actions or indeed inaction which were not in the best interests of patients thereby constate departures from that moral duty and, in specific ways, those ethical rules. This Inquiry must not fall into the trap of treating the decision making of those with the power to make decisions on behalf of the infected and affected community as if this were a clinical negligence litigation in which the traditional defence might have been simply to point to others who did the same thing. Consistency with the practice of the day, however misguided, non-patient focussed and ill-judged such practice might have been cannot be the standard to be applied by this Inquiry. The Inquiry cannot make findings of criminality or civil

---

[10] In the opening words of its publication "Good Medical Practice" the GMC makes clear says that "as a good doctor you will make the care of your patient your first concern". Acting in the best interests of patients is thus the fundament of these specific ethical rules, which in themselves are the practical means by which the State discharges its moral duty to them, through its agents, the doctors.

liability. Equally, the Inquiry must not shy away from making findings which may be equivalent to such findings if judged by others with responsibility for doing so.

3.9 It is also of great importance that matters are judged both (a) from the point of view of the reasonableness or otherwise of decision making at the time, in light of what was or ought to have been known and (b) looking at events with the benefit of hindsight. Though the latter exercise is helpful in trying to judge acts and omissions now with a view to making recommendations in the present, it is also important in the allocation of responsibility to judge what could or should have happened in the context of what was known and could have been achieved consistent with reasonably practicability at the time in order properly to allocate clear culpability and responsibility for what has happened. It is by doing that, in our submission, that it will become apparent that the State was culpable for the occurrence of the blood contamination disaster in multiple ways and that that culpability has created a moral duty for those who have been infected and affected to be looked after and fully compensated for the outcome.

3.10 There is a need for the Inquiry to pay close attention to the identification of those who had responsibility for adverse outcomes, in particular where evidence shows that individuals often took charge of decision making/ policy development. This is not civil litigation and poor practices ought not to be legitimised simply by pointing to others in the same field who did the same thing. Whilst such an approach would not even absolve a clinician of a finding of clinical negligence based on *Bolitho* principles, certainly this approach ought to be of no application here, except insofar as to illustrate the failings of medics, ministers and officials who adopted this inadequate and self-serving approach at the material time, as if their responsibilities to act in the best interests of the infected and affected ended with their legal duty.

(d) <u>The time period with which this Inquiry should concern itself</u>

3.11 We submit that it is important that the time frame within which the Inquiry approaches its final report is not limited. There are various time periods which may be deemed important for the purposes of the Inquiry's examination of certain topics. However, the fact that this Inquiry is concerned with a broad remit, including infection with hepatitis B means that it required to look back significantly into the past in order to understand with clarity the full extent of its remit. Further, in this submission we will stress the importance of looking at the whole issue of the dangers of blood transfusion and any particular period within it in context. It has frequently been claimed both by clinicians responsible for the care of patients infected as a result of blood or blood transfusions and the government that the viral causes of those infections took them by surprise or that their response to the risk of such infections was justified based on incomplete knowledge of the causation and risks of emerging adverse outcomes. Properly understood in their historical context, we will submit that this approach is illustrative of a fundamental problem with the way in which those with control of and responsibility for patients who were treated with blood products were cared for, namely, that despite knowledge of the risks of blood and, in particular, pooled products derived from plasma, they maintained a system which was essentially reactive to the occurrence of infection and not designed to be able to prevent it or react with appropriate alacrity to it. As Professor Contreras stated in her lectures to students the context was one of risk and danger - "Blood can kill". In particular, knowledge of the risks of pooling and the industrialisation of the production of products derived from blood meant that the risks had increased many times over the years, not only from the fact that ever larger plasma pools were adopted but also from the fact that multiple products would be prepared from a single donation, meaning that a single infected donation could transmit infection to the recipient of its various components.[11]

[11] PRSE0002052_0036 – Dr Wallace identified 6 fractions at that time which would be made from a single donation (1977)

(e) The evidence from the Penrose Inquiry and other public inquiries connected to the issues here

3.12 This Inquiry has had the disadvantage of being held any years after the events with which it is principally concerned. The delays in having this UK wide public inquiry are criticised elsewhere in this submission. However, the Inquiry is faced with a real issue in determining how it goes about assessing the various layers of evidential material which it has available to it. Where evidence relates to matters beyond the direct patient experience, there has also been an issue with the reliability of testimony with which the Inquiry has been provided. There are numerous reasons for that including the fallibility of memory and the fact that in certain areas the records of events seem to be incomplete. One witness on whose behalf this submission is presented talked about efforts he had made over the years to try to complete the jigsaw of what had happened to cause the disaster. He frankly admitted that there were areas in which he had had managed to obtain to more of the pieces than others and that the Inquiry would be faced with a similar problem.[12]

3.13 Of particular relevance to the events in Scotland which fall within this Inquiry's terms of reference is the evidence which was gathered and heard by the Penrose Inquiry. Though also held at a period unreasonably removed from the events in question, with different terms of reference and subject to jurisdictional limitations which do not apply to this UK Inquiry[13], the evidence gathered by that Inquiry needs to be considered as part of the evidence available to this Inquiry. This is all the more important as in some instances evidence available to that Inquiry is not available to this one, for example as a result of key witnesses who gave oral or other evidence to that Inquiry having died in the interim period (such as Professor

---

[12] IBI transcript for 09/06/21; 19(20) to 22(19) (Bruce Norval)

[13] See for example the limitations imposed by section 28 of the Inquiries Act 2005 which enable a Scottish inquiry only to look at "Scottish matters" and not to be able to compel production of documentary evidence from the UK government under sub-sections (3) and (4) respectively. The result of these limitations (which are addressed in more detail below) was that the Penrose Inquiry did not have access to the same range of material potentially available to this Inquiry, given its wider powers as a UK Inquiry under the Act, in particular section 27.

Charles Forbes, Dr Ruthven Mitchell, Professor John Cash and multiple medical advisors to government in the 1970s and 1980s) or (as frequently occurred) witnesses who were still able to provide testimony to this Inquiry claiming now to have forgotten the details of events or otherwise relying on the evidence which they gave to the Penrose Inquiry as being more reliable as being nearer to the occurrence of the events in question or prepared or given for example when still in medical practice. In addition, there are certain instances in which the examination of certain topics has necessarily been more limited in this Inquiry, given the width of the respective terms of reference of each Inquiry and the need to consider delay and public expense in getting through the material. As a result and consistently with the approach taken by this Inquiry to the Scottish witnesses, in particular, this submission draws on oral evidence given to both Inquiries as representative of the position of witnesses who gave evidence to both. This consideration applies less to documentary evidence than oral evidence. This is because all of the documents available to the Penrose Inquiry upon which its report was based and which were made available to core participants are, it is understood, available to this Inquiry (Courtbook). The significance of that factual material must of course be analysed in this Inquiry in light of and as a part of the full evidence to which it has access. This is not to say that the analysis of evidence available to the Penrose Inquiry should be approached in the same way as was done in its final report. This is a wholly independent Inquiry with its own terms of reference and access to a huge array of evidential material which was not available or the production of which could not competently have been insisted upon by the Penrose Inquiry, given that it was a Scottish Inquiry in terms of the provisions of the 2005 Act. In accessing it using the evidence available to the Penrose Inquiry, this Inquiry should not accept it or the Chair of that Inquiry's interpretation if it. This Inquiry should approach the material which was available to Penrose judiciously, in light of its full terms of reference and in light of the whole evidence available to it.

3.14 The Penrose material should be looked at predominantly for factual evidence in the form of contemporary documentation or explanation. That should not be confused with subsequent gloss frequently presented to that Inquiry in an effort

to achieve self-exoneration which, it is submitted below, should be viewed with some scepticism. It is inherent in the nature of relying so heavily on the evidence of those who might have been criticised as they held positions of responsibility at material times (as the Penrose Inquiry did) that the gloss given by such witnesses will be designed to achieve self-exoneration. In addition, there is a need for this Inquiry to take care to avoid acceptance of expert evidence in Penrose Inquiry as independent expert evidence as much of its was given by individuals (predominantly medics) from England whose conduct in itself may have been deemed culpably to have caused infections or other harms. Though often expert in the sense of coming from someone with the requisite qualifications, such evidence often (though not invariably) was not independent as it too was tinged with the desire for collective and hence self-exoneration. It seems clear that key witnesses considered themselves to have been giving evidence in that Inquiry in an expert capacity. Both Dr Foster and Dr McClelland confirmed in their statements that they were employed on a full-time basis to work on the Inquiry. In a tribute of which Professor Lowe was a co-author to Professor Forbes, written after his death in 2017, he said the following:

"After retirement, he also spent significant amounts of time as an expert witness to the Scottish Public Inquiry into HIV and Hepatitis C infections acquired as a result of NHS treatment with blood and blood products (the Penrose Inquiry)."[14]

3.15 This Inquiry has access to its own independent expert evidence. In addition, it should not be assumed that all relevant documentary evidence was available to the Penrose Inquiry. For example, advice appears to have been given that any documents held by doctors "personally" were not required for submission to the Penrose Inquiry, even if relevant to its terms of reference.[15] It is unclear why this happened, how it was interpreted or what was lost to consideration as a result.

[14] available via the Royal Society of Edinburgh website
[15] PRSE0001485

Indeed, as pointed out above, this Inquiry has access to all of the documents released by the Penrose Inquiry, which are the documents which that Inquiry based its analysis.

3.16 Additionally, the Penrose evidence of certain individuals who held positions of responsibility should be assessed with care as, although their testimony was nearer the events in question, it was still many years after those events. That evidence was generally not analysed from the victims' perspective, as it was not given against the background of the volume of consistent evidence prepared by the victims of the disaster themselves. The limitations of the passage of play a role in the assessment of the quality of the evidence available to both Inquiries. As time had progressed, the value of what contemporary documentation has increased as a reliable indicator of what happened and why. In order for this Inquiry to be able to reach meaningful answers and conclusions, it should be prepared to draw reasonable inferences from the documents as to what happened, who was responsible etc. This must be the approach which the Inquiry adopts to its assessment of the evidence, in particular where so much of the evidence given to this Inquiry by those who bore some responsibility for the occurrence of infections or their treatment in the aftermath of the infections stated was based on general and/ or specific warnings that they did not remember what happened or that they were not the person directly responsible for the decisions under scrutiny at the time. It should be borne in mind that from the earliest investigations into the disaster, governments have tried to take advantage of the fact that it was difficult to investigate the facts as the events in question had taken place in the past.[16] This is despite the fact that even where limitations on evidence gathering have occurred as a result of the passage of time, it has been inaction on the part of government and its emanations (including the NHS) to secure evidence and take seriously the need for such an investigation that has resulted in that state of

[16] See MACK0001929_029-3 – 23 May 2001, evidence of the then Health and Community Care Minister, Susan Deacon MSP to the Scottish Parliament Health and Community Care Committee in which the fact of events having occurred 15 – 20 years in the past (in the context of information given to patients about the risks and fact of infection) is prayed in aid to defend the Scottish Government's internal inquiry on the issue. The patients' testimony on those matters (discussed below) has remained consistent.

affairs. The infected and affected community has played no part in that. Their right to a thorough investigation into the disaster should not be compromised by it. In order to avoid such an outcome, the Inquiry requires to approach the evidence with this in mind and be prepared to make reasonable inferences from the available material and understand and recognise that in many cases, as a result of this background, the evidence of the infected and affected themselves is the best evidence of what occurred.

(f) <u>The general approach which we would advocate to the evidence of those who may be held responsible for the occurrence of the disaster</u>

3.17 Much of the evidence (which will be analysed in more detail below) involved an *ex post facto* justification for decisions/ actions taken or not taken at the material time. Memories were poor. Generally, this had led to a situation where the evidence given by these individuals to this Inquiry is inherently unreliable as it does not distinguish between the reality of whether matters were thought through at the time, if they were what thought process/ justification lay behind decisions, actions or inaction or whether the justifications or "party lines" which have been adopted subsequently in response to other Inquiries, litigation, investigations and the like have taken over from reality.

3.18 Due to this lack of memory of what actually happened and why, and the distinct possibility of conflation with these justifications for events and memory being clouded by their repetition of these, the best approach is to look at the contemporaneous documents and use reasonable inference. In any event, in many key areas, the evidence provided to this Inquiry was limited by the lack of memory of certain key individuals, who preferred generally to defer to the documents as the most accurate record of what happened.

3.19 Where there are missing documents, those who were responsible for the retention should not gain a forensic advantage from the fact that they are no longer available, in particular where they are documents which in light of the

ongoing controversy surrounding the blood contamination disaster ought reasonably to have been retained by those responsible for them for subsequent examination.

3.20 The "party lines" developed by government and the medical profession should not be accepted at face value. We would urge the Inquiry to be careful in its assessment of the assertions of those in positions of responsibility as to reasons why certain attitudes prevailed at certain times amongst decision makers or for certain actions or indeed inaction on any given issue. In our view, many of the assertions which those in responsibility would claim to be a given or at least an acceptable prevailing point of view, on further analysis can be called into question. Many were formulated subsequently in an *ex post facto* attempt at collective or individual exoneration, as is analysed more fully below. In many cases the impression of what happened at the time the infections were occurring has been heavily influenced by these party lines being taken as the gospel truth when they are often misleading, based on a particular spin or at least not the whole truth. These lines are identified and analysed below as well as the genesis of them. For present purposes, some examples might suffice to illustrate the general point. The party line was developed that there was no alternative to treatment with factor concentrates in haemophilia patients – this line clearly permeated much government thinking about why the disaster in that community had occurred as is explored below. The more detailed analysis of the evidence demonstrates that there is much more to this proposition which required to be examined, such as the difference between bleeding disorders of different severity, the limitations on the analysis often presented about the disadvantages of alternatives such as cryoprecipitate, DDAVP or indeed of avoiding treatment altogether at times the absence of patient involvement in that assessment, and the spin put on the life expectancy advantages of concentrates as opposed to cryoprecipitate. Another example is received wisdom about the state of knowledge of viral infection from blood such as the assertion that NANBH was thought to be benign, that screening had eradicated HBV transmission or that AIDS might not be parenterally transmitted. These arguments have been designed over the years to create confusion when on balance there should have been far more clarity as to the risks

at the time. Similarly, the focus of the transfusion service in Scotland in its self-assessed triumphs when asked about the disaster has resulted in certain mantras being repeated which ought not be accepted as fact. These have been spun to give an impression of what happened and to deflect attention for the failings. For example, the triumph of heat treatment being introduced in Scotland in December 1984 so often presented in the SNBTS's analysis failed to mention that it occurred as result of technology uncovered by others which happened to be able to be implemented by the PFC, that it did not preclude infection with another fatal disease (HCV) on first infusion from a concentrate until April 1987 and that it was instituted after many avoidable infections had already occurred in Scotland. These party lines require to be challenged by this Inquiry in its final report. Often, they are found to be wanting in light of the whole evidence available.

3.21 In general, the approach which the Inquiry should take to the evidence of those who might be responsible for the disaster can be split into two groups. Those whom this submission will criticise as bearing responsibility (or at least representing entities which should bear responsibility) showed certain traits in the way in which their evidence was presented. Many were defensive in the way in which their evidence, as if they resented having to answer for their actions at all; Duncan Macniven, Malcolm Chisholm, Dr Keel and Lord Clarke were examples of such witnesses. Many claimed to have poor memory of certain key elements of the evidence. It was notable that in the evidence of certain witnesses, like Professors Ludlam and Lowe, their memories appeared to fail them at the most crucial points, or the point at which they might be subject to criticism or exposed to conflicting factual evidence. At times, despite having a bespoke arrangement with the Inquiry to give evidence for shorter days than other witnesses, Professor Ludlam found himself "a bit tired" to account for the actions or inaction which brought death or serious disease to so many. Professor Lowe suffered from the same fatigue. In contrast, infected and affected witnesses from Scotland, many ill or discussing the most intimate and horrific experiences of their lives did so with dignity, courage and courtesy, in their cases in person. Professors Ludlam and Lowe had attempted (we understand) to present an unsolicited report of their position to the Inquiry before they gave evidence. We understand that it was

refused. This was an attempt to "capture" the Inquiry with pre-prepared institutional answers, utterances of the "party lines" as opposed to their answers in oral testimony, in our submission. In their oral evidence, they would frequently return after breaks and before being asked the next question, would ask to return to matters previously covered. Such answers should be treated with caution, attempts in our submission to impress pre-prepared answers upon the Inquiry, as opposed to those given spontaneously. Similarly, these clinicians would often not answer the question put to them, instead engaging in lengthy monologues about things they appeared to come with an agenda to discuss, such as Professor Ludlam's lengthy monologue about the diagnosis of the first haemophiliac AIDS patient in Cardiff, as discussed below. A similar, collective report by the haemophilia directors had been prepared and presented to the Penrose Inquiry.[17] In another document, entitled the "Key Topics" paper, the SNBTS sought to define the main issue for that Inquiry.[18] A similar approach was taken by Dr Peter Foster who saw fit in his statement to provide unsolicited "clarifications" of evidence heard by the IBI, as if he were the ultimate arbiter of the matters before the Inquiry.[19] Some seemed very anxious to exonerate themselves individually at all costs, in contrast to the reflective, self-critical approach of others, described below. Examples included Lord Clarke, who was keen to distance himself from any actual involvement in the emerging HIV crisis. Another was Professor Ludlam. In his evidence it was hard to discern that he accepted any even minor criticism at all. It seems hardly credible that he could have made not even a minor mistake. That he was hardly willing to accept any casts doubt on the legitimacy of any of his positions, in our submission. In fact, he was keen to deflect it onto others such as the GMC for not allowing complainers access to his responses (though the very fact of their ignorance of had of course originally been down to him) or the

---

[17] See para 34.71 of the Penrose final report re the "Collective Response" which again indicated that the "part line" was the result of collaboration amongst the directors. As Lord Penrose pointed out, it was not legitimate to refer to a collective response when the directors had been asked about practice at their own centres regarding the provision of information to patients about risks

[18] Para 34 of Brian McClelland statement at WITN6666001

[19] WITN6914001 (witness statement of Peter Foster)

government (for not distributing to clinicians information like the Council of Europe recommendation on AIDS or the Dr Galbraith letter) when he, as an expert in the field, had access to ample information to allow him to make patient-centred decisions. At the time of the infections, Professor Ludlam clearly enjoyed total control over the Edinburgh unit and indeed had significant influence and beyond, in particular in the other east of Scotland units. He rose to be the Chair of the UKHCDO. In hie evidence however, he took no responsibility. In relation to the GMC he said he was appalled by the fact that the explanations had not been given to a complaining patient whom he described as having "very legitimate anxiety" about what the AIDS study was.[20] This showed an almost dissociative state. In blaming the GMC for failing to provide the patient with an explanation about the AIDS study, a state of ignorance which had caused him legitimate anxiety over many years, Professor Ludlam appeared not to understand that the very reason the complaint was being made was that **he** had created that state of ignorance and that anxiety over all those years by keeping patient in the dark about his involvement in the study, such that an explanation he had provided was reasonably views with considerable suspicion. Similarly, Professor Lowe, named as author on the Glasgow immune study research, when asked about it, simply said that he had in fact had no substantive role in it. The opportunity to provide important answers about its contents was simply rejected. By way of contrast, others like Professor Hann fought his corner robustly but accepted responsibility for his shortcomings and took overall responsibility for his unit as the consultant.

3.22 Numerous witnesses who have responded to criticisms made by other witnesses in rule 9 responses have seen fit to blame patients, rely on the sanctity of medical notes (never seen by patients and hence at best a subjective account of events), in the knowledge in many cases that they are incomplete, or their "standard practice" to cast doubt on the testimony of the infected and affected, in the face of their honestly given sworn personal testimony. In many cases in such responses, clinicians have seen fit to mount a forensic challenge on the testimony of the

[20] IBI transcript for 04/12/20; 98 to 99 (Professor Ludlam)

infected and affected in aggressive and defensive tones. The evidence of witnesses like these must be treated with extreme caution, as their testimony as a whole has the appearance as one tailored to suit exoneration as its ultimate goal. Such testimony, like the party lines described below, sought to emphasise certain factors in the analysis, whether they were in fact weighty or not. Care must be taken not simply to accept the analysis as objectively entered into. It was often, in fact, designed for the subject purpose of self-exoneration, in our submission. The familiarity of the mantras, whether applicable or not, had the ring of testimony so often repeated that it had become true to the speaker, whether it was accurate in reality or not.

3.23 Many referred to their evidence to the Penrose Inquiry or indeed the conclusions of that Inquiry as if desperate not to diverge from the evidence they had given at that time or keen to emphasise the conclusions which had been reached in that separate process. The best example of that was Professor Lowe, who frequently referred to the Penrose final report, as if it had determined the matters with which this Inquiry is concerned already. Some gave evidence which was generally vague, lengthy and hard to comprehend, reflecting (by way of example) in the case of Susan Deacon, we submit, a poor grasp of the issues both at the time of her involvement and at the time of her evidence.

3.24 The clinicians, ministers and officials who are criticised in this submission generally gave evidence to the Inquiry without apparent insight or genuine compassion for the suffering of the infected and affected whatever its cause. Such witnesses included Professor Ludlam, Professor Lowe, Lord Clarke (who at time not only lacked insight but was positively and openly disrespectful to the Inquiry process), Dr Keel, Mr Chisholm, Mr MacNiven and Ms Deacon. Their positions can be contrasted with the many witnesses who gave evidence showing genuine compassion for suffering, such as Lord Forsyth and Dr Lorna Williamson to name but two. It should be borne in mind that others who are criticised, including but not limited to Professor Cash, Dr Mitchell, Professor Forbes and Dr Forrester were not able to give evidence to the Inquiry but all have evidence to the Penrose Inquiry. As such they have had their right to give their versions of events under

oath. Others like Mr Kerr and Mr Stock gave statements but were not called to give oral evidence. Their actions are also addressed below.

3.25 Factor concentrates clearly offered many potential advantages in the treatment of patients in Scotland and elsewhere. Their advantages were listed frequently and forcefully in evidence by haemophilia clinicians who gave evidence to the Inquiry. the single-mindedness of this evidence can be explained, it is submitted, for two reasons. First, it reflects the blindness of the time, in particular during Dr Winter's golden interval when the commitment to concentrates became irreversible, though unsafe. Secondly, it represents the mantra of a profession which has been unprepared on the whole to reflect upon the foolhardiness of its approach at that time and to learn from it. The instinct for self-protection has been stronger than any professionally mandated requirement to reflect upon and learn from one's mistakes.

3.26 Others, who are predominantly if not exclusively from the group of clinicians, government officials or ministers whom we would deemed to have mostly done their best at the time, were far more willing to accept criticism of the system. It is no coincidence in our submission that those who performed best at the time were those who were prepared to be self-critical in their evidence. Their willingness to reflect and learn, usually in the interests of providing a natter service to patients was precisely the reason why their efforts at the time of the disaster are less amenable to criticism, in our submission. Examples who broadly fall into that category are the likes of Dr Brian McClelland, Dr Jack Gillon and Professor Ian Hann. The very fact that there were individuals in positions of responsibility who showed themselves to be orientated towards the interests of the patient and patient safety, reflective and self-critical showed, of course, that there was no good reason why others could not and should not have held themselves to the same standards.

3.27 By way of contrast, in our submission, the evidence given to this Inquiry by the infected (and to an extent affected) witnesses was balanced and fair. Their criticism of medical professionals or others who held positions of responsibility was generally clear and specific. It was not gratuitous. Numerous witnesses gave evidence about examples of medical care which they had received which they

wished to be clear to the Inquiry they had found excellent and expressed gratitude for which they wished to register. One such patient infected with HIV and HCV as a result of his treatment for severe haemophilia A wanted to point out to the Inquiry that his treatment for these conditions and indeed his more recent haemophilia treatment had been excellent.[21] In circumstances where disputes arise between the testimony of the patients and the doctors, this factor weighs in favour of the patient evidence being accepted by the Inquiry, in our submission.

B. EXECUTIVE SUMMARY

1. Introduction

1.1. This submission is presented on behalf of 293 individual and 2 charitable core participants represented by Thompsons Scotland. The focus of this submission is on the occurrence and effects of what happened in Scotland; Scotland had its own separate national health and transfusion service throughout the period with which this Inquiry is concerned, and accordingly, we focus on the matters arising from that. However, there is also a UK-wide context that had considerable impact on the position in Scotland; the nature and impact of that UK-wide context is accordingly also explored in detail within this submission.

1.2. Within this submission, we focus on the systemic issues that we say have caused or contributed to the disaster. In doing so, we refer to individual cases where they are illustrative of those systemic issues; we are aware that the Chair of the Inquiry has undertaken to read all infected and affected core participant's witness statements and do not rehearse each and every statement. The community has suffered multiple harms, compounded over the years. Medical and political-decision making has had a profound effect.

---

[21] WITN2117001, para 25 (first statement of WITN2117)

1.3. The Inquiry has heard an overwhelming body of evidence in favour of the conclusions which we submit it should draw as set out throughout this submission. The evidence presented by the infected and affected community must be given due weight. The infected and affected are in the best position to give evidence about what happened to them; their individual stories form the bedrock of the evidence on which we rely to show what happened to each person involved in the disaster, but also demonstrate clear themes that emerge regarding their treatment at the hands of clinicians and the state. There are clear and consistent issues that arise from that evidence, both written and oral, given to the Inquiry in emotional and extremely powerful testimony. On the contrary, the testimony of the clinicians and politicians involved was rarely as open and transparent. Frequently, 'party lines' were rehearsed without apparent recognition of the need to consider their position in light of the evidence heard within this Inquiry. Further, unlike the infected and affected, the clinicians and have little reason to remember a single consultation, meeting, or event amongst the many that they invariably had over the course of their careers decades ago, whereas the infected and affected involvement and recollections of those consultations, meetings, or events are inherently more personal. The Inquiry must accord due weight to the infected and affected's powerful testimony, and must avoid the risk of seeing the evidence of the clinicians as 'expert' or definitive.

1.4. We submit that, in assessing how the disaster occurred, why it occurred, and what the effects of the disaster were, the Inquiry must analyse events on the basis of whether decisions made and policies applied were reasonable, and in the best interests of patients. For the reasons set out throughout this submission, we say that it was because the interests of patients were not put to the front and centre of the minds of the clinicians and the government that the disaster unfolded.

2. Statistics

2.1. The contaminated blood scandal is frequently referred to as being the biggest treatment disaster in the history of the NHS. For the reasons we set out below, this description is not merely a soundbite; it is the reality.

2.2. Indeed, the number of infected and affected is one of the many reasons why the harms suffered by the community have been compounded. The scale of the disaster, and fears about the number of people who may be involved, has influenced government thinking in relation to the response to the disaster; across the decades since concerns first started to emerge, there has been a reticence at the highest levels of government to look into matters, for fear of the true scale being realised.

2.3. In the bleeding disorder community, we submit that the most likely minimum number of infections with HIV in Scotland is 71. Although the position is less certain in respect of HCV infections, we submit the likely number of individuals infected probably ranges from between 459 and 778.

2.4. In the transfusion-recipient community, we submit that at least 18 HIV infections were caused by this route. In terms of HCV infections, the position is even less certain in respect of transfusion-transmitted infections than it is in the bleeding disorder community, but it would seem that at least 2,500 individuals were infected with HCV in Scotland (and the figure could well be higher).

2.5. The evidence suggests that the level of HIV infections amongst those who received blood transfusions is proportionately higher than would be expected having regard to the population size of Scotland. The minimum of 18 infections represents at least 18 times that the systems in place to seek to protect recipients of blood by excluding HIV donors was breached. The system in Scotland was unsafe for reasons explored in Section F of this submission.

2.6. Accordingly, we say at least 89 recipients of blood or blood products contracted HIV as a result of the administration of contaminated blood/ blood products, and at least 3,000 contracted HCV.

2.7. The depth of the impact is immense. The breadth is also enormous. The number of people affected by the disaster is impossible to estimate meaningfully; whole families and, indeed, communities, have felt significant impacts as a direct consequence of the infections of their loved ones.

3. Impact

3.1. The impact of the disaster is impossible to overstate. This Inquiry must catalogue and recognise the themes that have been shown in the evidence to have emerged from the experiences of the infected and affected communities in Scotland.

3.2. It is important that it be recognised that the impact is multi-factorial, and the harms visited upon the communities by the fact of their infections have been compounded again and again by the medical community, the state, and the media.

3.3. The effect of the infections has been wide-ranging; the evidence demonstrates that in very many cases, the infection has had an impact on almost every facet of life: family lives, relationships, social lives, employment, community engagement have all been affected. Trust in fundamental relationships between individuals and the medical community and the state have been destroyed. Countless lives have been lost. The infections and associated treatments have caused life-changing pain and suffering.

3.4. It is essential that the Inquiry consider the impact on a holistic basis, recognising the depth and breadth of the wounds caused by the disaster. The extensive and complex harms have been consistently underestimated. This Inquiry is in a unique position to recognise the true impact of the disaster on the infected and affected.

4. Knowledge about the risk of infections from blood and blood products

4.1. Issues relating to the knowledge about the risks of infection from blood and blood products are multifactorial. They cut across the spectrum of the scientific, medical, and political communities.

4.2. Those responsible for collecting blood cannot claim realistically or credibly that they were unaware of the risks of viral transmission via blood. That serious and

often fatal infections could be transmitted via blood was long known cannot be denied; there was plenty of warning.

4.3. The outbreak of hepatitis following the widespread administration of yellow fever vaccine proved, if proof were needed, that infections could be and were transmitted via blood and blood products.

4.4. Clinicians involved in the administration of blood and/ or blood products were aware of the risks of transmission or should have been; knowledge of the risks was well-known. Acknowledgment of those risks and the understanding of them should have underpinned every decision made regarding the collection of blood and the use of it.

4.5. The knowledge of hepatitis B, and the fact that it could be fatal, should have influenced thinking about the administration of blood and blood products throughout the period over which this Inquiry is primarily concerned. It cannot be said that the risks of blood and blood product usage were unknown or poorly understood; the dangers of administration of them were clear to see for all who cared to look. Pooling of plasma was known to increase the risk of an infection being transmitted to countless recipients.

4.6. Yet recipients were not warned of those risks, so could not make informed decisions about their treatment plans. The knowledge of the risks was not passed on to the vulnerable recipients of the products.

4.7. There was a tendency in the medical community and within government to focus on incidence, rather than risk, irrespective of the knowledge that there were many diseases with a long incubation or prodromal period. Attempts to predict the future by mere reference to the present ignored this known fact. By the time the long-term consequences and effects of infections were accepted, it was far too late. It would not have been had proper attention been paid to the actual and potential risk of the blood and blood products, rather than focussing on the number of patients presenting symptoms from the outset.

4.8. Although in Scotland there were considerable opportunities for clinicians to share knowledge, these opportunities were missed repeatedly. A culture of silos within the medical profession developed, such that different specialities did not adequately liaise with others. Transfusionists were responsible for the collection

and processing of blood and the management of donors. Scientists were responsible for the fractionation of pooled plasma products. Virologists were responsible for looking at viruses. Haematologists were responsible for dealing with bleeding disorders. Obstetricians were responsible for the management of pregnant women and the delivery of babies. Accident and Emergency consultants were responsible for trauma response. There was no or inadequate sharing of information. Assumptions at each stage were made as to the safety of blood and blood products. They should not have been and would not have been had proper systems of information sharing and education been in place.

4.9. It was inevitable that new pathogens would emerge in due course; recognition of this should have meant that precautionary approaches to treatment should have been insisted upon. The ever-increasing use of factor concentrates over the period this Inquiry is primarily concerned with amounted to the unleashing of a juggernaut of treatment based on the use of dangerous concentrates. The dangerous juggernaut of factor concentrate treatment had repercussions across the entirety of the health system. Increasing usage of concentrates necessitated increasing rates of blood and plasma donation to keep up with demand; that meant that donations were collected that should never have entered the system.

4.10. Politicians responsible for oversight and the state's response to known and emerging threats misunderstood and underestimated the nature and scale of the issue. There seemed to be an assumption that the issue was limited to the importation of blood products from the USA, and that the issue was confined to those with bleeding disorders. There was no recognition that in Scotland domestically produced factor concentrates and blood collected within the country were the source of the vast majority of the infections.

5. The collection of blood

5.1. The system for the collection of blood in Scotland was unsafe. It was not focussed on the best interests of end users of the blood and blood products.

5.2. There was a false sense of security that because blood was collected from volunteers it was safe. Donor drives in prisons and military institutions meant that the donations were not, in reality, voluntary. Nor were they safe. Rather, they were the domestic equivalent of the skid row donors which drew condemnation and concerns for safety. That condemnation and those concerns should equally have applied in Scotland.

5.3. There was a failure to recognise that, even in broad terms, safer did not mean safe. There was excessive deference given to the donor because of fears that intimate questioning would result in donors being less willing to donate. It seems that concerns over donors' wellbeing and comfort outweighed any consideration given to the ultimate recipient of the donations, ignoring the fact that, by definition, those recipients were vulnerable in some way.

5.4. Attempts to exclude donors based on vague medical histories taken only from the donor depended on (a) that donor understanding their own medical history sufficiently, (b) donors being in a position to be wholly honest about matters that might give cause for concern from an epidemiological point of view in light of the circumstances in which they were giving blood, and (c) an erroneous assumption about the nature and effect of illnesses that might be transmitted via infection.

5.5. When the threat of AIDS emerged, the reaction of the blood services in Scotland was slow and inadequate. Although attempts were made at the South East Scotland Blood Transfusion Service under Dr Brian McClelland to reduce the risk of high-risk donors giving blood, these were not replicated across Scotland. Blood continued to be taken in some regions from particularly high-risk communities (specifically, prisons and military institutions), leading to multiple breaches of the system, and the infection of scores of recipients of blood and blood products.

6. The screening of blood for viral infection

6.1. Opportunities to introduce surrogate testing for both HIV and HCV were missed in Scotland. In circumstances where (a) the identification of the virus causing illness

took time and (b) the development and introduction of assays to identify those viruses, surrogate testing was the only testing regime that could be introduced to attempt to identify those more likely to be carrying a transmittable virus in their blood.

6.2. Concerns, which were often ill-defined and, in any event, misguided, about the interests of the donors outweighed concerns for the recipients of the end product. Insufficient recognition of the fact that donors might one day themselves require a transfusion meant that donors and recipients were seen in isolation from one another, without comprehension of the fact that it was in the interests of everyone that the collection and screening of blood was as safe as possible.

6.3. There were a series of delays regarding the introduction of direct screening for HIV and HCV, exposing recipients of blood and blood products to risks that could have been avoided or at the very least minimised.

6.4. There was excessive deference to the concept of co-ordinating the introduction of any testing regime with the regional transfusion centres in England and Wales. This created unnecessary delays and was unsafe. Scottish Regional Transfusion Centres could and should have introduced screening before some RTCs in England and Wales were able to do so. The funding models and management principles for the Centres were different between the two nations but the desire for co-ordination, apparently resulting from a misguided belief that if everyone was doing the same, no-one could be criticised, meant that the timing of the introduction of screening was determined by the lowest common denominator.

6.5. This approach, and the resultant delays led to long-term adverse consequences. Those who had the ostensible power in the system in Scotland to influence policy and improve the system disengaged with it when the system needed more engagement and influence. Infections were contracted that could have been avoided had screening been introduced at the earliest opportunities.

7. Treatment with blood products

7.1. Over the years on which this Inquiry is principally focussed, there was an inexorable increase in the use of fractionated concentrates for the treatment of those with bleeding disorders. There has become imbedded in the system over the years the idea that treatment with concentrates was 'necessary' because without them patients would have life-threatening brain bleeds. This was a 'party line' which we say developed after the event to explain why concentrates became and remained the first line treatment for those with bleeding disorders, irrespective of the individual patient's need and presentation.

7.2. There was misplaced focus on the fact that blood products used in Scotland were largely collected and processed domestically. This gave rise to a false reassurance that (a) blood and blood products were sourced from a voluntary system and (b) that made them safe. Although a voluntary donor system might be considered to be *safer* than a system that relied upon paid donors because those who were giving their time and blood without remuneration would be less likely to be incentivised to be dishonest, and more likely to be altruistic ("the gift relationship" concept), it did not in and of itself make the system *safe.* In any event, as explored in Section F of our submission, the collection of blood in Scotland involved collection from donors who could not reasonably be said to be voluntary. Blood was collected from prisoners who could be incentivised by the fact of time away from their cells, or given non-financial inducements such as cigarettes etc.

7.3. The suggestion that the introduction of concentrate therapy led to increased life expectancy amongst those with bleeding disorders is another party line trotted out without thought or proper consideration. Instead, the evidence suggests that treatment with cryoprecipitate had a significant impact on life expectancy; such treatment was less risky.

7.4. Patients were not involved in decision-making about their treatment. They were not told of the risks associated with any particular treatment approach, nor the alternatives that could be used. There was therefore no informed consent on the part of those receiving the products. In some cases, alternatives might have involved no treatment at all, with more focus on lifestyle management; in some cases, there were safer options for treatment such as cryoprecipitate, DDAVP etc. Equally, advice regarding the minimisation of effects of infection was not given.

There was a culture of blind exposure to risk and the denial of opportunities for patients to make informed and reasoned decisions about their own lives and treatments.

7.5. There is clear evidence of ethical breaches of rules about patient treatment and medical research. Patients were involved in research projects by their treating clinicians without their knowledge or consent. The emergence of risks and infections in the bleeding disorder community led to increasing focus on research; steps were taken with a view to advancing medical science, and not necessarily advancing the interests of the individual patient. Samples were taken from patients and tested without their knowledge, and without there being any benefit to the patient themselves from that testing. There is evidence that post-mortem research was carried out in the absence of proper consent.

7.6. The UKHCDO significantly contributed to the disaster; they were responsible for providing advice to government and also generated and disseminated information about haemophilia care amongst professionals. It was an unelected body, dominated by senior medics (many of whom had trained together) with little apparent appetite for dissent or discussion.

7.7. Although Scotland is often feted as having been self-sufficient in factor VIII concentrate, that was never the case until after the majority of the infections had occurred. The ever-increasing use of concentrates (including for home treatment and prophylactics) meant the target for self-sufficiency kept moving, and the need for risky sources of blood/ plasma to be exploited. Even with the emergence of the threat of AIDS, there was no consideration of alternative treatments; cryoprecipitate could have been produced even on a temporary basis whilst safe concentrate treatment was developed, small pool concentrates could have been used to minimise exposure, DDAVP could have been considered in certain circumstances. Yet factor VIII remained the mainstay of treatment.

7.8. Patients were not told of the fact of their infections – in some cases for many years. This gave rise to clear risks of onward transmission of the infections, and loss of trust in the medical community. Patients were tested without their knowledge or consent. We submit this was the result of a domino effect set in motion because of the failure on the part of clinicians to advise their patients about the risks.

Having failed to do so, they could not tell them that they were testing their blood for signs of infection that they had not warned them they might have. Then, when the tests came back demonstrating infection, the clinicians could not tell their patients that this was the case, because it would reveal the earlier failures.

7.9. The manner in which the infected and affected were treated gave rise to understandable and reasonable concerns that they were treated as guinea pigs, that there was a high-level decision to nefariously cover-up the cause of infections, negligence and, indeed, criminality (including suggestions of matters such as intentional infections). Issues with medical records being destroyed, redacted, or incomplete added to such concerns. The secrecy of the clinicians, the contempt for respect for rules and principles of ethics including recognition of patient autonomy, and the failure of those involved to engage with the patients in any meaningful or caring way merely compounded the problem. That people have been left with such beliefs is an indictment of the way they were treated. That is entirely the fault of the clinicians and the state.

8. Treatment with blood transfusion in Scotland

8.1. Blood transfusions were frequently administered by clinicians who were ignorant of the risks associated with such practice. There was inconsistency in practice across the country, and even within hospitals, as to when to give blood and in what quantities. Guidelines were ignored or not even recognised as existing. Blood transfusion was too often seen as a 'simple' intervention when the reality was very much the opposite. Studies showed that there was an overuse and thus unnecessary use of blood.

8.2. Patients were rarely consented; it was considered unnecessary by clinicians administering blood. Although in some cases, the presentation of a patient meant that they were not in a position to consent due to their injuries, there is clear evidence that there was little if any attempt after the critical, acute phase had concluded to ensure that patients were aware of the fact of their transfusion. Little

or no information was provided to patients regarding the risks or effect of transfusion, with little or no long term follow up.

8.3. Record keeping was inadequate so that the fact of transfusion would not always be recorded, or the records would be destroyed without recognition of the long prodromal period associated with some transfusion-transmitted infections. Discharge notes from hospitals were inadequate to allow GPs to recognise or record the fact that their patient had received a transfusion.

8.4. In Scotland, the drive for ever increasing amounts of plasma meant blood was collected from donors who were not truly voluntary. That led to increased risks for the recipients of the red cells derived from those risky donations.

8.5. Many of those infected via blood transfusion were not recognised as such for extended periods; attempts at lookback were inadequate and identified only a small number of those infected. Doctors regularly treated their own patients with disdain, discounting the possibility that symptoms and/ or infections were a result of infections caused by the state, and instead accusing their patients in shocking and destructive ways of behaviour that could cause the infections, such as intravenous drug usage or sexual practices.

9. Domestic production of blood products

9.1 Systemic failures in the collection and processing of blood, poor planning, lack of investment, and a lack of focus on patient safety, combined with a lack of proper licensing control led to the production of factor concentrates at the Protein Fractionation Centre at Liberton which were unsafe.

9.2 The risks associated with the industrialisation of blood products had been known for years, but were ignored in the rush to produce more concentrates before such time as steps to ensure the safety of the product could be undertaken.

9.3 The myth of the single implicated batch was allowed to promulgate the party lines in the response to the disaster. It is clear that there were far more breaches of the blood collection system than focus on that single batch would suggest.

9.4 Party lines have developed that the PFC was one of the first producers in the world to have a heat treated concentrate that rendered it non-infective for recipients in respect HIV. This was the result of a breakthrough in technology developed elsewhere; the PFC simply happened to have the ability to implement that technology at that time. The claim that Scotland were the first country in the world to have an HCV safe factor concentrate for all haemophiliacs was (and remains) an attempt to divert attention from the reality on the ground. By the time that heat treated concentrate was developed, all those with bleeding disorders who had received factor VIII concentrate before then were already infected, given the 100% infectivity rate on administration of concentrates at the time. There was no real benefit for those patients derived from the fact that they *now* had an HCV concentrate. The focus should have been on ensuring that those with bleeding disorders who had not previously been treated with concentrates were able to receive HCV-safe treatment.

9.5 The opportunity provided by the capital investment in the PFC was lost by the ever increasing demand for concentrates and lack of control over the use of products by clinicians. The loss of that opportunity, with fatal effects, means that Scotland was all the more culpable.

10. The procurement of blood products from beyond the United Kingdom

10.1 There could have been no doubt about the increased risks associated with imported products by 1975 when the World in Action programme exposed the clear and considerable risks associated with plasma collection seen in the USA. Yet no attempt to rein in the anarchic principle of clinical freedom having regard to those clear risks was made. The government and its Medicines' Division encouraged the use of products known to carry a materially higher risk than those produced domestically.

10.2 HIV infections in bleeding disorder patients, in particular the infection of children at Yorkhill, could have been avoided had 'clinical freedom' been reasonably constrained.

11. The response to the disaster

11.1. The response of the state to the blood contamination disaster compounded the considerable harms suffered by the infected and affected community. It had started even during the period in which infections were still being contracted. The lack of recognition – indeed, the repeated and uninformed denials – of the nature and scale of the disaster persisted for decades.

11.2. There is clear evidence of the government seeking to avoid taking any responsibility for the disaster from the outset, much less any attempt to engage with the community and learn lessons. The government formulated a co-ordinated response to the HIV litigation in the late 1980s with the oft repeated mantra, "no negligence, no compensation". The focus was not on seeking to ameliorate the condition of those who, through treatment provided by the state, had been left with a disease that was at the time considered a death sentence.

11.3. That approach led to the development of 'party lines' repeated as stock defences for decades in relation to all aspects of the disaster. As knowledge of the scale of the contaminated blood scandal grew, and more and more were found to be infected, the response of the government was not one of openness, transparency and care. It was about shutting down conversations and investigations.

11.4. Many politicians' understanding of the disaster was limited and, in many cases, mistaken. Evidence heard in this Inquiry demonstrates that even some of those in high offices of state were simply wrong about fundamental aspects of the scandal, even when giving evidence to this Inquiry, many years after the event and in light of evidence heard in this Inquiry. Civil servants controlled the information that was given to ministers, and 'lines to take' were repeated even in the face of emerging knowledge and new information. However, it seems that, even now, individuals in

key roles did not see fit to take the opportunity to educate themselves of those fundamental aspects before giving evidence to this Inquiry.

11.5. The tenor and tone of some of those giving evidence, including some of the clinicians from Scotland, over the past 4 years of oral hearings is indicative of the dismissive approach taken to the disaster since it started. Whilst some witnesses have been contrite, apologetic, cognisant of the strength of feeling amongst the community, and aware of the effect their evidence would have on the infected and affected following the proceedings of the Inquiry, others remained combative, aloof and condescending. That they could not even recognise that such an approach would have real impact on the infected and affected speaks volumes.

11.6. In Scotland, there seemed to be a greater willingness to engage (post-devolution) but there remained no real insight into the issues or how to solve them. Early investigations were pointless due to the way they were carried out, but no less damaging to the community who campaigned for justice over the years.

11.7. When apparent progress was made (such as during and following the Ross Committee investigation and report), the hopes of the community were dashed; recommendations were not implemented, proposals were watered down, and there were repeated delays. Those delays tended to end when Westminster intervened, undermining the progress that had been thought to have been achieved, and rendering the final position nowhere near what had been so strongly fought for and recommended in Scotland.

11.8. The hard fought for Penrose Inquiry was required because of the failures of Scottish government to discharge its responsibilities to the Scottish victims of the disaster. That it required a legal challenge for the Inquiry to be set up shows that the system was entirely broken; in Court it was held that the failure to hold a fatal accidents inquiry was a breach of the human rights of those involved.

11.9. Trusts and Schemes which were set up were inadequate to deal with the scale of the disaster; there was no assessment of need, loss, or the moral duty on the state to help those impacted by the scandal.

11.10. The history of the state response in Scotland to the disaster is a sorry one. It compounded the harms in multiple ways. An open, honest, and transparent approach from the outset would have avoided a significant proportion of the

damage caused to the infected and affected community in Scotland over the decade since the disaster first started.

12. Financial trusts and schemes

12.1. The history of the set up, management, and approach of the schemes in place over the years has resulted in confusion, distrust, and frustration amongst the infected and affected community.

12.2. The schemes have frequently been shrouded in secrecy, with little or no engagement with the community. Although the creation of SIBSS was welcomed by the community, and the approach taken by the Scheme and government regarding engagement with the community has served to improve relations, the fact that it focusses on need and not loss means that, even decades after the campaigns for justice began, there has been no state recognition of the moral duty to *compensate* those who have suffered as a result of the disaster. Many affected remain entirely unsupported. Some infected are unable to access the support due to failings on the part of clinicians historically.

12.3. The existence of the SIBSS cannot and must not be considered to discharge the moral duty of the state to the community.

13. Recommendations

13.1. The Inquiry has heard extensive evidence about the issues that led to the contaminated blood disaster and which could and should have been avoided. We seek recommendations that aim to ensure that those mistakes are not replicated. Lessons can and must be learned from this Inquiry.

13.2. The report of Sir Robert Francis KC is welcomed, as were interim payments of compensation to the infected and those who had lost their spouses or long-term partners. The issues are complex, but for a community who have suffered harms

compounded over and over again by multi-factorial matters, and who have contracted serious/ fatal diseases, the issue of compensation is pressing.

13.3. The importance of this Inquiry drawing on all of the evidence it has heard about what went seriously wrong and caused or contributed to the biggest treatment disaster in the history of the NHS and making clear, informed recommendations cannot be overstated.

13.4. It is essential that those who are responsible are held to account.

C. STATISTICS

1. General

1.1 By way of introduction, we would like to emphasise that, in our view, we consider the statistical analysis which the Inquiry has tried to undertake to be an extremely important part of it fulfilling its remit. It requires to assess the numbers infected in terms of term of reference 2. Given the fact that the infections in Scotland occurred as part of a separate health system which was controlled by a separate government department, figures should be given for those infected in Scotland. The Inquiry has been assisted in this regard by the report compiled by the expert statistics group.[22] In addition to performing the important task of recording the numbers infected by the blood contamination disaster, an accurate analysis of the statistical material available to the Inquiry is important for an understanding to be reached as to:

(a) The scale and devastating effects of the blood contamination disaster in Scotland. As we submit below the scale of the disaster is, in itself, a reason why

[22] EXPG0000049

the harms suffered by the infected and affected groups have been compounded. Fears about the numbers who may be involved have clearly influenced government decision making in relation to issues such as financial support and efforts made to trace the infected such as lookbacks, both in the transfusion and bleeding disorder communities. This analysis gives context to those decisions. We consider it imperative that the Inquiry is able to furnish those with the responsibility of caring for the victims of the disaster (and indeed those responsible for preventing a re- occurrence of similar such disasters) with an accurate impression of the numbers of victims involved and the populations in which those victims might be traced, supported and, where necessary, treated;

(b) The causes of and reasons for infection in different populations in Scotland. A thorough statistical analysis enables the proper appreciation of the likely timing of the infections and the infection routes of those infected which, in turn, assists the Inquiry's on what measures might have been taken to avoid such infections;

(c) The role played by measures actually taken to prevent infection in minimising actual infections. A retrospective analysis of the statistical material, in particular in the necessarily epidemiological calculation of the numbers of individuals infected with HCV from blood transfusions requires consideration to be had to the likely effects of screening, donor exclusion etc. By extension this provides a framework within judgements can be made about the likely effectiveness of risk reduction measures which were not taken but could and, in our submission, should have been;

(d) The ability to look at matters across the UK enables a full analysis of the infections in Scotland to be undertaken. A full reconciliation of the information available UK-wide will allow greater accuracy, in particular given the fact that individuals move around the country and so there may be multiple sources of information relevant to the task. Further, the relative success of measures taken by the authorities across the UK can be judged by the numbers of infections in each area and a comparison done;

(e) The accuracy and validity of the assertions of those responsible for the care of those infected. A thorough statistical analysis enables the theoretical assertions

made by those responsible for the administration of blood and blood products to be tested against empirical reality; and

(f) The context within which each individual patient was infected. Many patients and families affected by the disaster described experiencing a sense of isolation, in particular those infected by blood transfusion. Through clarification of the numbers, places and methods of infection, infected patients and bereaved families can gain a greater understanding of the place which they occupy within the disaster.

1.2 The evidence available to the Inquiry to assist with the statistical analysis, in particular in relation to Scotland, comes from a number of sources. The expert group report is, to an extent at least a re-appraisal of the analysis which was done at the Penrose Inquiry. Though this Inquiry's analysis has been done by an independent expert group, the analysis of the numbers infected in the bleeding disorder community was undertaken by the then haemophilia directors in Scotland and the then UKHCDO Chair, some of whom were responsible for the treatment of the patients at the time when they became infected. Thus, the analysis done at that time was not independent. As will be apparent in the analysis, there appear to be some discrepancies in the results which should be noted by the Inquiry.

2. HIV infections amongst people with bleeding disorders

Background

2.1 As was set out in the preliminary report of the Penrose Inquiry, there are a number of figures from different sources as to the total number of HIV infections in Scotland amongst the population of those with bleeding disorders.[23] As on any

[23] Penrose Inquiry preliminary report, paras 3.60 to 3.61 and footnote

view the number of infections is less than 100 in a population of patients who were under regular medical care, giving regular blood samples and were being regularly monitored, it would be a significant failure of the system if an accurate number in this regard could not be arrived at. These are, of course, real people whose lives were inevitably devasted by this condition, not just numbers. Initial figures provided to the Penrose Inquiry suggested that the number of Scottish infections in this population might be either 87 (HPS) or 72 (UKHCDO). As is also recognised in the Penrose preliminary report, there is a need to reconcile these figures.[24] It would appear that the figure of 87 represents the cumulative total number of HIV infected persons who have been resident in Scotland who are believed to have been infected by treatment with coagulation factors.[25] Even in December 1989 (a figure unlikely to have been affected as much by migration as more recent estimates based on residence rather than place of infection) a response to a parliamentary question indicated that there were 76 haemophiliacs who had been infected with HIV in Scotland.[26] It seems hard to believe that migration amongst mostly severe haemophiliacs was particularly prevalent due to their reliance on their local haemophilia centre. The Penrose Inquiry heard oral evidence from the then haemophilia directors, and the UKHCDO as an organisation provided updated material to that Inquiry on the numbers of patients whom it claimed were infected with HIV as a result of exposure to blood products in Scotland.[27] It concluded that the appropriate number of infections in this category was 60, thought the haemophilia directors had reported only 59, about whom information about the precise circumstances of infection are available.

The evidence of the Scottish haemophilia directors at the Penrose Inquiry

---

[24] Penrose Inquiry preliminary report, paras 3.60 to 3.61 and footnote
[25] Scottish Centre for Infection and Environmental Health. HIV infection and AIDS: quarterly report to 31 December 2000. *SCIEH Weekly Report* 2001; 35(3): 18-26
[26] PRSE0004527 (21 December 1989)
[27] PRSE0002887

2.2 The material compiled by and the oral evidence given by the then Scottish haemophilia directors at the Penrose Inquiry regarding the numbers of patients so infected within Scotland did not give a complete picture of the numbers so infected. The information which has been provided to that Inquiry by those directors was taken from the database of the UHKCDO. The directors then applied a certain methodology to that information in order to try to derive a total number of infections likely to have occurred in each of the 6 Scottish haemophilia centres, resulting in a total number of infections for Scotland as a whole. Two of the centre directors wrote to the Inquiry to indicate that they did not think that, on the UKHCDO information provided to them, there had been any infections of patients under the treatment of their centres (namely Inverness[28] and Dundee[29]). An analysis was provided to the Penrose Inquiry for each of the other 4 haemophilia centres in Scotland of the number of patients thought likely to have been infected in each centre. The analysis includes details of the treatment received by each of those patients and the methodology adopted by the appropriate current haemophilia centre director in each centre in the compilation of the information in respect of that centre. These documents came from Edinburgh[30], Glasgow Royal Infirmary[31], Yorkhill[32] and Aberdeen[33].

2.3 Professor Ludlam gave evidence to the Penrose Inquiry on this material and suggested that the total number of infections with HIV of people with bleeding disorders in Scotland was around 59.[34] As indicated above, a further analysis presented to the Inquiry by the UKHCDO as an organisation suggested that the likely number of infections of bleeding disorder patients with HIV in Scotland is likely to be between 68 and 70.[35] Researches with the Macfarlane trust at around the time of the Penrose Inquiry indicated that 67 individuals in Scotland with

---

[28] PRSE0002328
[29] PRSE0000768
[30] PRSE0004860 (spreadsheet) and PRSE0003885 (compiled by Professor Christopher Ludlam)
[31] PRSE0004861 (spreadsheet) and PRSE0004768 (compiled by Dr Campbell Tait)
[32] PRSE0004862 (spreadsheet) and PRSE0001187 (compiled by Dr Chalmers)
[33] PRSE0000235 (spreadsheet) and PRSE0001248 (compiled by Dr Henry Watson)
[34] Penrose Inquiry transcript for 30/03/11 (day 14); 57 (16) to 58 (3) (Professor Ludlam); PRSE0006014_0057 to 0058
[35] PRSE0002887_0035

bleeding disorders who were infected with HIV as a result of their exposure to infected blood products had received payments from the trust. Given the criteria which require to be satisfied before a payment from the trust will be made (including the fact that qualifying patients require to be registered with the trust by their haemophilia clinician), this would tend to suggest that the figures provided by the haemophilia directors (and indeed the number of payments from the trust for that matter) are likely to represent a minimum figure for the likely number of infections in this community in Scotland. Further, the information provided to the Penrose Inquiry by Health Protection Scotland suggested that their records indicated that there were 76 patients with haemophilia who were assumed to have been infected by their receipt of contaminated blood products in Scotland.[36]

2.4 The statistics group in this Inquiry expressed the view that 74 individuals are likely to have been infected with HIV from blood products in Scotland.[37] This information has been obtained from the National Haemophilia database, which is controlled by the UKHCDO. Thus, there is a discrepancy between the figures provided to the Penrose Inquiry by that organisation and the figures which were provided to the expert group. Though the precise reasons for this discrepancy are unknown, it may be accounted for by the fact that a full national analysis has allowed patients resident in England, Wales or Northern Ireland to be identified as infections which occurred in Scotland.

2.5 As a result of an analysis of these various figures, one can conclude that the methodology used in the compilation of the estimates spoken to at the Penrose Inquiry by the haemophilia directors (in oral evidence by Professor Ludlam and Dr Tait) was flawed in a number of respects, with the result that the figures shown by these sources are likely to be an underestimate of the likely total number of HIV infections in this population in Scotland. There are a number of observations which we have to make about this, as follows:

---

[36] PRSE0003663

[37] Statistics group expert report (EXPG0000049) at para 1.14

(a) As the detailed analysis of products and infection timing (based on an analysis of stored samples) was restricted in the Penrose analysis to only those whose infections had been identified by the haemophilia directors, that analysis (undertaken below) is only able to be undertaken on the lower number. This assists in giving a broad picture of the timing and cause of infections, but it cannot be precise as this information was not provided for all of the infections which the UKHCDO now appears to have accepted occurred in Scotland; and

(b) The Inquiry should investigate the reasons why the haemophilia directors came to provide such an under-estimate of the numbers infected to the Penrose Inquiry. For whatever reason, that Inquiry was misled by the evidence by the UKHCDO and its directors.

2.6 In analysing these figures, it should be borne in mind that the information contained within the UKHCDO database is unlikely to be completely accurate. The information spoken to by the haemophilia clinicians at the Penrose Inquiry (even Professor Ludlam who would have had first-hand experience of many of the patients about whom he was speaking) all came from the UKHCDO database.[38] Oddly, Professor Ludlam seemed to derive his understanding of the numbers infected in Edinburgh from the database when one would have expected him, as centre director in Edinburgh throughout the period of both infection and diagnosis with HIV to be able to speak to the numbers infected more directly. To this extent, all of the evidence heard depended on the accuracy and comprehensiveness of the UKHCDO records.

2.7 Further, Dr Hay in his Penrose evidence suggested that details of the products received by each individual patient were historically not provided to the UKHCDO by the clinicians. Other information (including the total quantities of products used in a centre) was traditionally provided but patient specific information about product usage was not, according to Dr Hay, provided until around 5 years before

---

[38] Penrose Inquiry transcript for 30/03/11 (day 14); 10 (25) to 11 (8) (Professor Ludlam); PRSE0006014_0010 to 0011

Penrose.[39] This information was heavily relied upon in the calculation of the likely place, timing and method of infection of individual patients. It was also accepted that the data particularly from the west of Scotland may not have been as reliable as one might have hoped.[40]

2.8 Further, it was accepted by Dr Hay at Penrose that patients at the milder end of the spectrum (in particular sufferers from von Willebrand's disease) may not have had treatment at one of the recognised centres and may therefore not be registered within the system.[41] The data was deemed to be more reliable for the severer patients who would be more likely to be registered with and receive treatment from a recognised centre which would report certain data to the UKHCDO. This did not rule out the possibility of patients having received treatment in Scotland outwith the recognised centres and therefore not having been included in the UKHCDO records at all. Dr Hay appeared to accept that there may well have been patients who were managed outwith specialist centres on whom the UKHCDO would have no data, particularly in the west of Scotland.[42] This would be more likely to give rise to the statistical material missing an infection with hepatitis C than HIV (see below) but given that even blood transfusions transmitted HIV, missing data regarding the infections of milder patients cannot be ruled out. That milder patients treated with plasma derived products (and hence at risk of having been infected) may have escaped the analysis of the UKHCDO was accepted by Dr Hay in his evidence.[43]

2.9 In his Penrose evidence, Dr Hay also confirmed that the database maintained by the UKHCDO was a named database and that they required to comply with data protection legislation (from 1968) which meant that they required the patients' permission for information to be kept within their records.[44] We would suggest that this may have resulted in patients having opted out of their data being

---

[39] Penrose Inquiry transcript for 18/03/11 (day 8); 17 (11) to 18 (2) (Dr Hay); [PRSE0006008_0017 to 0018]
[40] Penrose Inquiry transcript for 18/03/11 (day 8); 10 (9) to 11 (12) (Dr Hay); [PRSE0006008_0010 to 0011]
[41] Penrose Inquiry transcript for 18/03/11 (day 8); 22 (19) to 23 (9) (Dr Hay); [PRSE0006008_0022 to 0023]
[42] Penrose Inquiry transcript for 18/03/2011 (day 8); 54 (1 to 6) (Dr Hay); [PRSE0006008_0054]
[43] Penrose Inquiry transcript for 18/03/2011 (day 8); 41 (6 to 18) (Dr Hay); [PRSE0006008_0041]
[44] Penrose Inquiry transcript for 18/03/11 (day 8); 18 (6 to 11) (Dr Hay); [PRSE0006008_0018]

included within the UKHCDO system.

2.10 We would submit that all of these factors are likely to render the figures spoken to from the UKHCDO database as likely to be minimum figures, given the fact that they all create a risk of patients or patients' data not being included in the analysis presented to the Inquiry as a complete analysis. Further, as regards the analysis conducted by the Scottish haemophilia directors, the way in which infections have been allocated by the haemophilia directors as between Scottish infections and infections likely to have been acquired elsewhere in the UK was flawed. No account was taken of infections of patients who received treatment in Scotland but have not been allocated as a Scottish infection. The methodology applied in the determination of the likely place of infection by the haemophilia directors relied on the proposition that a patient was likely to have become infected (when he has received treatment in Scotland and elsewhere) in the place where he received the majority of his treatment prior to infection.[45] This approach was flawed. The timing of the treatment required to be taken into consideration as there are clearly time periods within which it is far more likely that an individual would have been exposed to an infected product than at other times. None of the material available seems to suggest that anyone became infected in Scotland before 1980. This is due to the fact that the virus was simply not present in the products at that time. The likelihood of a haemophilia A patient being infected from a factor concentrate in Scotland after December 1984 is small given the fact that Scottish factor VIII concentrate was heat treated so as to inactivate HIV by that time. Therefore, a focus on the source of the majority of the treatment over a patient's entire lifetime (prior to infection) may well give an inaccurate impression of the likely place of infection. Further, it appeared to be the position of Dr Tait that the assumption applied to the place of likely infection based on the location of the majority treatment received by the patient prior to the infection was not, in fact, based on the majority of treatment but rather the majority of years of treatment as individual data about the quantity of product received in

[45] See (for example) the methodology statement relating to the patients infected with HIV in Glasgow - PRSE0004768_0001 at Para 4

any one place was not available.[46] Further, the calculations carried out by the Scottish haemophilia directors was carried out in a way which does not allow further scrutiny of their methodology. The analysis which has been carried out and the conclusions which have been presented to the Inquiry by the Scottish haemophilia directors to the Penrose Inquiry were unreliable on this basis.

2.11 In the analysis presented by the UKHCDO in its updated paper to the Penrose Inquiry on statistics, the starting point for this analysis appears to have been individuals who were reported to the UKHCDO by a Scottish centre as having been infected with HIV (73 in total).[47] Dr Hay had spoken (in connection with the figures initially presented to the Inquiry by the UKHCDO on this subject) to the fact that the data provided by the UKHCDO appeared to provide the data as to how many people with bleeding disorders who suffered from HIV were managed in Scottish centres, rather than how many people were infected in Scottish centres.[48] The records relating to the 73 individuals have then been subjected to analysis of those patients (11 in total) who also received treatment outside Scotland and who may, therefore, have actually been infected outside Scotland though the report of their infection came from a Scottish centre.[49] The analysis of these 11 individuals has shown that five are likely to have been infected in Scotland.[50] Of the 11 analysed, there are 3 for whom it is hard to tell the place of infection. All of these were classed as non-Scottish infections in the report. The analysis appeared to have been conducted on the balance of probabilities. As far as patient 2 is concerned, he was excluded on the basis of his infection prior to November 1984 and the absence of treatment records for the period 1980 to 1984. There is an indication that he was resident overseas. It is not clear when but it is assumed this was over this period. He had been treated only occasionally in London prior to 1980. In our view, the available evidence (omitting speculation as to the period which may have been spent abroad for which no records exist) suggests that the

---

[46] Penrose Inquiry transcript for 30/03/11 (day 14); 97 (21) to 98 (5) (Dr Tait); PRSE0006014_0097 to 0098
[47] PRSE0002887_0035
[48] Penrose Inquiry transcript for 18/03/2011 (day 8); 26 (10 to 12) (Dr Hay); [PRSE0006008_0026]
[49] PRSE0002887_0035 to 0039; 0042 to 0045 (Table 4); 0047 to 0056 (Table 6)
[50] [PRSE0002887_0036 to 0037

treatment received in Edinburgh in 1984 was the source of his infection. Patient 10 is also excluded. This patient received treatment in both Glasgow and Manchester in the year of likely infection (1985). The earlier the treatment, the more likely it seems, in our view, that it was responsible for the infection as processes are likely to have improved during 1985 for the exclusion (by screening or testing) of donors likely to be positive. It therefore seems more likely that this patient was infected in Glasgow than in Manchester. Patient 11 is also excluded. We are of the view that the infection of this patient is likely to have occurred in Inverness where he received most of his treatment between 1982 and 1984 when most infections appear to have occurred in Scotland. This would mean that 8 out of 11 should be deemed to be Scottish infections. This brings the total on this analysis to 70 infections.

2.12 Further, this report itself recognised that there may be individuals whose test may have been done in a centre outside Scotland (and who therefore would not be included in the base figure of 73) who may have been infected in Scotland as a result of having received treatment there. 23 such patients whose positive test was first reported by an English centre have been analysed and none were deemed to have been likely to have been infected in Scotland (at least none have been added to the total figure of 68 given in the report).[51] Patient 21 received the majority of his treatment between 1980 and 1983 in Edinburgh. It therefore seems likely that he was infected there, in our view. Further, there are 16 other patients who could have been infected in Scotland given that the dates of their first positive tests post-date treatment received in Scotland.

2.13 On the basis of this analysis and subject to the limitations outlined above, we would propose that a figure of 71 be the most likely minimum number of infections with HIV in the bleeding disorder community in Scotland based on this analysis in the Hay paper presented to Penrose (which may not include all relevant, possibly Scottish infections). This figure could, of course, be higher in the event that other possible infections are included in the final total. Further, there are

[51] PRSE0002887_0039

limitations on the information available to the UKHCDO and also the analysis has not given any consideration to the possibility that there could be individuals who were infected in Scotland and whose infection has been discovered somewhere other than England. Further, we note from the UKHCDO tables that 488 tests appear to have been carried out on Scottish patients.[52] In 1985 there were 690 bleeding disorder patients registered with Scottish haemophilia centres.[53] This would suggest that not even all of those registered who may have been infected with HIV have been tested. Therefore, the figure of 71 should, in our view, be considered to be a minimum number of the number of patients infected with bleeding disorders infected with HIV by their exposure to blood products in Scotland.

2.14 Further papers, such as the one prepared by Dr Cuthbertson on the number of patients likely to have been infected by domestically produced products[54], have been prepared on the basis of this limited initial analysis. Therefore, such evidence requires to be considered with caution as it does not analyse, in our submission, the full cohort of those infected with HIV in the bleeding disorder community.

2.15 Subject to the limitations expressed above about the accuracy of the data and the analysis conducted on it by the haemophilia directors, the material which is available would suggest that no mild haemophiliacs were infected with HIV in Scotland and only four moderate patients were so infected (two at Yorkhill and two at the GRI).[55] The chief distinguishing characteristic amongst the different severity classes would, of course, have been the quantity of products to which each patient would have been exposed. The more severe the condition, the greater the amount of product to which the patient would be likely to have been exposed. The statistical material would, therefore, tend to suggest that the greater the exposure to potentially harmful products, the greater the likelihood one had of becoming infected with HIV. This is at consistent with the Ludlam analysis

---

[52] PRSE0002887_0041
[53] PRSE0002887_0041
[54] PRSE0000460
[55] Penrose Inquiry transcript for 18/03/2011 (day 8); 32 (9 to 25) (Dr Hay); PRSE0006008_0032

(considered below) of the infections in the Edinburgh cohort group.

2.16 As regards the timing of the infections, Dr Hay conceded at Penrose the possibility that patients could have been infected earlier than the available material might suggest based on the fact that there might not be archived samples for infections going back to the 1970s or even the early 1980s in some centres.[56] He suggested that archive samples would be more likely to be available for the first half of the 1980s for the Edinburgh centre than for other centres in Scotland.[57] It was explained by Professor Ludlam at Penrose that the collection of samples in Edinburgh started in the 1970s "when we were interested in looking at hepatitis B infection and its transmission in haemophilia".[58] This appears to be a more pressing issue when one considers that the samples held for bleeding disorder patients appear to have been kept for numerous purposes, in various places and over a long period of time.[59] In addition to the possibility that some infections may not have been able to have been identified or properly timed as a result of the inconsistency in the practices surrounding sample storage in Edinburgh differing from the other centres. The Inquiry has heard evidence about Edinburgh being unique in Scotland (though not in the UK) in having a longitudinal sera store. It is submitted that this research focus in Edinburgh was one of the main reasons why Dr Ludlam was attracted to move there from Cardiff. The research potential of the Edinburgh patients due to this approach to storing samples was his main focus. As is submitted below, this was allowed to become the predominant motivation in the way that they were treated. The Inquiry has heard evidence from numerous Edinburgh patients about large amounts of blood being taken from them with little or no explanation as to what it was for. This evidence given by Professor Ludlam

---

[56] Penrose Inquiry transcript for 18/03/2011 (day 8); 36 (17 to 22) (Dr Hay); [PRSE0006008_0036]

[57] Penrose Inquiry transcript for 18/03/2011 (day 8); 37 (2 to 8) (Dr Hay); [PRSE0006008_0037]

[58] Penrose Inquiry transcript for 30/03/11 (day 14); 18 (11 to 25) (Professor Ludlam); [PRSE0006014_0018]

[59] Penrose Inquiry transcript for 30/03/2011 (day 14); 18 (16 to 20), 26 (12 to 15) 31 (16) to 32 (24) and 34 (2 to 14) (Professor Ludlam) - the purposes for which and the places in which these samples were kept are elaborated upon in these passages which include reference to collection "for virological assessment principally in relation to hepatitis B in the 1970s", "when blood was being taken for other purposes to check their haemoglobin or their blood chemistry", in virology...parallel to samples in haematology" and for clotting tests" "we also stored a serum sample" and "duplicate samples...to guard against the loss of potentially valuable samples"; [PRSE0006014_0018; 0026; 0031 to 0032; 0034]

at the Penrose Inquiry confirms that blood was being taken *inter alia* for the study of disease, haemophiliacs being a useful source of information about that, given that their treatment regimes were likely to expose them to a wide variety of transmissible disease before most of the rest of the population.

2.17 It should, of course, be borne in mind that it is statistically virtually certain that all patients with bleeding disorders who were infected with HIV were also infected with hepatitis C. This assertion is based on the fact that the greater prevalence of hepatitis C in the Scottish blood donor population meant that if a patient with a bleeding disorder contracted HIV from a blood product, it is almost certain that that patient would have contracted hepatitis C as well. That virtually all of the HIV patients also contracted hepatitis C from blood products in Scotland was accepted in evidence by Dr Campbell Tait in his Penrose evidence.[60] It was suggested by Dr Hay that all HIV infected patients would also have been exposed to HCV but that such patients may have cleared the hepatitis C virus.[61] HIV-infected haemophilia patients have a much lower chance of clearing the hepatitis C virus than otherwise healthy patients who have only been exposed once to a single subtype of hepatitis C. We refer to the submission made below concerning the low likelihood that multiply exposed haemophiliac patients would clear the hepatitis C virus. The statistical information presented to the Inquiry would suggest that almost all of the HIV infected patients were severe patients who would have had such multiple exposures. Secondly, given the immuno-suppressant qualities of HIV, it seems likely that such patients would not fall within the category of those who clear the hepatitis C virus.[62] Therefore, it is highly likely that patients with bleeding disorders who contracted HIV as a result of their exposure to blood products will have been co-infected. In our view, the issue of co-infection and its likely impact upon the prospects of clearing the hepatitis C virus or responding well to treatment for hepatitis C is not well understood. Therefore, we have suggested below that government-funded research into this important category of patients be

---

[60] Penrose Inquiry transcript for 30/03/11 (day 14); 132 (7 to 11) (Dr Tait); [PRSE0006014_0132]
[61] Penrose Inquiry transcript for 18/03/2011 (day 8); 46 (13 to 16) (Dr Hay); [PRSE0006008_0046]
[62] Penrose Inquiry transcript for 18/03/2011 (day 8); 47 (21) to 48 (18) (Dr Hay); [PRSE0006008_0047 to 0048]

recommended in order that their position and likely treatment and support needs be understood more fully.

2.18 The Inquiry has heard evidence about the particular problems of co-infection, including the worsening of symptoms of hepatitis C due to the immuno-suppressant characteristics of HIV infection and the difficulties which can be experienced when receiving treatment for both infections simultaneously. The statistical material would suggest that it would be erroneous to consider the evidence of the effects of HIV infection independently from the effects of hepatitis C infection as all of those with bleeding disorders infected with HIV in Scotland were likely to have been co-infected.

3. Hepatitis C infections amongst people with bleeding disorders

3.1 Professor Goldberg provided the Inquiry with a statement regarding the methodology adopted within Health Protection Scotland to calculate the number of individuals with bleeding disorders likely to have been infected with hepatitis C through their use of blood products in Scotland.[63] HPS was aware of 351 patients with bleeding disorders who were infected with hepatitis C and for whom there was no information that factor concentrates had been received outside Scotland. Therefore, this figure does not take any account of those who may have been treated outside Scotland but whose infection may have originated here. Further, it is clear that this analysis was based on the number of confirmed infections within this group. It serves as little more than a starting point for the Inquiry's analysis. It is noteworthy, in our view that the position of Health Protection Scotland as regards identifying and recording the likely route of infection appears to be that it is of little significance to them as (a) their priority lies in the prevention of further transmissions and there are likely to be few such transmissions by blood or blood products in the future and (b) the fact that those infected by blood or blood

[63] PRSE0003337

products represent only a small part of the total number of infections with hepatitis C in Scotland.[64] Further, we note that evidence of this type which focuses on the number of confirmed infections tends to underestimate the numbers infected. It is, in our view, important that numbers such as this be clearly understood in the context in which they were arrived at. They have the potential to give a misleading impression of the total numbers infected. We would wish to stress that we consider it important that the standard of proof applied to the establishment of figures such as this is an important general issue for those who suffer from HIV or hepatitis C. There requires, in our submission, to be a clear, fair and consistent standard applied to the establishment of whether individuals are infected and whether they became infected by their exposure to blood or blood products in Scotland. Figures which require absolute certainty that an individual is infected and that he was infected by blood or a blood product are both unfair and lead to an underestimate of the total likely number of infections by these routes in Scotland.

Evidence presented to the Penrose Inquiry from the UKHCDO

3.2 Evidence was also made available to the Inquiry from the UKHCDO regarding the methodology adopted by that organisation in trying to arrive at a total figure for infections within this group.[65] The group provided a spreadsheet which detailed the treatment histories of the individuals who the UKHCDO had thought had been infected with hepatitis C in Scotland.[66] This spreadsheet was based on information held within the UKHCDO database and included the treatment histories of the apparently infected individuals (insofar as they were available to the UKHCDO). Clearly the accuracy of the treatment histories was dependent on the accuracy and completeness of the treatment information provided to the UKHCDO by the local Scottish haemophilia centres about treatment received for bleeding disorders within Scotland (see above).

---

[64] Penrose Inquiry transcript for16/03/2011 (day 6); 111 (18) to 112 (7) (Professor Goldberg); [PRSE0006006_0111 to 0112]

[65] PRSE0000637

[66] An update was provided entitled "Scot HCV Full Final Spreadsheet"

3.3 Evidence on the methodology which had been adopted by the UKHCDO in the compilation of this material was given by Dr Charles Hay and Dr Campbell Tait. Dr Hay accepted that epidemiological evidence was now to the effect that individuals treated in the UK (including Scotland) would have been likely to have been infected with hepatitis C on their first exposure to a concentrate, had they not been infected by being exposed to large amounts of cryoprecipitate before receiving a concentrate for the first time (which would have infected them before their first receipt of the concentrate). According to him, this approach was epidemiologically sound irrespective of whether the patient had received commercial or domestically produced concentrate. He did not, in his analysis, distinguish between factor VIII or factor IX concentrate in this regard.[67] It is clear that the material available to the UKHCDO may have limited its ability to provide the Inquiry with a comprehensive assessment of the numbers of patients likely to have been infected with hepatitis C (see the submission on HIV infections amongst the bleeding disorder community above). Further, it was pointed out by Dr Hay that there was an ongoing hepatitis C lookback exercise within the UKHCDO which had not yet been completed. The very existence of this exercise and the fact that it had not been completed by the time the UKHCDO material was presented to the Inquiry suggests that that material cannot be taken to be a comprehensive assessment of the numbers of bleeding disorders patients infected with hepatitis C in Scotland.[68] We wish to suggest that this exercise must be completed without delay and funded so that it can be completed as comprehensively and accurately as possible.

3.4 A figure of 410 patients was spoken to by Dr Hay as being the number of patients whom they knew to have been exposed to concentrate in Scotland. He regarded that to be a conservative number.[69] He accepted that this number would exclude those who may be infected in the community or those who received treatment locally outside the mainstream UKHCDO treatment system, whom the UKHCDO

---

[67] Penrose Inquiry transcript for 18/03/2011 (day 8); 60 (23) to 61 (11) (Dr Hay); [PRSE0006008_0060 to 0061]
[68] Penrose Inquiry transcript for 18/03/2011 (day 8); 26 (10 to 12) (Dr Hay); [PRSE0006008_0026]
[69] Penrose Inquiry transcript for 18/03/2011 (day 8); 60 (6 to 8) (Dr Hay); [PRSE0006008_0060]

was still trying to trace.[70] It seems more likely that individuals infected with hepatitis C could have escaped detection by the UKHCDO system than those infected with HIV given the greater prevalence of that virus within the donor population in Scotland and hence the greater likelihood of infection, even if exposed to small amounts of treatment, particularly with factor concentrates. Hepatitis C is often a silent killer, destroying the liver over a period of decades, but remaining undiagnosed.

3.5 In the additional material presented to the Inquiry by the UKHCDO, this figure (corrected for double counting) had been adjusted to 447 of whom 193 (43.18%) were dead.[71] Dr Hay continued to consider this to be an underestimate based on those who continued to be excluded from the data based on the fact that they had been treated outwith the mainstream system.[72] It is interesting to note, in our view, that if one takes the figure of patients who were registered with Scottish centres for treatment in 1985, there were 690 such patients registered.[73] This figure has been corrected for double counting. The position appears to have been that it was the milder patients who were both most likely not to have been registered with a centre and also most likely to have not been exposed to treatment, including treatment with concentrates, outwith the centre. The discrepancy between the estimated number of hepatitis C infections in Scotland in the bleeding disorder community and the total number of patients registered in Scotland would tend, in our view, to suggest that the actual number of Scottish infections in this community is likely to be higher than the UKHCDO have estimated, based on their apparently valid assumption that infection would result from first infusion of a concentrate.

3.6 Prior to the updated UKHCDO statistical material being submitted to the Penrose Inquiry, the methodology document originally produced by the UKHCDO[74] was spoken to in evidence by Dr Campbell Tait.[75] The starting point for the

---

[70] Penrose Inquiry transcript for 18/03/2011 (day 8); 26 (10 to 12) (Dr Hay); [PRSE0006008_0026]
[71] PRSE0002887_0058
[72] PRSE0002887_0057
[73] PRSE0002887_0031
[74] PRSE0000637
[75] Penrose Inquiry transcript for 30/03/2011 (day 14); From 75 (Dr Tait); [PRSE0006014_0075]

methodology adopted by the UKHCDO was the compilation of a list of all patients who had (according to the UKHCDO records) received treatment in Scotland between 1970 and 1989. In this list it was assumed that patients who had received factor concentrate treatment prior to 1989 had become infected with hepatitis C. Further, it was assumed that all patients who received treatment with cryoprecipitate prior to 1989 would also have been infected (unless they had tested negative for infection) on the basis that "it was known that patients treated with cryoprecipitate also commonly became infected with HCV" (no evidence cited).[76] It was assumed that no patients would have been infected after 1989.[77] It is not at all clear why this starting point was used since the assumption that a patient treated with cryoprecipitate only (or fresh frozen plasma for that matter) would have become infected is, in our submission, epidemiologically unsound. The likelihood of infection via this route alone would depend on the quantity of such treatment which each patient had received. Further, given that cryoprecipitate (and FFP) was not heat treated, the list excludes any patients who received treatment with cryoprecipitate in sufficient quantities to infect them after 1989 but before the introduction of routine anti-HCV testing in September 1991. Further, if this exercise was a genuine attempt to arrive at the total number of infections in the bleeding disorder community in Scotland, we would suggest that there is equally no legitimate basis for assuming that none occurred prior to 1970.

3.7 The number of patients treated or registered in Scotland between 1970 and 1989 (according to the UKHCDO) was 715. Assumptions about infection were necessary on the basis that the UKHCDO did not have information about whether these individuals had or had not tested positive for HCV infection.[78]

3.8 A further assumption was applied that every patient on the list was infected in the place where he first received treatment, whatever that treatment was.[79] Given that some of the patients on the list had received their first treatment outside Scotland, this reduced the potential number of Scottish infections to 544. The

---

[76] PRSE0000637
[77] PRSE0000637_0001
[78] PRSE0000637_0001, para 1
[79] PRSE0000637_0001 , para 3

epidemiological assumption that a patient was infected by his first treatment if that treatment was not with a factor concentrate is, in our view, unsound. Being manufactured from only a small number of donations, cryoprecipitate was considerably less likely to transmit hepatitis C infection on first infusion than factor concentrate. This may have resulted in patients who received treatment outside Scotland with either cryoprecipitate or FFP having been deducted from the Scottish list without good cause if they were subsequently treated with factor concentrates in Scotland. A further 76 were deducted from the list on the basis that UKHCDO information suggested that they had tested negative for HCV on PCR testing. No consideration appeared to have been given to (a) the possibility that PCR testing of the blood would not be a completely reliable guide as to whether a person's liver had been damaged by hepatitis C infection or (b) the timing of the test, important as it would have meant that people who tested negative but who had been infected and had responded to treatment may have been excluded. A further 8 were deducted on the basis that they had not received treatment with plasma derived products. That 15 patients were identified by Scottish haemophilia centres and did not appear on the UKHCDO list makes it clear that the raw data from which the directors were working from UKHCDO was not complete.[80] A total of 475 patients was arrived at by this method.[81] A further 16 appear to have been discounted either based on information that they had, in fact, tested negative for HCV infection (8) or that they had received extensive treatment outside the UK prior to infection (8), resulting in a final total of 459.[82] 314 of these patients have tested HCV positive and so this must be considered as the absolute minimum number of infections in this group based on the UKHCDO data.[83] It is noted that the number of individuals included within this total who have received cryoprecipitate therapy only is likely to be overstated (and who have not been tested as many of those excluded from the initial list who had tested negative will

[80] PRSE0000637_0002 , para 6
[81] PRSE0000637_0002, para 7
[82] para 8 of PRSE0000637_0002
[83] Penrose Inquiry transcript for 30/04/11 (day 14); 83 (5 to 18) (Dr Tait); [PRSE0006014_0083]

have been included in this group).[84] However, when one considers the increased usage of concentrate therapy in Scotland in the 1980s (considered below) we would estimate that there are unlikely to be very many individuals registered with or treated by a haemophilia centre in Scotland over this period who would not have received at least one concentrate treatment.

3.9 The position of the statistics expert group in this regard appears at paragraph 2.30 of their report. In her oral evidence to the Inquiry, Professor Bird addressed the apparent discrepancy between the total figure which they arrived at in the analysis presented to them by the UKHCDO for Scotland (406) and the figure provided to the Penrose Inquiry (447). She suggested that the higher Penrose figure for this cohort might be the most appropriate (447) but it does not appear that the group had been able to look at the "reconciliation" exercise done in Penrose by the haemophilia directors and the UKHCDO.[85] It would appear, therefore (a) that the evidence presented to the Penrose Inquiry by the UKHCDO again differed from their more contemporary analysis and (b) that the expert group ultimately deferred to the Penrose figures (analysed above) in this area.

3.10 In her report of the Ross Committee published in March 2003, Dr Kate Soldan had estimated that around 500 individuals with bleeding disorders had been infected with hepatitis C as a result of their exposure to infected blood products in Scotland.[86]

Conclusion

3.11 In conclusion, we would suggest that the numbers infected in this community are likely to be nearer the number of patients registered with Scottish centres (690 in 1985 and 778 in 1990[87]). We would suggest that it is likely that a number between

---

[84] para 12 of PRSE0000637_0003
[85] IBI transcript for 09/11/22; 83 to 84 (Professor Bird)
[86] Report of the Expert Group on Financial and other Support (March 2003) @ paragraph 4.8 - http://www.scotland.gov.uk/Resource/Doc/47034/0024918.pdf (including the material to be found in PRSE0003921)
[87] PRSE0002887_0031; 0032

the current estimates from the UKHCDO (447 and 459) and these numbers of registered patients is likely to represent the number of infections with hepatitis C of patients with bleeding disorders in Scotland. Given (a) that Scottish concentrates continued to be administered to Scottish patients which were not virally inactivated for hepatitis C until April 1987 (the number of registered patients had risen to 778 by 1990[88]) (b) the fact that by 1985 certain infected patients may already have died and (c) the number of infections may include patients not registered with a centre who actually received treatment in Scotland, the UKHCDO numbers must be regarded as minimum numbers. Given this, we would obviously refute the suggestion of the UKHCDO directors that their number of 459 presented to the Inquiry was likely to represent the maximum number of infections in Scotland.[89]

3.12 On the basis of the epidemiological assumptions made by the UKHCDO in the compilation of the statistical material which they have presented to the Inquiry (as explored in more detail above) we would suggest that, certainly amongst the moderately and severely affected patients whose treatment would have been likely to have involved concentrate therapy prior to April 1987, the vast majority of patients with bleeding disorders in Scotland treated prior to that date will have been infected with hepatitis C. Many mild patients will also have been infected. In what is a close community, we submit that this disease has had a devastating and all consuming effect. Further, given that haemophilia is a hereditary disease, this high rate of infection has also affected many families who have required to come to terms with the infection of multiple members already affected by haemophilia.

3.13 As is submitted above, the prevalence of hepatitis C in the Scottish donor population meant that infections with the virus came from all parts of the bleeding disorder community. All patients treated with factor concentrates in Scotland are very likely to have been infected. As far as the Scottish factor VIII concentrate used prior to April 1987 was concerned (heated to 68 degrees for 24 hours) the PFC did not receive regular reports of apparent infections as it was assumed that most

---

[88] PRSE0002887_0032
[89] para 12 of PRSE0000637_0003

patients, if not all patients, who received concentrate prior to 1987 became infected with NANB hepatitis.[90]

3.14 Professor Goldberg presented some data from HPS regarding the 351 blood disorder patients whom he had designated as infected in Scotland. Given that he did not have data regarding the type of bleeding disorder for 240 of them, the data he presented is, in our view, of little value.[91]

3.15 Dr Hay of the UKHCDO presented data relating to 447 patients who, it was assumed, had been infected due to their exposure to concentrate therapy in Scotland. Above, we have argued that this is likely to be an underestimate of the total number of patients infected with the disease in Scotland. However, of the 447 on whom information has been provided by the UKHCDO, 339 (75.84%) suffered from haemophilia A, 81 from haemophilia B (18.12%) and 26 from von Willebrand disease (5.82%) (one had a temporary coagulation disorder). It is interesting to note the low numbers of infections amongst the von Willebrand community. These are the patients who are most likely to have escaped the analysis of the UKHCDO. As Dr Hay pointed out in his analysis, the disease was likely to have been under-diagnosed at the material time.[92] This may have had the effect of it not being treated (and so minimising the number of infections in that community). Equally, however, it may have meant that it was not generally treated within a recognised centre but elsewhere with the result that infections within this community may have occurred which are not recognised within the UKHCDO system.

3.16 The analysis conducted by the UKHCDO and spoken to in evidence by Dr Tait included allocation of the 475 patients which the exercise uncovered amongst the Scottish centres based on (a) the place of first treatment (which as we have argued above includes the false assumption of infection if the first treatment with otherwise than with a concentrate) and (b) by arbitrary allocation to a centre in the event that treatment was received at more than one centre in the first year of

---

[90] Penrose Inquiry transcript for 7/12/11 (day 74); 61 (8 to 16) (Dr Perry); [PRSE0006074_0061]
[91] PRSE0003337_0002
[92] Penrose Inquiry transcript for 18/03/11 (day 8); 22 (19) to 23 (9) (Dr Hay); [PRSE0006008_0022 to 0023]

treatment.[93] Given the assumption that patients will have become infected with hepatitis C on first infusion of a factor concentrate the place of infection of the infected bleeding disorder patients will be likely to follow the population distribution of this group, given that most patients would tend to receive treatment locally (or at least at their nearest haemophilia centre). The figure provided by the UKHCDO for infections per centre come to a total of 600 infections.[94] This does not appear to have been corrected for double counting (see the total of 447 quoted earlier).[95] An allocation of the figure corrected for double counting would require to be undertaken and this figure compared with the distribution of patients being treated at the various centres over the relevant period during which infections occurred. This would enable any unduly high infection rate in any one centre to be detected.

3.17 As far as the timing of infection is concerned, the assumption of infection on first exposure to a concentrate would tend to suggest that some infections may have occurred long into the past, or at least at the time when larger pooled concentrates came into regular usage in Scotland. As noted above, it would seem legitimate to assume (as the PFC did) that first exposure to a concentrate would have been the most likely infection route in this community.

3.18 We would refer to the evidence of Professor Thomas to the Penrose Inquiry regarding the fact that infections amongst the haemophilia community have tended to be with genotype 1 hepatitis C to a greater extent than is evidenced in the infected population at large.[96] We would suggest that further government-funded research into the impact of multiple exposures to the hepatitis C virus on the likelihood of responding successfully to treatment be recommended.

---

[93] para 7 of PRSE0000637_0002
[94] PRSE0002887_0059
[95] PRSE0002887_0058
[96] Penrose Inquiry transcript for 11/10/11 (day 52); 49 (4 to 6) (Professor Thomas); [PRSE0006052_0049]

4. HIV infections amongst the recipients of blood transfusions

4.1 Information available as to the number of individuals who are likely to have been infected with HIV as a result of a blood transfusion received in Scotland comes partly from the results of the HIV lookback exercise which was spoken to in evidence by Dr Jack Gillon (which identified 10 such infections) and reports from clinicians of possible blood transfusion related infections (which discovered a further 8 such infections).[97] In his evidence to the Penrose Inquiry, Dr Gillon clarified that one of the 18 had in fact come to his attention from the Health Protection Scotland database about which SNBTS had previously known nothing.[98]

4.2 The limitations of the lookback exercise as a means of identifying the total number of patients likely to have been infected by a blood transfusion received in Scotland is addressed below in connection with the hepatitis C lookback exercise. Similar limitations can be identified in the HIV lookback exercise which has been used as the primary means of ascertaining the number of HIV infections through blood transfusion. However, as Dr Gillon observed in his Penrose evidence, the HIV lookback exercise is probably inherently more likely to have identified a more accurate number of infected persons than the HCV lookback. This, as he pointed out, was because of the fact that HIV had only been in the population for relatively few years when compared with HCV which had been around for longer, with the result that once a positive donor had been identified it was only his donations in the last few years which could have been infective and not necessarily those going back many years (as was the case with hepatitis C).[99] This would result in fewer recipients having to be traced and tested, making the process more likely to identify all infected recipients. Further, very much fewer HIV positive donors were identified and so efforts could be concentrated more fully on the identification of potentially infected recipients as there would be fewer of those given the lower number of positive donations. The lower

---

[97] PRSE0000350

[98] Penrose Inquiry transcript for 16/03/2011 (day 6); 59 (14 to 16); [PRSE0006006_0059]

[99] Penrose Inquiry transcript for 16/03/11 (day 6); 18 (6 to 24) (Dr Gillon); [PRSE0006006_0018]

prevalence of the HIV virus in the population (including the blood donor population) would also be likely to result in fewer transmissions than with hepatitis C. However, the greater likelihood of sexual transmission of HIV means that it is more probable that there would be secondary transmission of the disease though there would be likely to be fewer infections in blood transfusion recipients.

4.3 Dr Gillon suggested in his evidence to this Inquiry that *"there would have been one or two probably missed".*[100] Although this can be little more than an educated guess, the context of why Dr Gillon considered the exercise he undertook to be broadly accurate is noted above. It should, however, be noted that Dr Gillon was not himself aware of all of the relevant positives and relied on other agencies to provide some of the information. His ability to provide numbers was thus limited by that factor. In his evidence to this Inquiry, Dr McClelland accepted that this meant that there were at least 18 separate donations which were HIV positive, demonstrating that there were at least 18 separate 'breaches' of the system in place to seek to ensure that donations were not taken from HIV positive donors.[101]The Statistics expert group, in their report to this Inquiry, noted that the minimum of 18 HIV infections via blood transfusion was *"somewhat higher"* than would be expected with reference to population sizes, and concluded that this indicated a *"higher HIV risk by transfusion in Scotland".*[102] This, in our submission, is an important statistic. It shows, in our submission, that the Scottish system was comparatively less successful in preventing HIV positive blood donors from giving blood which ended up being transfused to patients. The blood collection system was less safe than it was elsewhere in the UK. This is consistent with our submissions below about the limited measures taken to screen out donors at risk for HIV having been comparatively ineffective, in particular in light of the known risks of HIV penetrating the donor population in Scotland. It is also consistent with our submission that between 1982 and 1985 (the period over which we know that HIV infection was penetrating the system and screening for HIV started) the

---

[100] IBI transcript for 19/02/22: 134(23) to 135(4) (Dr Jack Gillon)

[101] IBI transcript for 28/01/22: 163(11) to 163(22) (Dr Brian McClelland)

[102] EXPG0000049 at page 37

system of blood collection was working on the basis of the need to collect all the plasma it could to satisfy the demand of haemophilia clinicians for factor VIII concentrate. This meant that donor exclusion measures needed to be kept to a minimum to meet collection targets. These practices were not revised in light of improved yield at the PFC obtained as a result of processes introduced by Dr Foster. The same factor VIII concentrate production could have been achieved with more restrictive and hence safer donor exclusion policies. In any event, we submit that haemophilia A patients should have been offered (and would have accepted) changes to their treatment regimes over this period to minimise their risk. This would have involved measures including using less factor VIII concentrate, better lifestyle and greater use of cryoprecipitate. Any of these measures would have eased the pressure on the amount of blood/ plasma which needed to be collected and safer practices to have been adopted. Given the relatively low number of transmissions, the exclusion of only a few positive donors by such measures is likely to have had a significant impact on the transmission of disease.

4.4 Professor Bird was asked to elaborate on reasons for the disproportionately high figure of (a minimum of) 18 HIV blood transfusion infections in Scotland in her oral evidence. She gave two possible reasons. The first was the IV drug using population and the prevalence of HIV infection in the Edinburgh area. It is submitted that this was a major part of the reason for the infections in Scotland. The second reason, she suggested, was that the figure may have been part of a reconciliation exercise done for Scotland at around the time of the Penrose Inquiry, which may have made the Scottish figure more accurate than the figure for the rest of the UK and hence apparently out of kilter.[103] This second reason is not a legitimate reason as the figures which were quoted in the expert report did not derive from the time of the Penrose report but had instead been, broadly speaking figures which had been used for these populations for many years.[104]

---

[103] IBI transcript for 09/11/22; 90 to 91 (Professor Bird)

[104] DHSC0002921_009 – which gave a figure of 75 cases and a figure 18 in Scotland, which was proportionately high based on population at roughly twice what one would have expected

Consistent with this was the testimony of Dr Gillon who confirmed (a) that the figures did not derive from any reconciliation exercise done for this cohort at around the time of the Penrose Inquiry (meaning that Professor Bird's second reason was not a valid one) and (b) that the majority of the 18 such infections of which he was aware (around 10) were due to donations given in Edinburgh.[105] In our submission, this is consistent with our assertion below that Edinburgh was a known HIV risk area which should have made greater efforts to prevent transmission (as is explored below). The conclusion that the IV drug population will have played a role is also significant in that this is a common infection route with HCV, which is only rarely sexually transmissible. This is consistent with the studies which looked at prevalence rates for HCV in the donor population when testing became available, which also showed a higher prevalence rate of 33% in Scotland when compared to the rest of the UK, in particular England. As is set out in the statistics group expert report, the prevalence rate from the Crawford paper was 0.088% in Scotland whereas an equivalent study in England showed a prevalence rate of 0.066%.[106] Though some of the more dangerous collection practices (like collection from prisons and military institutions) had stopped by 1991, we submit that this shows that in Scotland there was a disproportionately high rate of infection for both infections in the Scottish donor population pre-screening for anti-HIV and anti-HCV which resulted in higher infection rates. The explanation which we propose for that is that less safe donor selection practices were used in order to achieve and maintain self-sufficiency, which meant that donors were allowed to donate who would not have been allowed to do so elsewhere in the UK. The expert report also commented upon the number of HCV-only infections as "Scotland is substantially higher, possibly reflecting the greater proportion of HCV infections through transfusion than the roughly 50:50 recorded in the Skipton Fund".[107]

4.5 Dr Gillon has always accepted that the discovery of blood transfusion as the source

---

[105] IBI transcript for 19/02/22: 134 (Dr Jack Gillon)
[106] EXPG0000049, page 107 at para A.5
[107] EXPG0000049 at para 5.5

of infection by way of reports from a treating clinician is also an unreliable way of ascertaining a complete picture, as it is reliant on the treating clinician considering the possibility that might be the infection route, knowing how and taking the trouble to report it. This is considered in some more detail in connection with Dr Gillon's evidence on hepatitis C caused by blood transfusion below. There was no legal obligation on the clinician to report HIV either to the SNBTS or indeed to Health Protection Scotland as HIV was not a reportable disease.[108] There has never even been any agreed policy or an administrative requirement for possible cases of transfusion transmitted infection to be reported by clinicians to SNBTS.[109] It would be in the interests of disease management and control that it should be a legal requirement that all cases of infectious diseases should be reported to a public health body (now Public Health Scotland) and that all those cases of diseases which are transmissible through blood and blood products should also be required to be reported to the SNBTS.

4.6 An Infection Surveillance Report by the National Microbiology Reference Unit includes data on the number of anti-HIV positive (repeat reactive) blood donations collected in Scotland between the introduction of testing in October 1985 and 12 July 2010.[110] The data produced shows that in tests undertaken on blood collected between the introduction of testing and the end of 1985, the total number of positive donations per 100,000 was 5.94 (a total number of 4 positive donations in that 3 month period), though the report suggests that the total number of donations figure is only an estimate. For 1986, this figure had fallen to 4.34 positive donations per 100,000 donations taken (a total number of 14 for that year). For 1987, this figure had fallen to 3.32 positive donations per 100,000 donations taken (a total number of 10 for that year). These figures give some insight into the numbers of positive donations which would have entered the transfusion system in the event that testing had not been implemented. One can assume that before donor selection measures were implemented in 1983/84 the number of positive

---

[108] Penrose Inquiry transcript for 16/03/11 (day 6); 63 (20) to 64 (1) (Dr Gillon); [PRSE0006006_0063 to 0064]
[109] PRSE0003049
[110] PRSE0001038_0004

donations in Scotland would have been likely to have been higher than the rates indicated here. However, this gives an indication of the number of HIV positive donations which would have been entering the system prior to the introduction of routine anti-HIV testing and despite screening measures. If one takes a figure of around 15 (a conservative estimate based on these figures) for the period between the time when the figures show that blood products in Scotland (around mid 1982, see GRI infection table analysed below) and October 1985, a period of around 3 years), this would suggests that around 45 positive donations may have penetrated the system.

Timing of infections

4.7 Dr Gillon supplied the Penrose Inquiry with information about the likely dates of infection of 15 of the 18 patients he had identified as having been infected with HIV through a Scottish blood transfusion.[111] His analysis of the available data suggested that the earliest known transmission was in August 1983 (patient 1), the latest in August 1986.[112] It is worthy of note that for the 3 patients for whom a date could not be ascertained with any precision, one (patient 2) may have been infected as early as 1981.[113] The data indicates that HIV had certainly entered the Scottish donor pool some months before August 1983 when the blood which was transfused in August 1983 was collected and that it had perhaps entered it as early as 1981. As stated, the blood products data (analysed below) shows that blood products had started to cause infections by 1982. The procedures being used to screen high risk donors in 1983 and 1984 failed to prevent the infections as a result of transfusions over this period identified in the Gillon report.

4.8 It is worthy of note that two of the infections were deemed to be due to transfusions which occurred in August 1986 (patients 11 and 18). Given that

[111] PRSE0000350_0001 to 0002
[112] PRSE0000350_0005
[113] PRSE0000350_0005

routine anti-HIV screening took place from October 1985, this indicates that the screening process which was implemented at that time was not fool proof in preventing HIV infection by way of blood transfusion even as late as 10 months after routine screening was implemented. Further, one infection was caused as a result of a transfusion received in September 1985 (patient 16). This infection might not have occurred had routine anti-HIV screening of blood taken place earlier in 1985.

4.9 It should be borne in mind that the expert statistics group provided the interesting statistic to the Inquiry that the mortality rate for those who acquired HIV infections from blood components is far higher (85%) in the population infected in the UK than the rest of the HIV infected population who were infected abroad (44%).[114]

5. Hepatitis C infections amongst the recipients of blood transfusions

5.1 In the first place, it appears to be accepted by all those who have commented that this is likely to be the largest population in Scotland of those infected with the viruses with which the Inquiry is concerned through blood or blood products. The population of blood transfusion recipients is unlike the community of those with bleeding disorders who usually contracted infections through their use of blood products as that latter community is relatively small, traceable and subject to regular blood analysis. Secondly, there is the nature of the disease itself. It has a long incubation period and the symptoms may not manifest themselves for some time after an individual has contracted the disease. These circumstances give rise to problems of detection. It is therefore possible that potentially large numbers of individuals have been infected who are not aware that they are infected or how they became infected and have not received treatment. This is a significant public health issue and is why we recommend that further work is done on trying to find and help these people, even at this long remove from the

[114] EXPG0000049 at para 3.4

estimated date of latest infection, in around 1991. It is also necessary to have a starting point as to (a) the total number of infections likely to have been caused by this route and (b) the likely timing of these infections, in order to draw conclusions about the significance of failures to implement testing regimes designed to halt the spread of infection predominantly by this route in the latter half of the 1980s into the early part of the 1990s.

SNBTS data

5.2 The Penrose Inquiry received a report[115] and heard oral evidence from Dr Jack Gillon of the SNBTS[116] on his efforts to try to arrive at a figure for those likely to have been infected with hepatitis C as a result of a blood transfusion received in Scotland. He identified 4 groups of people who were definitely infected and were likely to have been infected by a blood transfusion in Scotland. He did not think it likely that there was any overlap between the groups.[117] In the first place, Dr Gillon had identified 59 blood donors who had tested positive on giving blood whose only risk factor for the source of their infection was having received a blood transfusion themselves.[118] It was confirmed by Dr Gillon in his evidence that this category included those who had tested positive on giving a donation (867 in total) who had identified blood transfusion as the only risk factor for them.[119] This is clearly unreliable as (a) it depends on reporting from the individual and no further examination (b) it does not mean that those who were positive but who had another risk factors were infected by the other risk factor and not the transfusion and (c) it takes no account of where the person even alleged to have had their transfusion which they have claimed was their only risk factor.[120] These individuals

---

[115] PRSE0000405
[116] Penrose Inquiry transcript for 16/03/11 (day 6); 1 to 88 (Dr Gillon); [PRSE0006006_0001 to 0088]
[117] Penrose Inquiry transcript for 16/03/11 (day 6); 40 (11 to 14) (Dr Gillon); [PRSE0006006_0040]
[118] PRSE0000405
[119] Penrose Inquiry transcript for 16/03/11 (day 6); 37 (17 to 20) (Dr Gillon); [PRSE0006006_0037]
[120] Penrose Inquiry transcript for 16/03/11 (day 6); 73 (24) to 74 (3) (Dr Gillon); [PRSE0006006_0073 to 0074]

are just individuals who happen to have presented as blood donors in Scotland. Identifying potential patients by looking at donors is clearly a very limited way of accessing the patients who may or may not decide to be blood donors themselves.

5.3 Dr Gillon also relied upon data of confirmed positives which had been linked to blood transfusions as a result of reporting to the SNBTS by clinicians treating patients with symptoms of hepatitis C. Investigations had identified 28 individuals by this route.[121] He had attempted to arrive at a number by cross referencing his figures with figures from other sources, such as Health Protection Scotland. Despite this, he accepted that the numbers which he proposed were likely to be a restricted representation of the likely total in reality due to the fact that identification of an infected individual would depend on it occurring to a clinician presented with a patient showing the signs of hepatitis C infection that it might have been transmitted by a blood transfusion and going to the trouble of reporting that possibility to the blood transfusion services.[122] He also pointed out that Health Protection Scotland were more likely to receive reports of infection as they were able to put in place systems which made it automatic that they would receive notification of every confirmed positive test. The reporting was thus more likely than the reporting system relied upon by the SNBTS which was much more dependent on the clinician making a deduction and then a report.[123]

5.4 Further, he gave evidence as to the way in which reports of possible transfusion transmitted infection had been investigated both before the conclusion of the lookback exercise in 1998 and since then. He identified that there were 58 such reports which had been made and that there were difficulties in identifying whether transfusion was the most likely cause.[124]

5.5 Dr Gillon also identified confirmed positive patients likely to have been infected by blood transfusions in Scotland by referring to the data compiled as a result of

---

[121] PRSE0000405_0002
[122] Penrose Inquiry transcript for 16/03/11 (day 6); 9 (3 to 18) (Dr Gillon); [PRSE0006006_0009]
[123] Penrose Inquiry transcript for 16/03/11 (day 6); 9 (19) to 10 (14) (Dr Gillon); [PRSE0006006_0009 to 0010]
[124] Penrose Inquiry transcript for 16/03/11 (day 6); 33 (18) to 36 (17) (Dr Gillon); [PRSE0006006_0033 to 0036]

the HCV lookback exercise. A UK wide lookback exercise was undertaken from April 1995 and was deemed practically complete in 1998. 133 individuals were identified as definitely having been infected with hepatitis C by a blood transfusion in Scotland via this process.[125] In fact, further evidence available to the Inquiry demonstrates the limitations of this process in providing a definitive answer to the number of blood transfusion related infections. The full results of the lookback exercise demonstrate that, in fact, 880 patients had been identified as having been exposed to the virus by having received a blood component from a repeat donor found to have been infected when his repeat donation was tested.[126] Only 70 of these recipients were tested and found to be negative. The position of the others is either that they were tested and found positive (the figure of 133 given by Dr Gillon) or they were not tested either because they were dead (536) or not traced (78). In any event, the 880 only represents the recipients of a proportion (1,356 out of 2,026 - 66.9%) of the components made from blood donated by donors found to be positive from the lookback process. Clearly the number of potentially infected individuals even identified via this limited process is potentially much greater than the figure of 133 given by Dr Gillon. The lookback exercise was generally commendable as means of tracing individuals infected by blood transfusions who would not otherwise be traced and who could receive counselling and treatment for their infection. Further, it provides a useful amount of "hard data" relating to infections amongst a small proportion of the community infected via this route. However, it represents, in our view, an inadequate means of identifying a total number those who are likely to have been infected as a result of receiving blood transfusions in Scotland.

5.6 The lookback exercise is of limited use in finding a definitive answer to this issue as it only starts with repeat donors who come back and are therefore able to be tested and their previous donations tested. It would not identify any infections which occurred as a result of the donation of a donor who either (a) did not return

---

[125] PRSE0000405_0002

[126] PRSE0000730_0003 to 0004 - report by Andy Kerr to the Health Committee of the Scottish Parliament on the HCV lookback exercise conducted by SNBTS dated 31 January 2006

to give blood again or (b) for whom the records of his previous donations were not adequate to identify any or all of the recipients (either as a result of faulty record keeping relating to the timing of any previous donations or relating to the identification of recipients of those donations). As addressed below, the delays occasioned in the introduction of a hepatitis C lookback exercise in Scotland resulted in the process being less likely to identify as many positive recipients of blood as an earlier process may have done[127] and (b) the limitations an exercise based only around repeat donors.[128] We also refer to the evidence of Dr Alexander at the Penrose Inquiry on the limitations of the lookback, in particular the decreasing likelihood of positive donors returning to donate at the material time.[129]

5.7 Dr Gillon presented evidence to the Penrose Inquiry as to the likely dates of transmission for 103 of the 133 infected patients identified via the lookback and for those identified via a clinician report.[130] The earliest transmission accepted as definite was in 1977, and the last in March 1991. As far as the earliest date of transmission revealed via this process is concerned, the process could never have been an accurate representation of the likely earliest date of transmission via this route. Dr Gillon gave evidence to the effect that it was thought that hepatitis C was an ancient virus and that blood transfusion had really started at around the time of the Second World War.[131] The proposition that the lookback data demonstrates that the earliest infection in Scotland was in 1977 is inaccurate, given the likelihood that the virus existed before that time and the likelihood (discussed above) that the further back one goes in time, the less likely it is that the infected recipient will still be alive to be able to be identified, either due to death, problems in tracing the individual due to moving etc or due to the lack of

---

[127] PRSE0000537_0007 to 0010
[128] PRSE0000537_0010 to 0011
[129] PRSE0000537_0010 to 0011; and Penrose Inquiry transcript for 17/01/12 (Day 85); 125 (2 to 18) (Dr Alexander); [PRSE0006085_0125]
[130] PRSE0000405_0003 to 0004
[131] Penrose Inquiry transcript for 16/03/11 (day 6); 19 (23) to 20 (20) (Dr Gillon); [PRSE0006006_0019 to 0020]

accurate records to enable the recipients of the infected blood to be traced.[132]

5.8 As was accepted by Dr Gillon in his Penrose and IBI evidence, the delay in the implementation of the lookback process meant that it was more likely that it would not have identified the total number of those infected by this route, in part because the longer one waits, the more likely it is that infected patients would have died (and would not therefore be traced) either from hepatitis C or some other cause.[133] We would refer to the submissions which we have made about the delays in implementing the lookback process below.[134] These delays have rendered the comprehensiveness of the results even more questionable than they would otherwise have been.

5.9 Finally, Dr Gillon identified a further 18 individuals who were definitely positive for hepatitis C who had been identified by the west of Scotland renal unit when they started testing their patients in 1991. As was accepted by Dr Gillon in his oral evidence, the deficiencies of the methods of blood related infection identification which he had used resulted in the number of blood transfusion recipients identified through that process as having been so infected only being able to be a regarded as a minimum number of individuals so infected.[135] This, in our view, means that his evidence is merely the starting point for a thorough consideration of this important matter.

<u>The epidemiological analysis of the scale of infection in this population</u>

5.10 Against this background, the Penrose Inquiry procured a report[136] and heard evidence from the epidemiologist Professor David Goldberg on this issue.[137] In

---

[132] Penrose Inquiry transcript for 16/03/11 (day 6); 23 (3) to 24 (8) (Dr Gillon); [PRSE0006006_0023 to 0024]
[133] Penrose Inquiry transcript for 16/03/11 (day 6); 22 (7 to 12) (Dr Gillon); [PRSE0006006_0022]
[134] PRSE0000537_0007 to 0010
[135] Penrose Inquiry transcript for 16/03/11 (day 6); 77 (15 to 20) (Dr Gillon); [PRSE0006006_0077]
[136] PRSE0000893
[137] Penrose Inquiry transcript for 16/03/11 (day 6); from 95 (Professor Goldberg); [PRSE0006006_0095]

light of the oral evidence which he gave, further lines of inquiry were pursued with him.[138] The conclusions reached by Professor Goldberg on the material which he has presented to that Inquiry (and available to this) on this issue would appear to amount to the following:

- The total number of reports made to HPS (as was) and recorded on their hepatitis C database (established in 1996) of individuals infected with hepatitis C possibly as a result of blood transfusions in Scotland (excluding those reported with a known history of injected drug use and those who had received blood transfusions in England) was 304.[139]
- Professor Goldberg & Ors provided a report to the Inquiry which attempted to conduct a more epidemiological analysis of the numbers of individuals likely to have been infected by blood transfusions in Scotland. A report in this regard was provided in October 2011.[140] This paper estimated the likely number of infections by way of lower, mid and upper estimates, which are 1183, 1532 and 1978 respectively.[141]

5.11 As was indicated by Professor Goldberg to the Penrose Inquiry in his letter of 28 February 2012, the epidemiological analysis which he and others at HPS had carried out in conjunction with Drs Gillon and McClelland from SNBTS was "not subjected to rigorous quality assurance (peer review) because of time constraints."[142] The starting point for the analysis of the likely prevalence of HCV

---

[138] From the material available to us it would appear that the Penrose Inquiry wrote to Professor Goldberg seeking his further input and he replied with an updated report in October 2011 [PRSE0002181], a further letter was sent to him on 14 February 2012 [PRSE0003944] which prompted a letter which was sent to the CLO on 28 February 2012 [PRSE0003944] and a further report dated 1 March 2012 [PRSE0001962]. A further request was sent to Professor Goldberg on 23 March 2012 [PRSE0001059] enclosing comments made by Professor Oliver James on the analysis which had been presented by Professor Goldberg [PRSE0000265] which prompted a final response from Professor Goldberg dated 29 May 2012 [PRSE0001252]

[139] PRSE0000893

[140] PRSE0002181

[141] PRSE0002181_0003

[142] PRSE0003944_0003

in the donor population was the study compiled by Crawford & Ors from 1991/92 when anti-HCV testing came into being. This gives a starting rate of 0.088% HCV prevalence. That prevalence rate was then subjected to a number of reductions in order to try to predict the likely prevalence rate for the period during which the analysis is being conducted.[143] The starting prevalence comes from a limited study at a particular point in time. Professor Thomas expressed the view at the Penrose Inquiry that between 1970 and 1990 the prevalence of HCV in the UK blood donating general community was around 0.5%.[144] He accepted that the levels were found to be lower than that in blood tested in the first 6 months to a year after anti-HCV screening was introduced (ie in the Crawford paper). Professor Thomas explained that the figure he had been using was using was derived from a paper by Minor[145] (whom he thought would be privy to the accurate figures) which reported "a frequency of 0.4% consistent with previously reported figures" in the plasma from UK donors used to make factor concentrates.[146] The application of these higher (though vouched) prevalence rates as the starting point for the Goldberg (or indeed the Soldan of this Inquiry's) analysis would have a significant effect on the calculation of the total number of likely infections. The resultant number would be significantly higher if this alternative starting point were used.

5.12 The Goldberg analysis attempts to factor in the fact that the prevalence rate would have been likely to have decreased over the period under examination. Rightly, in our view, he appears to wish to question the legitimacy of the 1991/92 rate being used as a basis for the estimation of infection at earlier dates. As is pointed out in the October 2011 report, the increasing measures implemented to exclude high risk donors from donating is likely to have had some effect in lowering the prevalence rate in the donor population in Scotland over the relevant period. In particular, the Goldberg report attempts to factor in the likely impact of measures taken by SNBTS to reduce the number of HCV positive blood donations entering

---

[143] PRSE0001962_0004

[144] Penrose Inquiry transcript for 11/10/11 (day 52); 78 (21 to 23) under reference to his report (Professor Thomas); [PRSE0006052_0078]

[145] PRSE0000390

[146] Penrose Inquiry transcript for 11/10/11 (day 52); 113 (Professor Thomas); [PRSE0006052_0113]

the system, in particular (a) the deferral of blood donors at high risk for HIV infection from 1984 and (b) the introduction of anti-HCV screening in 1991.[147] Given that the period under examination is 1970 to 1991, the latter of these seems totally irrelevant. As far as the impact of the former is concerned, the analysis conducted by the Goldberg team appears to be based on an unattributed, unsupported assertion that prevalence of HCV in the donor population reduced "constantly by 66% during 1984 to 1991".[148] The meaning of that assertion is not clear. Given that the donor deferral efforts introduced in the mid 1980s were predominantly designed to minimise the risks of HIV and not HCV transmission and the fact that efforts were focussed on the deferral of homosexuals, it seems hard to imagine how such a considerable, though indirect, reduction in the number of positive donations could have been achieved. An immediate 66% reduction has been applied with no consideration of the fact that the policy was introduced inconsistently throughout Scotland and would, in any event, have taken time to have any indirect effect on the number of HCV positive donations. There is no attempt to explain how this figure has been arrived at other than to say that it is derived from "limited local data and [unidentified] expert opinion". This constitutes assumption 3 in the methodology document provided to the Penrose Inquiry in March 2012[149] and, as can be seen from that document, this assumption has had a significant effect in reducing the number of infections which this group thinks have occurred in this population.[150].

5.13 Further, it was assumed in the analysis that 25% of infected individuals cleared the virus within 6 months of infection and thus, though they were exposed to the virus (and thus would test antibody positive) they would not be able to infect others if they donated blood (assumption 2). As is discussed further below, there appear to be a number of figures which have been quoted as possible clearance rates for the virus. 25% comes from the higher end of these figures. The source of this figure does not appear to be a particular local study but instead the "Global Burden of

---

[147] para 3 of PRSE0002181_0001
[148] response to question 2 of PRSE0003944_0001
[149] PRSE0001962_0002
[150] PRSE0001962_0004

Hepatitis C Working Group 2004".[151] As can be seen from the methodology document, this has a significant effect on reducing the prevalence rate of those who are antibody positive to those donors who may have been infectious.[152]

5.14 The Goldberg analysis assumes the average number of blood components made per donation.[153] This is based on "limited local data and expert opinion".[154] The Soldan analysis uses hard data from the lookback process to arrive at this figure (1.6 units). We are unsure why this could not have been done here. The same appears to be the case with the assumption made about the probability of a blood component being transfused (see below). Indeed, unlike the Soldan analysis, the Goldberg paper appears to make no use of the only hard data which does exist, ie that which emanates from the lookback process.

5.15 The Goldberg analysis assumes the likelihood of a blood component being transfused as 56%. This was based on "limited local data and expert opinion".[155] Given the assumption that each HCV contaminated unit was transfused to a different person (assumption 7)[156] this would have had the effect of reducing the final estimated number of infections by around half. This cannot, in our view, be a proper scientific basis upon which to make such a calculation. Without further explanation, we cannot accept that so many units of blood were being discarded at a time when blood donations were rare and valued. The Soldan paper uses a figure of 66% transfusion.

5.16 The calculation of the probability of a transfused blood component being infected with HCV is dealt with at paragraph 4.3.1 of the October 2011 report.[157] This seems to have been influenced to a large extent by data available relating to the number of injecting drug users in the general population. Assumption 4 in the methodology document confirms that it has been assumed for the purposes of the calculation that the prevalence of injecting drug users (derived from a report by

---

[151] PRSE0001962_0004
[152] PRSE0001962_0004
[153] para 4.3 of PRSE0002181_0001
[154] Assumption 5 of PRSE0001962_0002
[155] Assumption 6 of PRSE0001962_0002
[156] PRSE0001962_0002
[157] PRSE0002181_0002

Hutchinson) is used to calculate the likely prevalence rate amongst the donor population historically. As there were fewer intravenous drug users in the general population in the 1970s, it is assumed that the number of HCV antibody positive donors would be proportionately less. It is not clear why information about the number of injecting drug users in the general population should be taken to reflect the likely infectivity of blood donated in Scotland where there would appear to be other risk factors for transmission of HCV and no necessary correlation between the numbers of injecting drug users in the general population and in the donor population. This can hardly be taken to be representative of the likely number of such injecting drug users in the donor population, as that community is likely to be more socially responsible and thus contain a lower prevalence than in the general population. Further, no consideration appears to have been given to the fact that, even if there were a proportionate rise (as the Goldberg analysis contemplates) in the number of positive donors based on the size of the injecting drug user population, the donor exclusion measures used to stop them donating blood was also considerably less. In our view, these two competing factors may well have cancelled each other out, in particular given that until 1983/84 blood was collected from a population in Scotland (prisoners) which would be likely to have had a far higher than average intravenous drug using population.

5.17 There is a discrepancy between the numbers in the Goldberg analysis and those calculated by Professor James in his methodology applying, in the first place, (a) the number of payments to living patients infected by blood transfusions alive post 2003 (405/607) and (b) the numbers of those infected by this route who are still alive according to a Danish study published in August 2011.[158] We note (a) that this gives a figure of 2,670 likely to have been infected by contaminated blood in Scotland and (b) the fact that Professor Goldberg has dismissed this as a reliable indicator of the likely numbers of infections not due to the application of the Danish mortality data to the Scottish position but due to the reliability of the Skipton data.[159] The Skipton figure of 405 is likely to constitute an

[158] PRSE0000265
[159] PRSE0001252

underestimate of the likely number of living patients post 2003 who were infected by a blood transfusion. This is predominantly due to (a) the strictness with which the Skipton criteria were applied (in particular in cases where patients do not have sufficient medical records to support their claim) (b) the fact that there are likely to be significant numbers of individuals who may not know that they are infected with hepatitis C or indeed may not know that they acquired their infection via this route with the result that they have not considered making an application to the fund and (c) the fact that certain potential applicants may not even know of the existence of the fund. The figure proposed by Professor James (1.74 times the estimated median number of HCV infections by this route in the Goldberg analysis) constitutes a useful check and indicates that the Goldberg figures are likely to be too low. This is also the case with the other figures which Professor James has suggested, all of which are higher than the median estimate of the Goldberg group, one by as much as 2.61 times (4,000).[160] This figure of 4,000 is arrived at by trying to factor into the number of successful Skipton applicants an increase to account for the number who are likely to be alive but t received a payment for whatever reason, applied to the Danish survival rate as at 2011.

5.18 The Goldberg analysis therefore has reliability issues. It seems unlikely that (as the Goldberg group concludes) the implementation of donor exclusion measures (designed primarily to prevent HIV transmission) "prevented thousands of blood transfusion recipients becoming infected" when the reduction in the numbers of likely infections after these measures appears very hard to predict.[161] That the other measure taken by the SNBTS to reduce transmission of HCV (the introduction of routine anti- HCV testing) also prevented thousands of infections is also, in our view, an invalid assertion.[162]

The Soldan analysis

[160] PRSE0000265_0002
[161] PRSE0002181_0004
[162] PRSE0002181_0004

5.19 Dr Kate Soldan, an epidemiologist at the Department of Health's Public Health Laboratory Service Communicable Disease Surveillance Centre, conducted (along with others) a detailed analysis of this question for England.[163] The analysis conducted by here appears to have taken the UK wide HCV lookback as the starting point for the analysis. As far as the UK part of the analysis of concerned, the way in which the analysis was done is reflected in the article written by Soldan & Ors dated 2002.[164] As noted, the starting point is the English lookback data. There is a recognition at the outset (a) that the lookback only identified a limited number of infected components (with the result that some infected components and their potential to infect were not considered as part of the exercise) and (b) that for one reason or another certain components which were found to have been likely to have been infected based on an analysis of previous donations made by a positive donor were not analysed as part of the lookback process. The analysis undertaken appears to attempt to work from certain prevalence figures shown by the lookback data and extrapolate it to consider the many infected donations likely to have been given whose destination could not be traced by the lookback exercise. The calculations appear to have been complicated to a certain extent by the fact that the data available to the Soldan group did not represent all of the lookback data but only information from 8 blood centres which handled 80% (not all) of the blood components which entered the lookback programme.[165]

5.20 The methodology appears to work in the following steps:

a) Use existing prevalence figures for the donor population in England (derived from studies done in the first 4 months after routine testing was introduced in 1991) to work out how many positive donations were likely to have been given in England over the relevant period (by applying the prevalence rate to the number of positive donations). This resulted in a prevalence rate of 0.066%

[163] An abstract of that analysis appears is at PRSE0001715 and the article itself is at PRSE0000620
[164] PRSE0000620
[165] PRSE0000620_0002

being applied to the total number of donations taken made between January 1980 and September 1991.[166]

b) Work out how many infected components are likely to have been made from these positive donations (based on the fact that one blood donation is likely to be made into a number of components). This results in a total number of probably infected components. This was calculated by using the observed number of components made from the components made from donations in the lookback programme (a figure of 1.6 components per donation).[167]

c) Deduct from this the likely number of non-transfused positive components based on data for the proportion of components actually transfused (based on the fact that some will be soiled, lost etc). This will give you a figure for the likely number of transfused infected components.

d) A calculation of the number of likely infected recipients needs to be made. This can be deduced from the number of infected components by (a) reducing the number of components in order to reflect the fact recipients will receive a number of components (ie not every recipient gets a single unit of blood) and (b) making a deduction to reflect the fact that not all recipients of an infected component will actually become infected with the virus. This has been done in the Soldan analysis by using the infection rates observed in the lookback exercise and extrapolating them for the total number of likely transfused infected components to give an estimated overall figure of likely infections.

5.21 The analysis attempts to take the total number of infected components, work out the observed prevalence of anti-HCV in English blood donors at the start of testing in 1991 (which was assumed to give an indication of likely prevalence of HCV in the English blood donor population in the pre-testing years) and plot the likely number of recipients exposed to infected blood and calculate the number of likely infected recipients from that.[168] The analysis appears to have been carried out to the end

[166] PRSE0000620_0002
[167] PRSE0000620_0004
[168] PRSE0003921

of 1995. The results appear to demonstrate that there were less than 14,000 individuals likely to have been infected with hepatitis C as a result of blood transfusions in England in the decade prior to the introduction of routine anti-HCV testing (to 1991). Over 60% of these were expected to have died by the end of 1995.

5.22 It appears that this analysis works on the basis that the infected donations detected by means of the lookback exercise and traced through to the point where a recipient could be identified and was tested can be used as a representative basis for the assessment of the number of recipients likely to have been infected who received an infected component. Though the assumption that the infection rate amongst the lookback-identified positive recipients can be applied more generally to the population of those who received all blood components is not a valid one, the advantage of this approach is that it does take some cognisance of what limited "hard" data about the relationship between exposure to an infected donation and infection that the lookback was able to provide.

5.23 Dr Soldan also carried out an analysis of the numbers likely to have been infected in Scotland. She gave evidence to the Ross Committee to the effect that 3,498 people received components likely to have been infected with hepatitis C as a result of blood transfusions in Scotland.[169] This analysis appears have taken account of (a) the total number of recipients identified by the Scottish lookback exercise whether dead or alive or declining testing and those who had actually been tested and had been found to be positive (excluding only those who were tested and found to be negative) and (b) the prevalence data for HCV infection amongst Scottish donors. A reduction appears to have been factored in for the likelihood that an infected component was not transfused, though this was based on data available for English transfusion likelihood in the absence of Scottish data. The analysis does not attempt to investigate the possibility that infections were caused by a means other than the infected transfusion which would require a more in depth analysis of the individuals concerned and the possibility of their

[169] Report of the Expert Group on Financial and other Support (March 2003) @ paragraph 4.8 - http://www.scotland.gov.uk/Resource/Doc/47034/0024918.pdf (including the material to be found in PRSE0003921)

infections having been caused by other means. As the analysis recognises, many of the infected individuals remained unidentified and so it seems that such an analysis could not have been undertaken at the time when this estimate was prepared.

5.24 Whilst pointing out that the work done by Soldan & Ors had its limitations, Professor Goldberg acknowledged that the work done by Soldan was, in his view, very good and that Dr Soldan was probably the person who knew more about this field than anybody else in the UK.[170] The Soldan analysis relates only to the period from January 1980 to the introduction of routine anti-HCV screening in September 1991 and therefore cannot be taken to represent the total number of infections with hepatitis C from blood transfusions in either Scotland or the UK.

5.25 Further, the use of the figures as to HCV prevalence rates in the donor populations of England and Scotland for the few months after the introduction of testing in 1991 may result in a figure which is far less than the real total number of infections. As the Goldberg analysis attempts to recognise, the likely prevalence of infection in the Scottish donor population in 1991 is likely to have been different from the level it was at earlier in time. In our view, it was less then than it would have been previously. Measures about which the Inquiry has heard evidence, such as the introduction of measures to exclude high risk doors for HIV in 1983/84, the cessation of collecting blood from prisoners in the first half of the 1980s and the introduction of anti-HIV testing in October 1985 are likely to have resulted in less HCV positive blood getting into the system year by year over the decade. Experience of these processes will have been likely to have improved over time, hence lowering the rate to the point observed in 1991/92. Therefore, a higher prevalence rate would require to be applied to the flowchart analysis of the Soldan group for the earlier years of the analysis. This would result in the template producing a greater number of likely infections. Further for the period before the group's reference period (ie before 1980) the prevalence would, in our view, have been likely to have been significantly higher than the 1991/92 rate. Also, as is

---

[170] Penrose Inquiry transcript for 16/03/11 (day 6); 132 (22) to 133 (3) (Professor Goldberg); [PRSE0006006_0132 to 0133]

observed above, Professor Thomas has spoken to a far higher prevalence rate in the donor population in the 1970s and 1980s than was used as a starting point by either the Goldberg or the Soldan groups.

Conclusion

5.26 The Penrose Inquiry attempted an analysis of these different methods of epidemiological analysis in its final report and found that none of those approaches *"is capable of producing a firm and reliable estimate"*, and that *"only a rough and speculative estimate is possible"*, with the conclusion being reached that the number of transfusion-transmitted HCV infections was approximately 2,500.[171] In this Inquiry, the Statistics Expert Group noted that their own conclusions regarding the number of transfusion recipients chronically infected with HCV are uncertain.[172] Their median estimate for the number of transfusion recipients who were infected (including those who cleared the virus prior to the chronic stage) is 2,740 in Scotland.[173] Their hybrid model resulted in a mid-point being reached. At this remove these exercises are very hard to reconcile. We have attempted to bring together various important factors which may influence the Inquiry's final view on this important matter.

5.27 It is notable in itself that the statistics expert group was only able to have moderate confidence that their evidence about the number of units of blood being transfused from each donation per year is accurate.[174] That there was no central record keeping of such practices to permit a more straightforward analysis of the number of units of blood transfused is another example, we say, of the poor (or, in some instances, non-existent) record keeping regarding transfusion usage generally. It is not clear the extent to which the expert group was aware of

---

[171] Penrose Final report, paragraphs 3.255-256
[172] EXPG0000049 at page 7
[173] EXPF0000049 at page 29
[174] EXPG0000049 at page 64

different blood collection practices across the country (explored elsewhere in this submission) and how these might have impacted on the level of blood-borne infections within the relevant donor populations.

5.28 It is of course important that as accurate an estimate as possible be expressed, with the caveat that this would only be scientifically informed estimate. In any event, it can be said that well over 3,000 people were infected with HCV in Scotland by blood or blood products, most of which derived from a voluntary donor population which was, erroneously, considered to be safe. Assurances to that effect given to patients in both of these communities were totally false.

The likely timing of the HCV infections

5.29 As far as the place of transfusion of the infected blood is concerned, Dr Gillon provided material in respect of 103 infected patients as to the region in which the infective blood transfusion was taken. This data might tend to suggest that the practices of donor selection in the region with the higher prevalence region were of questionable effectiveness and quality. 42 were in Greater Glasgow/WBTS, 24 in Lothian, 21 in Tayside, 10 in Aberdeen and 6 in Inverness. The statistical significance of this is limited given the small number of patients for whom this information is available when compared with the full extent of the likely number of patients infected via this route.

5.30 The disparity between the figures spoken to by Dr Gillon and those estimated by Dr Soldan are indicative that there are likely to be large numbers of people who were infected with the disease by a blood transfusion who have not been identified and who may never be so identified. It is likely based on the evidence heard by the Inquiry that these people will have been exposed to stigmatisation based on assumptions about their infection route which were not accurate. The Inquiry must recognise that fact in its final report.

Progression of HCV disease

5.31 We refer to the evidence from Professor Thomas at the Penrose Inquiry regarding the fact that patients in the bleeding disorder community infected with hepatitis C from exposure to blood products are more likely to progress to the more severe stages of the disease due to multiple exposures.[175] In general terms, Professor Thomas stated in his Penrose evidence stated that 30% of those who are infected with hepatitis C will only advance to the acute stage and will not develop to the chronic stage at the 6 month period. The remaining 70% of those generally infected with the disease progress to the chronic phase.[176] In the original material presented to the Inquiry by the UKHCDO it was suggested that the clearance rate from hepatitis C would be in the region of 15% of those who have contracted the disease.[177] In his Penrose oral evidence Dr Hay described this initial analysis as conservative, suggesting that "recent discussions with various experts" had suggested to him that, in fact, 25 to 30% of cases would remit.[178] The source of these figures was not specified by Dr Hay on either occasion but later he did suggest that this had come from Professor Brian Gazzard who had been part of the Department of Health Committee which had advised the Secretary of State for Health regarding changes to the Skipton fund.[179]

5.32 In his evidence to the Penrose Inquiry, Dr Tait spoke to the fact that certain research was done in 2006/2007 under the guidance of Dr Watson in Aberdeen to research the progression of the disease in patients infected with hepatitis C amongst the bleeding disorder community who were receiving treatment in Scotland.[180] The research into these questions was not repeated for the purposes of that Inquiry.[181] The 2006/2007 research was conducted on less individuals than the number identified as probably having been infected in Scotland. Also, the

---

[175] PRSE0001814_0021 to 0022
[176] Penrose Inquiry transcript for 11 October 2011 (day 52) @ page 13, lines 3 to 9 (Professor Thomas); [PRSE0006052_0013]
[177] Penrose Inquiry transcript for 18/03/2011 (day 8); 40 (22 to 25) (Dr Hay); [PRSE0006008_0040]
[178] Penrose Inquiry transcript for 18/03/2011 (day 8); 41 (1 to 4) (Dr Hay); [PRSE0006008_0041]
[179] Penrose Inquiry transcript for 18/03/2011 (day 8); 64 (14 to 18) (Dr Hay); [PRSE0006008_0064]
[180] PRSE0001993
[181] Penrose Inquiry transcript for 30/04/11 (day 14); 126 (21 to 23) (Dr Tait); [PRSE0006014_0126]

2006/07 research did not focus on patients infected in Scotland but on those who were being treated in Scotland, irrespective of the likely place of their infection. Therefore, this 2006/07 research cannot be taken to be anything more than indicative of the likely progression of the disease in the Scottish-infected patients. Dr Tait summarised the conclusions of the 2006/07 research as having found that the progression rates amongst the patients with bleeding disorders who were studied were broadly the same as progression rates in other populations of individuals infected with hepatitis C.[182] However, the clearance rate which was observed was 17.7% which appears lower than the rates spoken to by Dr Hay in his evidence (see above).[183] It is interesting to note that this cohort only identified 33 co- infected patients (less than half the number actually co-infected in Scotland, as discussed above). As Dr Tait accepted in his Penrose evidence, it was likely that virtually all HIV positive patients would have been hepatitis C positive.[184] Professor Thomas pointed out that higher viraemia in co-infected patients would be likely to cause more rapid progression into the worse stages of the hepatitis C. He noted that given that immuno-suppression is a consequence of infection with HIV, there will be likely to be greater levels of the hepatitis C virus present, meaning that co-infection is likely to cause patients to progress more rapidly through the stages of the disease.[185] He pointed out in evidence that it is likely, therefore, to lead to a higher likelihood of severe disease and death than in mono-infected patients.[186] Therefore, had the 2006/07 assessment included all co-infected patients, the observed clearance rate would have been likely to have been lower than 17.7%. The observed progression rates to the later stages of hepatitis C are also likely to have been greater.

5.33 Multiple exposure to the hepatitis C virus has tended to mean that bleeding disorder patients are more likely to be infected with genotype 1 hepatitis C which

---

[182] Penrose Inquiry transcript for 30/04/11 (day 14); 91 (9 to 14) (Dr Tait); [PRSE0006014_0091]
[183] PRSE0001993
[184] Penrose Inquiry transcript for 30/04/11 (day 14); 132 (7 to 11) (Dr Tait); [PRSE0006014_0132]
[185] Penrose Inquiry transcript for 11 October 2011 (day 52) @ page 58, lines 9 to 13 (Professor Thomas); [PRSE0006052_0058]
[186] Penrose Inquiry transcript for 12 October 2011 (day 53) @ page 17, lines 9 to 15 (Professor Thomas); [PRSE0006053_0017]

has had the result of their infection being less susceptible to treatment.[187] This is borne out by the 2006/07 research conducted by the Scottish haemophilia directors who discovered that two thirds of the bleeding disorder patients in Scotland on which they had the relevant data (178 in total) were infected with genotype 1, resulting in them being less likely to respond to treatment.[188] The Health Protection Agency published a report entitled "Hepatitis C in the UK" on 28 July 2012 to correspond with World Hepatitis Day. The report was compiled in conjunction with Health Protection Scotland.[189] The report provides up to date figures to the effect that there are around 216,000 people who were chronically infected with Hepatitis C in the UK, with around 90% of those being infected with either genotype 1 or 3. The report noted that in the UK as a whole both hospital admissions and deaths from HCV-related end stage liver disease (ESLD) and hepatocellular carcinoma (HCC) are continuing to rise in the UK. Hospital admissions had risen from 612 in 1998 to 1,979 in 2010, while deaths had risen from 98 in 1996 to 323 in 2010. An overall increase in registrations for liver transplants with a code of post-hepatitis C cirrhosis has been observed from 45 in 1996 to 101 in 2011.[190] Whilst these figures are national and relate to the entire population of those infected with hepatitis C and not just those who contracted the disease through blood or blood products, they demonstrate the increasing severity of the disease as time progresses and the consequent increasing pressure on medical services for those who require treatment.

5.34 The report went on to state that of the estimated 39,000 people living in Scotland with chronic hepatitis C infection, only approximately half were thought to have been diagnosed by 2011.[191] It is interesting to note, in our view, that the section relating to initiatives aimed at increasing awareness of infection and detection appears to focus predominantly on those who may have been infected amongst the drug injecting population. There is no mention in that section (or in the entire

---

[187] PRSE0001814_0021
[188] PRSE0001993
[189] http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317135237219
[190] ibid @ page 7
[191] ibid @ page 9

report for that matter) of those who may have contracted the disease through blood transfusions in Scotland.[192]

5.35 Given these conflicting accounts of the position, the Inquiry should express a view on the need for a better understanding of the nature of HCV infection and its impact on likely clearance rates in the bleeding disorder community. Such individuals will have been likely to have been exposed to multiple strains of the virus given their repeated exposure to infected blood through their (usually frequent) use of pooled plasma products making the likelihood of clearance very much less than in the general population. Dr Hay accepted in his Penrose evidence that it was extremely common for the more severe (and therefore more frequently treated) patients to have been exposed to multiple genotypes and that one genotype would become dominant over the others.[193]

6. Mortality statistics

HIV

6.1 Dr Gillon indicated in his limited report on the 18 individuals of whom he knew who had been infected with HIV by a Scottish blood transfusion that 15 were known to have died as at 31 December 2010 (83.33%).[194] He did not provide any data on the cause of death amongst this group, which he had done in his similar report on those who had died in the group who had been infected with hepatitis C as a result of transfusion. In evidence, he did confirm, however that data

---

[192] ibid @ page 8
[193] Penrose Inquiry transcript for 18/03/2011 (day 8); 62 (3) to 63 (20) (Dr Hay); [PRSE0006008_0062 to 0063]
[194] PRSE0000350_0003

available to HPS suggested that many of these will have died of AIDS.[195]

6.2 As far as deaths amongst the bleeding disorder community are concerned, the Macfarlane trust indicated in 2012 that of the 67 infected individuals with bleeding disorders in Scotland in respect of whom payments have been made, 46 have died (68.66%). Of the 76 patients with haemophilia who were assumed to have been infected by their receipt of contaminated blood products in Scotland listed in the information held by Health Protection Scotland at that time, 46 were known to have died (60.53%).[196] Information from this source as to the cause of death depended largely on the accuracy of data on death certificates or local clinicians taking the trouble to contact HPS with information that HIV may have contributed to death.

6.3 The material presented by the Scottish haemophilia directors to the Penrose Inquiry would tend to suggest that there had only been 39 deaths in this community in Scotland. This is made up of 19 (out of 21) from the Edinburgh infections (which remains the position to this day),[197] 8 (out of 21) from the Yorkhill infections[198], 10 (out of 12) from the GRI infections[199] and 2 (out of 3) from the Aberdeen infections[200]. This comprises 66% of the total of 59 spoken to by the haemophilia directors. However, if one cross references that figure which were available from the UKHCDO relating to infections with hepatitis C and cause of death, it is interesting to note that there appear to have been either 48 AIDS deaths based on the collated figures (table 9)[201] or 58 AIDS deaths if one analyses the UKHCDO material broken down by Scottish centre (table 10).[202] This would be suggestive both of a higher number of deaths than the directors had spoken to and also a higher number of deaths from AIDS.

6.4 A varied approach appears to have been taken by the haemophilia directors as to

---

[195] Penrose Inquiry transcript for 16/03/11; 66 (3 to 6) (Dr Gillon); [PRSE0006006_0066]
[196] PRSE0003663
[197] PRSE0003885_0002
[198] PRSE0001187
[199] PRSE0004861
[200] PRSE0000235
[201] PRSE0002887_0060
[202] PRSE0002887_0062 to 0065

whether these deaths were caused by the HIV infection. Information about cause of death appears to have been derived from a combination of the HPS records and the UKHCDO database. As discussed above, the former appears to be derived solely from the death certificate and the latter is not really intended as a death recording system.[203] Professor Ludlam suggested in his Penrose evidence that it contained very little information at all.[204] Both sources are therefore of limited value for this purpose. Professor Ludlam acknowledged that there would have been certain anxieties amongst family members about having HIV or AIDS listed on the death certificate and so this might not now be viewed as the most reliable source of information about the cause of death in these patients.[205]

6.5 Further, Professor Ludlam suggested that it would be appropriate to sub-categorise deaths as (a) related to HIV/AIDS (b) HIV contributed (c) probably not related to HIV/AIDS or (d) not due to HIV/ AIDS.[206] In the first place, this approach seems unnecessarily complicated, in particular in light of the fact that, in our submission, the immuno-suppressant qualities of HIV infection will be likely to have made a material contribution to the death in almost all, if not all cases. Further, this approach is not consistent with the total number figures of deaths from AIDS (58) in the UKHCDO tables, as discussed above.

HCV

6.6 In Scotland, liver-related deaths among people diagnosed with hepatitis C increased from 44 in 1996 to 133 in 2010, at an average annual increase of 8.9%. In recent years (2007-2010), the average annual increase was 6.4%. By linking records in Scotland's National Hepatitis C Diagnoses Database to the national

---

[203] Penrose Inquiry transcript for 30/03/2011 (day 14); 23 (4) and 28 (8 to 11) (Professor Ludlam); [PRSE0006014_0023 and 0028]
[204] Penrose Inquiry transcript for 30/03/2011 (day 14); 45 (19 to 24) (Professor Ludlam); [PRSE0006014_0045]
[205] Penrose Inquiry transcript for 30/03/2011 (day 14); 28 (16) to 29 (1) (Professor Ludlam); [PRSE0006014_0028 to 0029]
[206] PRSE0003885_0002

register of deaths, it is possible to determine that only 609 (50%) of the total 1,222 liver-related deaths during 1996-2010 among people diagnosed with hepatitis C, had any mention of hepatitis C on their death certificate. Among the 133 liver-related deaths in 2010, 96 (72%) had liver disease recorded as the underlying cause of death (alcoholic liver disease was the most prevalent underlying cause in 49), and 37 (28%) had liver disease only as a contributing cause of death; 103 (77%) were male, and 73 (55%) were aged less than 50 years. End Stage Liver Disease-related deaths among people diagnosed with hepatitis C in Scotland increased from 16 in 1996 to 50 in 2010 (Figure 9), at an average annual increase of 9.2%. Of the total 532 ESLD-related deaths during 1996-2010 among people diagnosed with hepatitis C, only 300 (56%) had hepatitis C mentioned on the death certificate.[207]

Bleeding disorder infections

6.7 In the material presented to the Penrose Inquiry by the UKHCDO, it was assumed that deaths from liver disease amongst those exposed to hepatitis C as a result of blood product use were contributed to by hepatitis C infection.[208] In our view, this was a fair assumption to make. Even of those who do have alcohol intake as a likely contributing factor to their death, their underlying hepatitis C infection will have materially contributed to their death on the basis that they will have been considerably less tolerant to alcohol as a result of their infection than they otherwise would have been. Therefore, in our view, the approach advocated by Dr Hay to the effect that all liver disease deaths amongst the population of those who were infected with hepatitis C should be deemed to have had hepatitis C as a material contributor to the death was correct.

6.8 The material presented to the Penrose Inquiry by the UKHCDO on cause of death provided a cause of death for only 84 of the individuals in the bleeding disorder

[207] http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317135237219 @ page 18
[208] Penrose Inquiry transcript for 18/03/2011 (day 8); 51 (4 to 21) (Dr Hay); [PRSE0006008_0051]

community who were thought to have been infected with hepatitis C and had subsequently died (89 were listed with 5 unknowns).[209] This is only a fraction of the total number who are dead from this community, estimated to be 193 of the 447 infected in the UKHCDO tables (43.18%). Of this number (84), 21 were reported to have died from liver disease or liver related causes (26.19%) although cancer (which may include hepatocellular cancer) accounts for a further 22 (26.19%). In our view, these statistics are generally unreliable on the basis that many of the listed causes of death will have had hepatitis C as a contributory factor. The liver is a complicated and important organ and hepatitis C infection is therefore likely to have a contributory effect on death in some form even if not listed as a cause of death. This applies equally to the analysis of those infected by blood transfusions below.

Blood transfusion infections

6.9 The majority of patients identified as having been exposed to a potentially infective blood components had died by the time the lookback exercise was complete even in 1998 (536 out of 880 or 60.9%). In Dr Gillon's limited analysis of those identified by the lookback process as definitely having been infected by a blood transfusion and for whom the relevant information was available, just over half (53 out of 103) had died as at January 2011.[210] Hepatitis C was recorded as having materially contributed to the death in 15.09% of cases (8 out of 53).[211] It is suggested elsewhere that in fact this figure should be 14 out of 53 which represents 26.4%

6.10 In his oral evidence to the Penrose Inquiry, Professor Goldberg suggested that 85 of the 304 individuals whom he thought had been infected by blood transfusions

[209] PRSE0002887_0060 to 0061
[210] Penrose Inquiry transcript PRSE0000405_0005
[211] PRSE0000405_0005

in Scotland were dead as of December 2009 (27.96%).[212] The source of this information was the General Registers of Scotland. 31 of these deaths had liver disease (including alcoholic liver disease) as the primary or secondary cause of death (36.47% of known deaths). For the 351 bleeding disorder patients thought to have been infected in his statistical analysis, Professor Goldberg reports that 78 were dead as of December 2009 (22.22%). 30 of these deaths had liver disease (including alcoholic liver disease) as the primary or secondary cause of death (38.46% of known deaths).[213] The fact that alcoholic liver disease is listed as a separate category in the statistics is of interest. Hepatitis C infection would, of course, render an individual far more susceptible to suffering from alcoholic liver disease. Further, we would argue that certification of death from this cause may, in some cases at least, be based on an erroneous assumption regarding the cause of the liver disease.

6.11 In her report to the Ross Committee published in March 2003, Dr Kate Soldan had estimated that around 800 of the 3,498 individuals infected with hepatitis C as a result of blood transfusions in Scotland were likely to have been alive at that time.[214] She estimated that 365 of the 500 individuals with bleeding disorders infected with hepatitis C as a result of their exposure to blood products in Scotland would still have been alive in 2003.

6.12 The epidemiological methodology document provided to the Penrose Inquiry by the team led by Professor Goldberg at HPS was based on the assumption that the survival rate of those who received HCV contaminated blood components did not differ from the survival rate of those who had received non-contaminated components. We submit that this assumption will have had a significant effect on the conclusions of that group as its effect is to deny entirely that hepatitis C infection will increase the likelihood of an individual dying. That assertion is based

---

[212] PRSE0000893 and PRSE0001597

[213] PRSE0003337_0003

[214] Report of the Expert Group on Financial and other Support (March 2003) @ paragraph 4.8 - http://www.scotland.gov.uk/Resource/Doc/47034/0024918.pdf (including the material to be found in PRSE0003921

on a paper by Harris & Ors (2006)[215] which showed that all-cause mortality in infected blood transfusion recipients and controls at 16 years post transfusion did not differ significantly.[216] Given that the signs of hepatitis C will often take many years to manifest themselves, such an analysis at 16 years post transfusion cannot be said to be a reliable guide as to the likely increase in mortality from hepatitis C infection. As is noted in the Goldberg methodology analysis "information about later survival of that cohort was not available".[217] Further, the limitations of this analysis include the reliability of the data as to the cause of death which (as is observed elsewhere on this submission) is unreliable when it comes to the recording of deaths caused by hepatitis C.

6.13 The Penrose Inquiry heard evidence relating to the inadequacies of the recording of deaths from hepatitis C and HIV as having been caused or indeed contributed to by those diseases.[218] In his analysis of the available mortality data provided by Dr Gillon, only 15.09% or 26.4% were reported as having had hepatitis C infection contribute to their death. Given that all of the patients under consideration were definitely infected with hepatitis C, Dr Gillon considered it surprising that this figure was so low.[219] Despite the limited number of cases analysed, this certainly gives an indication that there is a distinct under-reporting of hepatitis C as a cause of death amongst those infected by blood or blood products in Scotland. Professor Goldberg was dismissive of the reliability of death certificates as a means of identifying hepatitis C as a cause of death.[220] He described the number of reported deaths from hepatitis C in Scotland as a "gross underestimate".[221] As a result, death certificates ought not to be used in the analysis of whether someone is likely

---

[215] PRSE0002804
[216] PRSE0001962_0003
[217] PRSE0001962_0003
[218] Evidence was heard from two professional witnesses in connection with the death of Mrs O'Hara that hepatitis C was not included on her death certificate but it should have been - see Penrose Inquiry transcript for 10/03/11 (day 3); 78 (14) to 79 (11) and 85 (10 to 19) (Dr Mutimer) and 130 (5 to 8) (Dr Dunn); [PRSE0006003_0078 to 0079; 0085; 0130]
[219] Penrose Inquiry transcript for 16/03/11 (day 6); 55 (4 to 6) and 56 (21 to 22) (Dr Gillon); [PRSE0006006_0055 and 0056]
[220] Penrose Inquiry transcript for 16/03/11 (day 6); 113 (13 to 19) (Professor Goldberg); [PRSE0006006_0113]
[221] Penrose Inquiry transcript for 16/03/11 (day 6); 114 (7) (Professor Goldberg); [PRSE0006006_0114]

to have died as a result of HCV. Given the analysis presented below about the significant hepatic and extra-hepatic manifestations of the condition, it should be presumed in any financial schemes that HCV materially contributed to any death where the person has infected with HCV.

7. Statistics relating to the use of blood products in Scotland

7.1 A general analysis of the amounts of the different types of blood products used in the treatment of people with bleeding disorders in Scotland is of use to the Inquiry in its analysis of what caused infections in that community and what infections could and should have been avoided or what effects of infection could have been lessened by different decisions, which we argue below should have been made in the interests of patient safety.

7.2 The Inquiry has access to statistical material provided to the Penrose Inquiry by the UKHCDO relating to the amounts of products used by patients with bleeding disorders in the various haemophilia centres in Scotland.[222] In our submission, these figures provide a useful general starting point for a proper analysis of the policies and ethos behind product selection and use in Scotland at a time before factor concentrates became heat treated so as to inactivate HIV and subsequently HCV in December 1984 and April 1987 respectively.

7.3 The precision of the UKHCDO material might be questionable as it is based on careful record keeping and reporting to the UKHCDO database of what products were used from year to year. There are limitations even in the tables which indicate that these systems were clearly not without their limitations. The information available to the inquiry can be supplemented by the detailed evidence given by individual witnesses about their or their relatives' treatment experiences, some significant and indictive examples of which are noted in the section of this submission about haemophilia treatment below. However, these tables are

[222] PRSE0002887

indicative of certain general trends which, in our view, are important in the Inquiry's analysis of product use in Scotland.

7.4 The divergence in practice as regards product use amongst the various haemophilia centres in Scotland is remarkable. The risks of viral transmission from imported commercial factor concentrates were well known, at least in the second half of the 1970s (which can be seen from the material discussed in the 1975 World in Action DVD considered by the Inquiry). Against such a background, it is hard to comprehend that such divergent practices could have developed as between, for example Yorkhill and Edinburgh as regards the use of commercial concentrates. The reasons for this are discussed in detail below.

7.5 If you were treated in Aberdeen, you would have been most unlikely to receive commercial products at all. Between 1969 and 1991, commercial products were only used in 1978, 1979 and 1998 and then in relatively small quantities.[223] These are indicative of such products being used for a small number of patients with inhibitors for the SNBTS product, possibly one. It would have been very unlikely that any HIV transmissions from commercial products could have occurred there as these products were not used at all in Aberdeen in the early part of the 1980s. One can deduce from this that despite the apparently limited amount of domestic factor VIII concentrate available to Aberdeen until 1982 onwards (more than 3 times as much PFC factor VIII was used in 1983 than had been used in 1980, possibly as a result of the better yield being achieved in the PFC processes devised by Dr Foster that year), those responsible for product selection there did not start to rely on commercial producers, instead making up the requirements of patients with the safer but less convenient cryoprecipitate. The position in Dundee shows a similar pattern of usage with no commercial product showing in its records at all until 1988 (Alpha's Profilate) and then in relatively small quantities.[224] Profilate was also used in Aberdeen in 1988 only.[225] That was as a result of a loss of self-sufficiency in 1988, which is explored below. The loss of self-sufficiency in 1988 (which ought not to have happened) meant that patients who by that time ought

[223] PRSE0002887_0009 to 0011
[224] PRSE0002887_0012 to 0014
[225] PRSE0002887_0010

to have been receiving the PFC heat-treated Z8, were, in fact, exposed to the risk of having to rely on imported products and the controlled processes of the commercial market, which had resulted in HIV infections in 2 Yorkhill patients from Factorate HT in 1986 (see below). Cryoprecipitate also played a prominent part in therapy there until 1982, when PFC factor VIII concentrate appears to have become available in greater quantities. A similar picture emerges from an analysis of the figures from the Inverness centre where commercial factor VIII was only used in 1974.[226] Thus, these centres were able to be self-sufficient in domestic product, be that factor VIII concentrate or cryoprecipitate, managing the use of the former to meet availability.

7.6 On the other hand, at Yorkhill, commercial concentrates were used in enormous quantities.[227] Between 1977 and 1979 inclusive, the proportion of the factor VIII concentrate used which was of commercial origin was 65.1%. In 1980, it was 80.9%, in 1981 58%, in 1982 48.5%, in 1983 (when Professor Hann took over) 3.18% and in 1984 0.5%. During the period when many of the HIV infections occurred at Yorkhill, there was a disproportionate reliance on commercial factor VIII concentrate. As is explored below, the treatment regimes there were simply not standard practice. In fact, they ran completely contrary to the near universally accepted ethos of the time. The deviation from standard practice was unjustified and unsafe. Very little cryoprecipitate was used over that period. It is also interesting to note that whereas the small usage of commercial product in Aberdeen came from different commercial sources (Travenol/Hyland and Alpha), the sole factor VIII product in use at Yorkhill between 1980 and 1984 inclusive (when its use ceased) was Armour's Factorate. The figures for the Glasgow Royal infirmary also show a considerable reliance on commercial factor VIII in the late 1970s and early 1980s, though from a wide range of sources and in considerably smaller proportions of the total quantities of factor VIII concentrate used than at Yorkhill. We make submissions below regarding the startling lack of co-ordination between the approach adopted in certain parts of the country where (a) a reliance

[226] PRSE0002887_0028 to 0029
[227] PRSE0002887_0025 to 0027

on domestic concentrates was considered to be the safer option for patients and (b) cryoprecipitate was used where supply could not keep up with demand and other areas where a completely different approach based at times almost entirely on commercial concentrates was preferred.[228]

7.7 The product usage in Edinburgh is also interesting.[229] No commercial products were used at all during the 1970s and there would appear to have been a heavy reliance on cryoprecipitate in order to deal with the fluctuating availability of domestic factor VIII (more than twice as much PFC factor VIII seems to have been used in 1976 than in 1979, for example). Therefore, the shortfall in domestic factor VIII concentrate appears not to have resulted in resorting to use of commercial products. We are aware that there was a change of directors at the Edinburgh centre in 1980, Dr Ludlam having been appointed to replace Dr Davies. This provoked a drastic change in approach in two respects. In the first place, far greater amounts of therapeutic material were used than had been used in the past. Over eight times as much PFC factor VIII was used in 1980 than had been used in 1979 (despite the use for the first time of a not inconsiderable amount of commercial factor VIII). Around twice as much cryoprecipitate was used. At the other centres, no such rise was evident. In the same two years the amount of factor VIII used in Aberdeen decreased.[230] In Dundee the usage increased by only 29%.[231] At the Glasgow Royal Infirmary usage of factor VIII rose by 15.5%.[232] At Yorkhill increased usage was around 72%.[233] In Inverness, the amount of factor VII used increased by around 79%.[234]

7.8 This increased factor VIII usage in Edinburgh when compared with the usage levels in the 1970s continued throughout the first half of the 1980s. The average annual usage of all factor VIII between 1976 and 1979 was 317,349 units. The average annual usage between 1980 and 1985 was 1,874,178 (almost 6 times as much). A

---

[228] PRSE0000624
[229] PRSE0002887_0015 to 0019
[230] PRSE0002887_0009
[231] PRSE0002887_0012 to 0013
[232] PRSE0002887_0021
[233] PRSE0002887_0025
[234] PRSE0002887_0028

similar analysis of the average annual amounts of factor VIII concentrate over these years used in the other centres shows increases in the following proportions - Aberdeen (2.39 times), Dundee (3.08 times), GRI (1.77 times), Yorkhill (3.96 times comparing the periods from 1977 to 1979 and 1980 to 1985 inclusive for which records are available) and Inverness (1.69 times). Though the usage of factor VIII concentrate rose across the country substantially, factor VIII concentrate in Edinburgh therefore rose out of proportion with the other centres by some considerable margin over this period. The centres with the greatest increased usage of concentrates in the first half of the 1980s account for large majority of HIV infections in Scotland (Edinburgh and Yorkhill). The vastly inconsistent product usage suggests that product selection policies were adopted and treatment programmes instituted by centre directors on a general basis and without regard for the needs of individual patients. This process was allowed to go on without control by or official guidance from government or the NHS, despite the fact that certain of the programmes (in particular those relying on large amounts of commercial products) must have been hugely expensive.

7.9 This increased demand, driven by the directors (in particular, Dr Ludlam) placed an enormous strain on the PFC to meet requirements. The manifestations of that strain on the relationships between SNBTS and the haemophilia directors are explored below. In 1975, 163 patients were registered to receive treatment in Edinburgh (before correction for double counting).[235] In 1980 there were 203.[236] In 1985 there were 265.[237] The number of patients being treated there had therefore increased by only 1.63 times. This increased usage was linked to the implementation of home treatment and prophylactic treatment regimes which resulted in patients being exposed to greater quantities of products (in particular factor concentrates) and greater strain being placed on the achievement of national self-sufficiency, as well as the need for all recipients of blood and blood products being out at unnecessary risk due to the donor selection practices which

[235] PRSE0002887_0030
[236] PRSE0002887_0031
[237] PRSE0002887_0031

required to be adopted to meet that demand.[238] Over this period factor VIII concentrates were known to be likely to be infective with NANBH, even on first infusion.

7.10 In addition, Edinburgh had an unprecedented reliance on commercial concentrate to meet demand where it could not be met out of domestic supplies. As noted above, before 1980, commercial concentrate had not been used in Edinburgh at all. Cryoprecipitate had been relied upon when there was not enough domestically produced factor VIII concentrate. In 1980, Factorate comprised 9.07% of the total usage of factor VIII concentrate in Edinburgh. In 1981, the only year in the first half of the 1980s (other than 1985) when the amount of available domestic factor VIII dropped, commercial factor VII usage rose to 34.37% of the total. In that year the amount of cryoprecipitate fell by almost half. Thus, contrary to his expressed philosophy of only using domestic concentrate, Dr Ludlam was prepared to pay for commercial factor VIII concentrate to meet his treatment regimes when he could not get domestic supply. The usage of that material at that time caused at least one HIV infection. This is important context to the exchanges between Dr Ludlam and Dr Bouton in 19 about his demand for factor VIII. It was known within SNBTS that of they did not meet those demands, Dr Ludlam would resort to commercial product as opposed to changing his regimes. He had done so before. According to all involved with that process at the time, that would have exposed patients to a known increased risk of NANBH and whatever other pathogens may be in the products which came from paid donors. It would also have cost a good deal more to the Health Board.

7.11 As far as the treatment of haemophilia B patients was concerned, due to the lesser numbers of patients with that condition, Scotland was self-sufficient in factor IX concentrate (other than some commercial usage in Glasgow in 1985, which is examined below as it is the only centre to have an HIV infection in that year). In Aberdeen, FFP appears to have been used until 1979 and then very small amount of factor IX concentrate until substantial increases in 1985 and subsequently.[239]

---

[238] PRSE0000624
[239] PRSE0002887_0010

This appears to suggest that low amount of concentrate were used until a safe factor IX heated concentrate became available in 1985, which appears to show that such an approach to treatment was perfectly feasible. In Dundee, FFP appears to have been used until 1976 and then of factor IX concentrate was used until substantial increases in 1984 and 1985 (largely pre-heat treatment) and subsequently.[240] In Edinburgh, FFP factor IX concentrate appears to have been available from 1969 (indeed there is literature on its usage from that time by Professor Cash). Its use rose steadily until as with factor VIII there was a substantial increase in usage in 1980 on the arrival of Dr Ludlam by 2.4 times and subsequently. By 1984, the usage was 5 times what it had been in 1979.[241] As with haemophilia A patients, exposure to viral load from these products was huge. The GRI records shows fluctuating factor IX concentrate usage, possibly due to supply issues described there as opposed to changes in treatment philosophy. In 1985, a quantity of immune factor IX concentrate was used. This is discussed below.[242] A similar fluctuating pattern is apparent at Yorkhill.[243] In Inverness very small amounts appear to have been used, probably due to the low number of haemophilia B patients there.[244] The statistics relating to the number of such patients registered there show that there were only 2 or 3 patients registered there between 1980 and 1990.[245] The maximum amount of factor IX concentrate used there in any year was only 6,000 units which seems to show that patients could be managed on small amounts of treatment.

Conclusions

7.12 Much of the information to which the Inquiry had access relating to patients with

---

[240] PRSE0002887_0012 and _0013
[241] PRSE0002887_0015 to _0016
[242] PRSE0002887_0022 to _0023
[243] PRSE0002887_0025 to _0026
[244] PRSE0002887_0028 to _0029
[245] PRSE0002887_0031 to _0032

bleeding disorders has come from the UKHCDO. In his evidence to the Penrose Inquiry, Professor Ludlam stated that he could not guarantee that the UKHCDO records of the treatment histories of patients were complete.[246] Such information must therefore be treated with caution, as discussed above though it is still helpful for various conclusions to be drawn against which the rest of the evidence heard by the Inquiry can be analysed.

7.13 Until legislative changes in 2008, the notifiable disease legislation required the reporting of viral hepatitis. HIV has never been a notifiable disease. In is evidence to the Penrose Inquiry, Professor Goldberg confirmed that this system resulted in clinicians rarely reporting possible infections with these diseases to health boards meaning that they were rarely reported to Health Protection Scotland.[247] It is noteworthy, in our view, that Professor Goldberg sought to explain to Penrose that the system of gathering and retaining information about hepatitis C in Scotland was better in Scotland than elsewhere.[248] That does not, in our view, lead to the conclusion that the system is a good one. This was also the impression of the statistics expert group.[249] The apparent (a) low likelihood of incidences of hepatitis C or HIV being reported to those responsible for monitoring public health in Scotland and (b) lack of investigation of the accuracy of the information reported to it are addressed above.

7.14 The evidence given by Dr Gillon about the lack of any requirement (legal or administrative) to report cases of possible transfusion transmitted infection to SNBTS is addressed above. The HPA appears to have maintained a national HCV register for research purpose since 1998. There was no requirement for SNBTS to report cases to them and the two systems appear to have been operating separately.[250]In his Penrose evidence, Professor Goldberg accepted that the main focus of HPS (now Public Health Scotland) in this area was on prevention of future

---

[246] Penrose Inquiry transcript for 04/05/11 (day 19); 58 (4 to 5) (Professor Ludlam); [PRSE0006019_0058]
[247] Penrose Inquiry transcript for 16/03/11 (day 6); 103 (11 to 22) (Professor Goldberg); [PRSE0006006_0103]
[248] Penrose Inquiry transcript for 16/03/11 (day 6); 110 (10) to 111 (2) (Professor Goldberg); [PRSE0006006_0110 to 0111]
[249] IBI transcript for 09/11/22; 41 (Professor Evans)
[250] para 5 of PRSE0003049_0003

infections and so blood transfusion does not play a large part in his organisation's consideration of these diseases.[251] There remains a need for there to be a greater focus in the identification and treatment of those infected with hepatitis C as a result of their exposure to blood in Scotland.

7.15 The systems for estimating, recording and monitoring the numbers of NHS patients in Scotland treated with blood and blood products and those at risk of exposure and exposed to risk of infection are important. They permit epidemiological estimates of the numbers of at risk patients and are important in planning a management strategy for known or possible pathogenic threats. They permit efficient appreciation of the scale of pathogenic exposure when threats do materialise, facilitating the prevention of further spread in the interests of public health and the identification and early care for the infected.

7.16 The evidence available to the Inquiry demonstrated that the quality of the systems in place for achieving an understanding of the scale of likely infection with infectious diseases like HCV and HIV, both at the time those infections were occurring and in retrospect was limited. The Inquiry should recommend that efforts be made by government to ensure that systems for disease prediction and detection and hence of disease prevention and control are as robust as possible. As far as the recording of statistical information relating to transfusion transmitted infection is concerned, we would suggest that it be made a legal requirement that such possible cases be reported to a single agency responsible for the maintenance of an official register of infections with information about the likely source of infection and the progression of the disease.

7.17 Given the apparent unreliability of the reporting of deaths from HIV and/or hepatitis C, we would recommend that government-funded research be undertaken to arrive at a more accurate picture of the number of deaths amongst the populations infected with these viruses by blood or blood products in Scotland which are connected to the infections. Particular research into the numbers who have contracted cancer in these populations is also necessary.

---

[251] Penrose Inquiry transcript for 16/03/11 (day 6); 111 (18) to 112 (14) (Professor Goldberg); [PRSE0006006_0111 to 0112]

7.18 It should also be noted that more work should be done on trying to identify patients who were infected with HBV in Scotland, both as a result of transfusion and from bleeding disorder treatment. In the former community, individual are likely to have been missed for similar reasons as the HCV group – as was accepted in the statistics group evidence this required an estimate to be arrived at as "we can't count these cases".[252] In the bleeding disorder group, we recommend below that these patients are likely to have experienced under-appreciated effects from HBV exposure which are not often considered due their HCV infections. This is exemplified by the apparent inconsistency in the statistics group expert which stated on the one hand that the group was able to attribute the relatively low rates of HBV in haemophiliacs to the success of donor screening[253] and on the other that in 1976 only 50% of cases were picked up by screening.[254] This requires further research.

D. IMPACT OF THE DISASTER ON THE INFECTED AND AFFECTED COMMUNITY IN SCOTLAND

1. General

1.1 The infected and affected communities in this Inquiry have, without doubt, suffered broad-ranging and deeply felt impacts across their lives. The Inquiry has heard copious evidence about the experiences of the communities in this respect. The evidence touches on an enormous range of impacts; there are some common themes that we say emerges from some of the evidence. But it would be wrong and improper to suggest that the impact of the infections across the communities has been consistent or easily recognised. Indeed, to fail to recognise the individuals' experiences would do the infected and affected a disservice and risk undermining the clearly stated intention of this Inquiry to put the infected and

[252] IBI transcript for 09/11/22; 103 (Professor Spiegelhalter)
[253] EXPG0000049 at para 7.11
[254] (EXPG0000049) at para 7.4

affected at the front and centre of the process. We accept, however, that to merely rehearse the witness statements of those on whose behalf this submission is made who have chosen to provide a statement, would not assist this Inquiry in its consideration of all of the evidence. Each individual's story is of clear importance; but the weight of the evidence regarding some repeated experiences is also important. Our submission sets out the numerous themes that we say arise from the evidence, drawing on examples to support those contentions. The submissions here are presented with the following principles in mind:

(a) The need to catalogue and recognise themes which are shown by the evidence to have emerged about the experiences of the infected and affected community in Scotland in order to gain a general impression of the impact of the disaster on that community as a whole;
(b) The need to draw upon themes which have emerged from the evidence heard across the UK from this community;
(c) The need to set this evidence in the context of the expert evidence heard by this Inquiry as to the general scientific understanding of these themes; and
(d) The need to draw attention to individual cases where they are of particular importance or significance in that wider context.

1.2 We submit that it is important that this Inquiry provides a comprehensive but accessible analysis in one place of the extensive and varied consequences of the blood contamination disaster in Scotland. Although in many instances the effects of the disaster may seem obvious, in particular where death and serious morbidity is associated with infection, there a number of areas where the impact of the infections may not have been holistically understood. There is undoubtedly a need for the complex impact of the disaster to be comprehensively catalogued, with particular attention being paid to the following:

(a) The full range of morbidity associated with infection, in particular the psychological and psychiatric effects, and the magnifying effect of the fact that all infected individuals were vulnerable at the time of their infections;

(b) The full range of consequential impact on social, work, personal, and family lives of the disaster;

(c) The full and compounding impact of treatment on both the infected and affected communities;

(d) The compounding, cumulative effect of the various harmful events and actions from which the infected and affected communities in Scotland have suffered as a means of understanding the entirety of the harm which the communities have suffered at the hands of the state;

(e) The full extent of the impact of the disaster on the affected community, not as an afterthought as is so often the case, but as a recognition of the distinct harms wrought on that community.

1.3 We recognise that there is a possibility that the Inquiry may take the view that the lack of research/ medical knowledge in certain areas may mean that it cannot make firm conclusions about the nature and extent of the harm suffered by the infected and affected community. In such areas, those on whose behalf this submission has been prepared would seek the commissioning of further research into these areas as opposed to the opportunity to understand them being lost by the failures of the medical community to properly analyse and appreciate them.

1.4 The Psychosocial expert group gave cogent, detailed, and powerful evidence regarding the impact of the disaster on the infected and affected communities. They noted that, *"for people who received infected blood or infected blood products, the psychological impacts were compounded over a long period of time by the experience of further serious medical problems and intrusive treatments, which in turn resulted in many debilitating symptoms and side effects... it was very clear from the witness statements that there was a wide range of serious psychological impacts, on both infected and those caring for them over a long period of time*[255]*".* They also provided a supplementary report responding to specific issues[256]

[255] EXPG0000003_0003
[256] EXPG0000042

1.5 Equally, the Inquiry has the benefit of expert reports in respect of HIV and Hepatitis infections. The intention of this submission is to draw together themes arising from those reports, and the evidence presented to this Inquiry by the core participants on whose behalf this submission is presented. In places, we refer to specific cases as examples of the themes; this is not to diminish or overlook the experiences of others who experienced similar issues.

2. The treatment of the infected – background

Bleeding disorders

2.1 In the treatment of bleeding disorders, the Inquiry should take account of the chronic nature of the condition and the consequent relationship with hospitals which that necessitates. The hereditary nature of the condition had the result that whole families of boys are treated, the result of infection being that whole families are infected and wider family devastated. Equally in some families spontaneous diagnosis meant that unexpected reliance on the NHS for whole families was created. As a result, there was a vulnerability about patients who are so reliant on medical care and indeed their families. Their need for and willingness to participate in their care left them open to abuse based on their reliance on and trust for the system.

2.2 An important part of the that trust involved the free handing over of blood samples for the betterment of the patient's medical care. The use of the blood and information of those with bleeding disorders as a means of providing medical knowledge not directly related to the care of the individual patient from whom the blood, other tissue, information was derived caused an exaggerated harm based on the vulnerability of the patients and their reliance on and trust in the system. The benefit derived from those patients by the State/ commercial

organisations who could use that information for profit was derived from that harm.

2.3 The impacts of the blood contamination disaster on this community arose from to infection, treatment, stigma and the way that the State (including the medical profession and others) treated victims are common in many instances, irrespective of the way that the infection was caused. However, there are a number of effects of those infected in the bleeding disorder community which deserve to be recognised and acknowledged by the Inquiry independently.

2.4 The fact that haemophilia was a genetic condition meant that members of the same family attended the hospital and were treated with the same products. This resulted in multiple members of the same family becoming infected at the same time in addition to their haemophilia. The Inquiry heard evidence from one family in which three brothers were infected in Edinburgh, one with HCV and two with HCV and HIV. The co-infected brothers (who were members of the Edinburgh cohort) died within weeks of each other.[257] This situation must have been beyond unbearable for the family. It must also have created the extra burden on the infected patients, a vicarious sense of devastation for your brother in addition to the sense of devastation about your own diagnosis. In this family, one would entirely understand feelings of survivor's guilt on the brother who remained alive, about which the Inquiry heard much evidence from across the country.

2.5 The Inquiry heard evidence of the significant impact on patients' bleeding disorders as a result of the infection with another disease. In the first instance, the lack of trust for the medical professionals who had caused the infections but who remained responsible for the care of the patients' bleeding disorders was an important and natural consequence of the infections themselves. It must be borne in mind that in the pre internet era, the trust placed in medical professionals was necessarily absolute. The doctors were the only source of information available about a patient's medical condition. This lack of trust is addressed elsewhere in this submission. In some cases, this led to patients or parents reasonably becoming apprehensive about their bleeding disorder treatments and the assurances being

[257] WITN2677001, para 29 (first statement of Agnes McNeish, widow of co-infected Edinburgh cohort patient)

given to them by the very doctors who had caused the infections in the first place. Some gave evidence to the effect that they stopped or minimised treatment as a result[258]. That was an entirely understandable response to the infections. In most cases patients and parents had had a lifelong association with the haemophilia centres and had built up a relationship of trust with them. One GRI patient also explained how he had to launch a campaign to get funding from the local health board for recombinant products which at that time were only funded for children. He had become too wary to continue taking human derived products due to his HCV infection and vCJD concerns. This and the funding issue resulted in his haemophilia related ailments deteriorating due to concerns around ongoing infection risk.[259]

2.6 The possibility of further infections emerging at some point was an important feature of the evidence heard by the Inquiry from bleeding disorder patients. Given that they were almost invariably exposed to infection as a result of being exposed to pooled products, the fact that their infections with HIV or more particularly HCV took time to manifest themselves symptomatically and the scientific likelihood that patients treated with pooled products would be likely to have been exposed to a range of pathogenic agents (that range being discussed elsewhere in this submission), these patients have often suffered from the lifelong fear that further symptoms may emerge from their past treatments. The nature and array of pathogens to which bleeding disorder patients are likely to have been exposed, in essence any infectious disease which could have been in the donor pools to which they were exposed means that these were and are very reasonable concerns and also a natural consequence of their known infections. In HIV cases this applies in particular due to the likelihood that the immune suppression caused by HIV infection would diminish the natural ability of the infected individuals to fight infections with other pathogens. This also applies to HCV infected patients. One postulated reason for the immune suppression discovered in haemophiliacs in Edinburgh in 1983 was infection with hepatitis. HCV infection resulted in

[258] WITN2203001, para 6 (first statement of WITN2203) – in which he narrates that his brother stopped his treatment after his delayed HIV diagnosis in Edinburgh
[259] WITN2118001 @ para 33 (first statement of WITN2118)

immune suppression which made the patients who were infected with that virus but not HIV also naturally prone to the ill effects of other pathogenic exposure from their factor concentrates. Similarly, immune function was also thought at that time to be reduced as a result of the antigenic overload from the protein in the concentrates. Even uninfected haemophiliacs were thus reasonably at an increased risk of suffering ill effects from other pathogenic exposure. One patient described the impact of this situation on his response to the information he was given by Professor Lowe at the GRI about the risk to him of vCJD. As he had kept his diagnosis of HCV from him until 1994, he felt he had lied and so he simply could not trust and continued not to trust what he was told about vCJD.[260] This entirely understandable reaction of fear and mistrust could have been avoided, had the initial diagnosis been handled honestly.

2.7 One thing which must be borne in mind is the limitations available for the treatment of conditions arising from or associated with infection due to the presence of haemophilia. The ability to undertake investigation the extent of liver damage caused by HCV infection would have been limited by the fact that few centres were able or willing to undertake biopsies on haemophiliacs, for example.

Stigma

2.8 The Inquiry has also heard evidence of damaging stigma associated with haemophilia and not just having an infection as a result of the disaster. The lesser HIV infection rate amongst bleeding disorder patients in Scotland resulted in there being many patients who were infected with HCV and not HIV. Despite this, the Inquiry heard that their experiences of stigmatisation were often as bad, given the assumptions that having haemophilia was associated with having HIV or AIDS. GRO-D

GRO-D

GRO-D [261]. Another had to move from his small

[260] IBI transcript for 08/06/2019; 103 to 105 (WITN2245, aka Mr V)

[261] GRO-D

town in GRO-B as people equated his haemophilia with AIDS, though he was not infected with HIV.[262] Another suffered prejudice at school as it was assumed he had AIDS, though he was not infected with HIV, only HCV.[263]

2.9 The wife of one HCV infected haemophiliac from Glasgow told the Inquiry that the stigma was as bad in 2019 as it had been 20 or 30 years before.[264] The idea that this was a transient phenomenon was illusory. The harm and ongoing stigma are the reality.

Family, friends and guilt

2.10 The fact that haemophilia was a hereditary disease had a number of additional consequences were experienced by those who were infected. The hereditary nature of the disease and the needs for hospital treatment for it and the 100% infectivity rate meant that along with one's own infection one had to deal with the vicarious pain for a family member or a friend whom one had met at the haemophilia centre becoming infected too. One HCV infected haemophilia who had grown up with other boys at Yorkhill, many of whom had died of AIDS showed the Inquiry a photo and some of those boys.[265] Boys like him must have felt a natural but unbearable sense of devastation at their own infections, vicarious pain for their friends and grief combined and their loss. One of the parents of a Yorkhill AIDS victim spoke of the funerals they all went to.

Parents

---

[262] WITN2274001, para 22 (first statement of witness WITN2274)
[263] WITN2245001, para 23 (first statement of WITN2245 – living Yorkhill and GRI patient infected with HCV)
[264] IBI transcript for 08/06/2019; 107 (Mrs V)
[265] IBI transcript for 08/06/2019; 131 to 132 (WITN2245, aka Mr V)

2.11 The Inquiry heard harrowing evidence from mothers who held themselves responsible for the causation of their sons' infections. They had been the scientific cause of their sons' haemophilia in the first place as they would have been the carrier of the gene which passed to cause their sons' haemophilia, in some circumstances where a family history was known consciously but in others unconsciously as a result of a spontaneous genetic mutation leading to the emergence of the condition. The evidence which was most striking in this regard was from the parents of children treated at Yorkhill Hospital, although this was an understandably common though heart-breaking feature of the evidence heard across the country. The particular circumstances of the familial relationships arising out of haemophilia left mothers feeling that they had damaged their children twice[266]. Treatment they had often administered to their children ultimately killed them. The feelings of pain and guilt arising in these situations are almost unimaginable and make this particular outcome unique. One patient who gave evidence to the Inquiry was infected at Yorkhill but was told of his diagnosis in 1994 at the GRI by Professor Lowe. He gave evidence not only as to the brusque manner in which he was told (with no counselling) and the devastating impact the diagnosis had had on him but also of the reaction that he blamed his mother who had injected him and also himself for the same reason[267]. That was a horrible and unnatural reaction but perversely that was what he felt in that moment. In addition, his employer and his GP knew of his diagnosis a matter of years before he was told.[268] He also told the Inquiry of the guilt his mother had suffered, thinking she had caused his disease as a result of the many infections she had given him.[269]

2.12 In circumstances where mother felt this unique kind of pain, one must also remember that were also often fathers who felt the same pain but experienced it in a slightly different way. The evidence heard by the Inquiry was that this led to significant familial problems and problems for fathers who had this experience of

---

[266] Eg WITN2245001, para 21 (first statement of WITN2245 – living Yorkhill and GRI patient infected with HCV)
[267] IBI transcript for 08/06/2019; 92(12) to 93(24) (WITN2245, aka Mr V)
[268] IBI transcript for 08/07/2019; 101 to 103 (WITN2245, aka Mr V)
[269] IBI transcript for 08/07/2019; 130 to 131 (WITN2245, aka Mr V)

the disaster. They too experienced the funerals. They too experienced the sense that their child would be next. Many children did die in the HIV infected communities in Scotland as AIDS and HCV ravaged their growing bodies. The Inquiry should take note of the dignified way in which these parents gave evidence to the Inquiry. it should also take note of the fact that, many years after the events which they were describing the pain was a raw as ever. Their wounds are ones which will never heal. That the State has ignored this clear element of the disaster in the support schemes which it has offered to the infected and affected community is illustrative of one of its main failures. Parents whose children have been infected with HIV and/ or HCV in this way have suffered loss which has inevitably led to need. It is submitted elsewhere in this submission that the pain which these parents have suffered and the loss and need which they have inevitably experienced must lead to financial redress. It is the very least the State has a moral duty to do.

Widows

2.13 The fact that most patients with bleeding disorders who were infected were men, haemophilia being a condition which predominantly affects men, means that there is an entire class of widows who have lost their husbands as a result of the disaster.

Impact of campaigning

2.14 The Inquiry should acknowledge the unique impact which has been suffered by those who have given up their time and effort, despite their own illness, grief or the effects of infection to campaign for justice on behalf of those who were the victims of the disaster. The circumstances in which the campaign for justice was fought and the innumerable and unjustifiable obstacles which were placed in the

way of campaigners have taken a heavy toll on them. Some have campaigned as part of the charitable effort. Some have campaigned as part of other organisations or in an individual capacity. The importance of the charitable effort on behalf of the campaign is addressed elsewhere in this submission. The impact on the mental health of campaigners was eloquently described in the statement of one witness. He was exposed by his campaigning efforts to the full extent of the secrecy and the harm which had been inflicted on the infected and affected community. This had a significant impact on his relationship with his wife[270]. As they learned more but continued to be denied an Inquiry and hence the possibility of answers, they were often forced to make inferences about what had gone on based on the incomplete picture they had been able to make out – the process of trying to piece together the jigsaw spoken to by one Scottish campaigner.[271] He described the effect on his family of how he saw his campaigning – digging a trench in his front room to go to war with the State.[272] This graphic imagery combined with the discoveries from this Inquiry are testament to the fact that this was a horrible war but it was one which needed to be fought, as the State was not going to give the deserving the answers they reasonably sought without a fight. The lack of bespoke psychological support for these campaigners compounded their loss even further.[273]

The Penrose Inquiry

2.15 Connected to the plight of these campaigners is the sense of frustration and disappointment felt by them and the entire community in Scotland at the process and outcome of the Penrose Inquiry. It is understood that this is not an Inquiry into an inquiry. A lengthy submission was presented to this Inquiry about the perceived shortcomings of the Penrose Inquiry in Scotland, with views about how

[270] WITN2219001, paras 58 and 59 (first statement of WITN2219)
[271] IBI transcript for 09/06/2021; 19(20) to 26(24) (Bruce Norval)
[272] IBI transcript for 09/06/2021; 215(5) to (12) (Bruce Norval)
[273] WITN2219001, para 65 (first statement of WITN2219)

this Inquiry might go about avoiding the same mistakes. Those submissions are incorporated and deemed repeated here for the sake of brevity. Evidence is available to this Inquiry as to the extent to which the disappointments of the Penrose Inquiry caused an additional, compounding impact on the infected and affected community, in particular in Scotland. The assessment of that impact is part of the terms of reference of this Inquiry.

3. Blood transfusions

3.1 The circumstances in which those infected via blood transfusion are many and varied. Clinical transfusion practice is considered elsewhere in this submission in more detail, including a more detailed analysis of the circumstances in which blood was transfused.

3.2 Many who received transfusions received a significant amount of blood in traumatic circumstances; we recognise that for a large number of those on whose behalf this submission is presented received the blood as a life-saving intervention to which there was little alternative. That is not to suggest that their infections were unavoidable; on the contrary, for reasons set out elsewhere in this submission, we say that blood could and should have been materially safer had better donor selection policies in place, and if surrogate testing and/ or direct screening had been introduced at an earlier stage. Even those who received significant amounts of blood might properly have been able to receive less blood than they did had those prescribing the blood been better educated about the risks associated with transfusion, and the alternatives to the practice.

3.3 Equally, there are some who received transfusions who may have been able to recover without receiving any blood transfusions. Treatment alternatives ought to have been considered in such cases; all too often we submit there was a culture in which blood was given without recognition of the risks involved.

3.4 In almost every case, there was no discussion between the medical practitioner and the patient (or their next of kin/ representative) regarding the risks associated

with transfusion (whether the transmission of blood-borne infection, or indeed other risks that the Inquiry has heard evidence about).

3.5 Many did not learn of their infections until many years later, by which time many had been living with troubling and life-impacting symptoms which were unexplained and all too frequently dismissed by GPs and other medics that ought to have taken their concerns more seriously and investigated them more thoroughly.

3.6 As the Inquiry has heard, and as is considered in more detail elsewhere in our submission, there are a number of individuals who have given compelling and credible accounts of the circumstances of their transfusion, but have found their medical records contain no reference to that transfusion (whether because the records have been destroyed, or because the fact of the administration of the transfusion has not been properly recorded). For such individuals, the absence of such records has caused considerable, and in some cases ongoing, impediment to accessing the support schemes available to those who have received contaminated blood. Financially, the impact has been enormous on many such individuals. Beyond the financial impacts, such patients have been left to seek treatment of their infections from clinicians who do not believe them as to the source of their infection. They (as, indeed, have many who do have evidence of the transfusion in their records) have been labelled as drug users.

3.7 A not insignificant proportion of those whom we represent believe they received blood from outwith the UK. In some cases, patients recall being told they had received American blood. As we set out below, although there is no evidence of whole blood being imported into Scotland, there is evidence of American blood being donated by US citizens in Scotland. We explore the issue of the concerns of some of the transfusion recipients that they received blood sourced from outwith the UK in more detail within the clinical transfusion practice section of our submission, but it must be recognised that these beliefs form a particular element of the impact on this community. It has fomented further mistrust of the medical community. Such concerns have arisen as a result of the way in which the community has been treated and must not be disregarded merely because there is no evidence that whole blood was imported for transfusion. Such issues have

compounded the harms suffered by the community and must be properly understood and recognised.

4. Infection

Introduction

4.1 The infections themselves have had long-reaching and life-changing consequences for very many people. Many have lost their lives to diseases contracted when they were at their most vulnerable, and requiring medical treatment from the state. The impact cannot be overstated. The decades of delays in having the matters investigated and their stories told has meant that the losses have increased considerably, and the wounds remain raw. The emotional testimony of the many affected who have given evidence to this inquiry speaks for itself. It is striking, we say, that the Inquiry has heard from those infected and affected who have experienced intolerable losses and other impacts over many years. The Inquiry has heard testimony from those who lost loved ones some decades ago, and those who lost their loved ones during the course of this Inquiry. The losses are individual and personal, but are also part of the community's combined experiences.

4.2 The fact of infections themselves have, of course, given rise to considerable fears for the future for those impacted. Many of those infected have co-morbidities which were already a source of vulnerability; a serious, potentially fatal infection in those circumstances has given rise to a separate, and in many cases, greater concern for their future health. For reasons that are explored in greater detail below, the very circumstances of infection have in themselves contributed to a risk or actuality of the worsening of those co-morbidities. Even without such co-morbidities, the infections themselves have caused considerable health effects, and significant concerns for the future for those who have contracted them, whether as a result of the infection directly, or the effect on trust and confidence

in the medical professions meaning that those members of society who needed increased medical assistance, surveillance and support, were perhaps rendered less likely to engage with or be able to access such treatment.

4.3 The chronic nature of some of the underlying conditions which were treated with blood or blood products led to some individuals being infected as a child. Some of those infected as children have considerable concerns regarding the damage that may have been caused to them by the infections as their bodies and immune systems were developing; we submit there is a need for better understanding of these concerns and research into the impact of these early infections, in order that those affected in this way can more fully understand their conditions, and that those treating them can more fully recognise the particular complications that may arise in those circumstances.

4.4 Furthermore, for those who were treated with pooled products or who were multiply transfused has inevitably led to the multiplicity of exposure to harmful agents, including the risks of repeat infections. We submit that there is a need for better understanding/ research as to the effect of such multiple exposures/ repeat infections.

4.5 We submit that the lack of knowledge and understanding of these issues not only means that risks to the physical health of those who might be affected in this manner go unchecked, but also that there is a significant psychological impact associated with the fears of other diseases emerging, the lack of understanding of the concerns of those affected in this way on the part of treating medics, and ongoing lack of trust in the medical profession as a result.

4.6 The infections have had far-reaching psychological and psychiatric consequences for the infected and affected, as explored in greater detail below. In some cases, the infections have had organic impacts on the brain itself, causing mood and emotional disturbances. The stresses and strains of living with the infections (practically, physically, mentally, and emotionally) has caused psychological responses in many of the community, with the stigma associated with the infections adding to the traumas. There has been a compounding psychological impact associated with the response of the State to the disaster; the State's response is analysed elsewhere in this submission but for reasons explored below

in this section, we submit that the State's response has, in itself, compounded the harms done to the communities.

4.7 Although in this section of the submission we look at various aspects and themes arising from the evidence in respect of the impact of the disaster on the communities separately, we submit that these issues must be looked at holistically. The consequences of this disaster are complex and multi-faceted, and the multiplicity of those harms must be recognised. The various harms are compounding and far-reaching.

4.8 For those who were told (or whose parents were told) that treatment with blood or blood products offered a life-changing opportunity to limit or avoid the risks or limitations associated with an underlying illness or condition, the fact of their infection often rendered such promises otiose.

HIV

4.9 The Inquiry has heard harrowing testimony about the impact of HIV infection on patients who were infected by blood products in Scotland. These are many and varied. In the first instance it should be borne in mind that all bleeding disorder patients who were infected with HIV in Scotland were infected by factor concentrates. The epidemiological prevalence of HIV relative to HCV in the donor population (both in Scotland relating to domestically produced products and in imported products) meant that if a patient was infected with HIV, he is almost certainly also exposed to HCV and infected with it too. Thus, in this population, infection with HIV was also co-infection with HCV, on top of also suffering from haemophilia. The patients had sought medical attention for this serious condition (serious in all but 2 cases as all infected patients in relation to whom information is available had severe haemophilia A) and thus had "a thin skull" as reparation lawyers might call it. That thin skull had been rendered thinner by the treatment they had received which inevitably contained HCV by around the start of the 1980s. In addition, the infection with HIV led to a cocktail of conditions which one

should reasonably infer would have been almost impossible to manage at the time. The immuno-suppression caused by the HIV infection rendered the patient less able to deal with the HCV infection. The fact that the information about the diseases was limited as they were in their infancy, inevitably contributed to the limited chances of a positive outcome. This was a death sentence for these patients, many of them children.

4.10 The Inquiry has evidence about one of the HIV blood transfusion infections in Scotland. Ironically, this case is also one in which the patient was co-infected. The Inquiry is aware that there are at least 18 transfusion recipients who were infected with HIV. We consider the impact on the only known co-infected transfusion recipient and her family within the core participants represented by Thompsons (Scotland) in further detail below. However, as set out above, we submit there is a real prospect that there may have been more than one co-infection in the transfusion recipient community.

4.11 The Inquiry has the benefit of an expert group report on HIV[274] and has heard considerable evidence regarding the effects of the illness on all aspects of the lives of those infected. We therefore do not seek to rehearse the evidence of the expert group with regards to the impact of the infection, but in this section draw on some of the themes that arise from some of the statements and oral evidence of those on whose behalf this submission evidence in terms of impact.

4.12 Amongst those represented by Thompsons are a number of families who were bereaved as a result of infection with HIV as a result of the administration of blood or blood products. The majority of infections in Scotland resulted in fatality. We also represent a number of individuals have survived into adulthood; their evidence is also explored below.

4.13 As the expert group has identified, the consequences of HIV-related immune dysfunction are affected by a number of factors, including the microbial exposure of the person throughout life, the pathogenicity of organisms encountered, and the degree of immunosuppression of the host. For those infected with blood or blood products and who have experienced the use of pooled products or multiple

[274] EXPG00000049

transfusions, we submit that such individuals have likely been exposed to a multitude of infections and pathogens, in addition to their HIV and HCV infection. The fact that they required blood or blood products is evidence in itself of potential vulnerability. As the expert group further recognises, those who were infected with HIV via blood or blood products were mostly treated with first generation antiretroviral treatments which had significantly more toxicity than the more advanced treatments which were to follow. The side effects of the early treatments in particular were extremely disabling for some recipients. Further, as identified by the expert group, sustained virological response rates to an HCV infection for those with co-infective HIV were much lower than those infected with HCV; as discussed below, treatments for hepatitis C infection were gruelling and caused considerable side effects. The expert group notes that for co-infected individuals, longer treatment durations were recommended in order to increase the prospects of SVR, but with that came greater risks of cumulative interferon and ribavirin toxicities.

4.14 An anonymous witness treated at Yorkhill hospital as a child and infected with HIV and HCV recounts the devastating effect on his life of his infection, revealed to his parents when he was about 14 years old in 1988. His parents were told that they had known of the infection for some years. The witness was not present at this appointment, and his parents had to break the news to him. The late notification of his diagnosis clearly presented risks of community-transmission. As his mother had been injecting him from the age of 5 with factor VIII concentrate at home, she would clearly have been at increased risk of contracting the disease in the event of a needlestick injury or the like. The witness was subsequently (6-7 years later) told of his HCV infection, but as "a throwaway comment and it was played down. [He] was told not to worry about the hepatitis C – it was the HIV [he] should worry about[275]." The witness describes the effect of his infection as being *"a lifetime of pain and suffering"*, noting the considerable physical and mental effects, including the organic changes in his brain leading to HIV dementia. He gives detailed and

[275] WITN2149001, para 10 (anonymous)

emotional evidence regarding the effects his HIV infection have had on his cognitive function, and his mental health.

HCV

4.15 As the Inquiry is aware, the impact on the health of individuals exposed with HCV is broad ranging. Many have died or suffered severe and prolonged ill-health, including liver failure and cancer resulting in the need for further gruelling treatment and, in some instances transplants, with the associated long-term medication required.

4.16 Many were unaware of their infection until many years after contracting it; in the meantime, some experienced troubling symptoms that were dismissed by the medical profession, or misdiagnosed as something other than the infection.

4.17 As detailed below, the early treatments for HCV infection were particularly brutal, with many finding the 'cure' to be worse than the disease. That is not universal; the infections themselves, caused significant illness in many, including those who were crudely considered to be at 'stage 1' in the support schemes.

4.18 For those who required transplants, the effect of the HCV sometimes caused their new livers to sustain further damage, leading to the possibility of the need for further transplants in the future.

4.19 Even those who have a sustained virological response to the treatment have understandable fears about their future. Many feel that, having achieved SVR, they have been cast out of medical care, and remain concerned about (a) the effects of their infection on the long term health and (b) whether the infection may return.

4.20 The Inquiry has heard emotional testimony from numerous witnesses regarding their experiences associated with HCV infections. Even within the course of this Inquiry, many have died.

4.21 One witness gave oral evidence in respect of her husband's infection and her own infection, passed on, unknowingly, by her husband. She gave that evidence less

than 4 months after her husband had died of the effects of his HCV infection. In the course of his final months, she was advised to restart her own treatment in an effort to clear the virus.[276]

4.22 Others lost their loved ones many years before the start of this Inquiry. Their evidence has demonstrated memorably that the effects of their losses have remained strong and raw even with the passage of time.

4.23 The manifestations of hepatitis are multiple; the effects on the liver can, and in many cases have, caused a plethora of extra-hepatic consequences. The expert group reporting on hepatitis have suggested that some studies that show a reduction in mental well-being and physical functioning amongst patients chronically infected with HCV are *"unreliable"* as the studies were carried out after the infection was known, such that it might be the knowledge of the infection which drives those symptoms. For the avoidance of any doubt, we submit that the 'direct' cause of such symptoms is largely irrelevant; the evidence clearly demonstrates that many individuals experience symptoms of reduced mental well-being and physical functioning in connection with their infection. Whether that is a result of the knowledge of the infection or the physical manifestations of the infection does not in any way diminish the existence of such symptoms.[277] It is also noted that the expert group do accept that some patients experience neurocognitive symptoms as a result of their infection, caused by, or at least associated with, low level inflammation in the brain. Such symptoms can persist even in the event of sustained virological response to treatment. It is therefore clear that hepatitis C is not an infection which 'merely' effects the liver; there are numerous long-term and potentially life-changing extra-hepatic manifestations of the illness which are suffered by a significant proportion of those infected as a result of the blood contamination scandal.

4.24 When the condition causes cirrhosis, there are also known symptoms affecting both the liver directly and other parts of the body; some witnesses have spoken of ascites and the need for enormous amounts of fluid to be removed from the

---

[276] IBI transcript for 31/10/19: 32 to 40 (Jryna Batters)
[277] EXPG0000001_0027

abdomen on a regular basis[278], confusion, hepatic encephalopathy, fatigue, and an increased susceptibility to bruising. As the expert group identifies, such symptoms are associated with reduced life expectancy in the absence of a liver transplant. As set out below, at least some of these symptoms are also experienced by many who underwent treatments to clear the HCV infection, with such symptoms persisting even after a sustained virological response has been confirmed. In some cases, individuals give evidence that they were unaware of any symptoms associated with their infection, but such symptoms developed after treatment started. However, in many of those cases, treatment was only recommended because of the increasing damage to the liver and the need to intervene to prevent further damage.

Natural clearers

4.25 It seems clear that whether someone qualified for a payment under the Skipton Fund was variable. The variation in the practice of haemophilia centres in deeming there to have been acute or chronic clearance is apparent in evidence available to the Inquiry.[279] This variation does not suggest that there is a clear-cut scientific basis for assessing the likelihood that a patient falls into one category or the other or that there is any great scientific significance to the 6 month it off. The lack of natural justice in that fact further compounded the harms for those in this group who did not receive payments.

4.26 Evidence from the hepatitis expert group, suggested that the 6-month figure was a blunt tool. [280] They said that in adult-acquired infection spontaneous clearance occurs in around 30% of cases (15-45%) within six months. The source they quoted for this did not seem really to be about the subject of the timing required for there

[278] IBI transcript for 1/07/19: 174 to 175 (anonymous, Mr Z)
[279] SKIP0000031_213
[280] EXPG0000001_0077

to be spontaneous clearance.[281] They also said that following mother to child transmission, around 25 to 40% of children spontaneously clear/cure the infection in the first four years of life. Another 6%-12% may clear the virus before adulthood and the remainder develop a chronic infection that persists into adulthood. The six-month period may not therefore be applicable in childhood infection.

4.27 They went on to say that the term 'acute' is used to describe a short duration of illness, in contrast to the term 'chronic' which denotes an illness of long duration or one which persists indefinitely. By consensus an acute hepatitis infection has a maximum duration of 6 months, so any infection which persists longer than this is considered as chronic infection. Nevertheless, all chronic infections have an acute phase which lasts up to 6 months. 'Acute' and 'chronic' do not signify anything about the severity of the infection, nor do these terms indicate whether the infection causes symptoms.[282] Thus, the definition does not preclude the possibility even of serious symptom within the 6 months. It focuses (much like the stage 1 and 2 definitions) only on the hepatic element of the exposure to infection, not anything else.

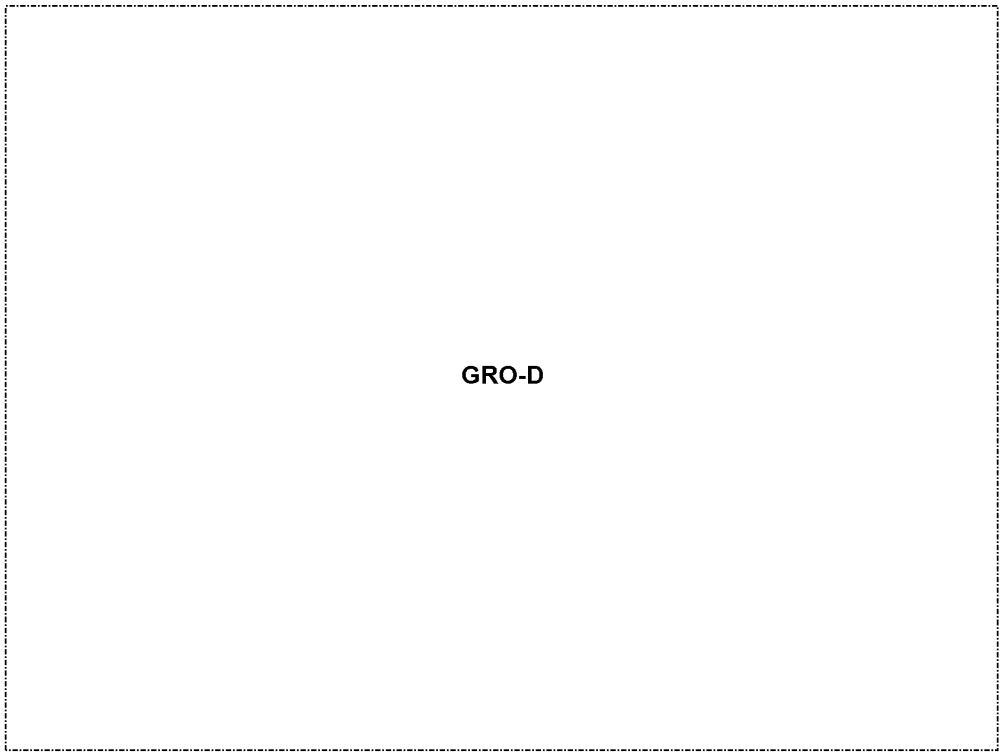
4.28 The expert group went on to report that acute hepatitis may be associated with symptoms and signs as described in section 15.8 of their report (the full list of possible symptoms of HCV infection). They said that these range in severity from a minor 'flu-like' illness accompanied by mild jaundice through to a severe illness characterised by abdominal pain, deep jaundice, joint and muscle pains and, in a very few cases, signs of liver failure, such as confusion and coma.

4.29 An example of the kind of impact which is not atypical of the kind of experience which natural clearers have experienced had been recounted to the Inquiry by a patient which was treated at the RIE. GRO-D

GRO-D

[281] Grebely J, Page K, Sacks-Davis R, et al. The effects of female sex, viral genotype, and IL28B genotype on spontaneous clearance of acute hepatitis C virus infection. Hepatology 2014; 59(1): 109-20

[282] EXPG0000001_0026



GRO-D

4.30 Hence, commensurate with much of the rest of the decision-making around the genesis of the Skipton Fund (designed to fit with a budget, not any concept of fairness), the cut off is really arbitrary. It may be that someone who has chronic infection may be minimally impacted and/or or may have had a sustained virological response from treatment. Someone who cleared the virus spontaneously may have had a severe acute reaction (see above). In many cases, in particular where the infection was caused by a blood transfusion, the late realisation of the fact of infection may well reasonably have caused a psychological reaction, anxiety about the implications and mistrust of the medical profession which may have led onto patients reasonably avoiding treatment for other health complaints in the future and/ or anxiety about the accuracy of information about the future implications of past exposure, in particular where adequate counselling has not been provided at the time of the tests results being revealed. Further, the

283 GRO-D
284
285
286

likelihood that a person in such a situation would have had no reason to have no tests for HCV infection until the point at which they realised they had been infected (often many years after the infecting event) means that such a person could not have proved for the purposes of the trusts and schemes that they had cleared the infection in the chronic as opposed to the acute phase – the evidence would simply not be available. As personal witness statements relating to periods of ill health which might have been caused by chronic infection would not have been accepted by the Fund as adequate evidence of chronic infection in the absence of testing/ medical records, in effect proof of chronic as opposed to acute clearance was nigh impossible. No account appears to be taken of the difference between clearance in those infected as children as the 6 month cut off applies to adults, from a scientific point of view.

4.31 Further, it was not possible for haemophiliacs who had concerns about the implications of hepatitis infection from their treatment with blood products to be informed that they were natural clearers until tests became available in 1991. As was pointed out by Professor Christine Lee in a letter to the DoH Blood Policy Unit in 2005, they thus had considerable worries in the 1970s and 1980s about the possible implications of their exposure to the virus(es).[287] Those in receipt of blood transfusions only avoided such similar concerns prior to testing in 1991 if they had not been informed of the risks of the virus(es) being transmitted by their blood which they had received. All patients have suffered the breach of personal autonomy in not being told about the risks of their treatment, something which has never been recognised in the cases of the so-called natural clearers.

4.32 All of these factors mean that those who have received blood or blood products during the relevant period who can prove antibody positivity who have been excluded as having cleared the virus in the acute phase should be included in financial schemes going forward and the compensation scheme going forward. That they are excluded is based on no logic. It is unfair and a relic of opaque decision making at the time the Skipton Fund was set up in around 2003/ 2004. There would be no logical reason, in our submission, as to why these individuals

[287] DHSC0004520_006

should not have the benefit of self-assessment. Applicants are asked to assess the level at which the virus affects their lives at the time of the application. For most acute clearance cases (other than those who can genuinely assert a lasting psychological reaction to finding out about the fact of infection) it seems likely that they would self-certify in the currently minimally affected group. Individuals who have or had chronic infection who certify in that group are currently entitled to a lump sum payment and annual payments. There is no requirement for them to be able to assert any impact at all of the virus on their lives. They are entitled to those payments as a recognition of the fact that they were infected by NHS blood or blood products. Those who cleared in the acute phase are also so affected. They should be included in both schemes going forward.

Other pathogens

4.33 The Inquiry has access to evidence which suggests that patients may are likely to have been exposed to multiple additional pathogens beyond the ones with which the Inquiry has been primarily concerned (HIV, HBV, HCV and vCJD), in particular (though not exclusively) as a result of repeated plasma derived concentrate therapy. The full nature of this pathogenic exposure requires to be understood before the full impact of the blood contamination disaster, in particular on the haemophilia community can be fully quantified. This is a matter which needs to be considered separately from the issue of the full extent of the effects of these four viruses, which we also submit is not fully understood. The effects of all of the viruses, in particular when children are so exposed needs to be understood. Medical evidence is available, for example on the effects of inflammation on the developing brain in children leading to long term neuro-cognitive damage, which suggests that this community may have undiscovered deficits which merit further investigation.[288]

---

[288] https://www.frontiersin.org/articles/10.3389/fped.2020.00583/full

4.34 There is a variety of evidence, some of which is directly available to the Inquiry and some of which is not, which may be instructive in relation to the possibility that other pathogens may have been transmitted by blood products and that harm may have been caused, either as a result of exposure to one pathogen or cumulatively. In our recommendations below, we suggest that the Inquiry ought to recommend that a research fund be set up in order to examine these matters more fully, as in some cases evidence is not available or has not been available to the Inquiry to allow it to draw conclusions. The general tendency to try to analyse the harms suffered by those exposed to blood or blood products by looking at "single virus paradigms" is reflected in medical literature which is available to the Inquiry looking at one virus in isolation and not their cumulative effects. The nature of pooling means that haemophiliacs, in particular, are likely to have been exposed to all pathogens which exist in human plasma. The fact that any infected patient has been exposed to one pathogen makes it more likely that they may have been exposed to another also transmissible by blood. The likely cumulative effect of these pathogenic insults on the immune system (particularly the immature immune system) is likely to be far reaching. Evidence of multiple pathogenic exposure such as currently exists has recognised that infections with several viruses complicate and confuse the clinical picture. For example, in HIV and HCV co-infected patients HIV infection increases the rate of progression to liver cirrhosis and decreases the response to interferon-based treatments.[289] This last effect has complicated treatment recommendations for these patients.

4.35 As a result of the steps taken in donor selection and viral inactivation to eradicate the main HBV, HCV and HIV viruses, it does appear to be the case that attention in the has literature turned, to a certain extent at least, to other blood-borne viruses/ pathogens. Their potential impact on human health needs to be better understood, either because of their potential pathogenicity or their possible

---

[289] Chung R, Andersen J, Volberding P, et al. Peginterferon alfa-2a plus ribavirin versus interferon alfa 2a plus ribavirin for chronic hepatitis C in HIV-coinfected persons. N Engl J Med 2004; 351: 451–59; Torriani F, Rodriguez-Torres M, Rockstroh JK, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection in HIV infected patients. N Engl J Med 2004; 351: 438–50.

significance as 'sentinel viruses' for other as yet unknown organisms.[290] Though much of this literature was composed at a time when the threats from these other pathogens remained current (ie before the advent of recombinant products which were not derived from animal cell lines or human plasma either directly or in some form such as the use of human albumin as a stabiliser), they are helpful in indicating the threat which actually existed in the past and should form part of the Inquiry's conclusions about the extent of the impact on the infected community. Some may constitute potential threats which needed to be guarded against in the future.

The potential viral threats

4.36 A question being posed of Professor Iain Franklin, then the head of the SNBTS by Charles Kennedy MP on behalf of his then constituent, Bruce Norval. The response (dated 12 May 2004) lists the pathogens which the SNBTS accepted had been ones to which haemophiliacs had been exposed by their haemophilia treatment, generally.[291] Those listed are:

a) Hepatitis A virus
b) Hepatitis delta (associated with Hepatitis B)
c) Human parvovirus
d) GBV-C virus (sometimes called hepatitis' G virus although not known to cause hepatitis)
e) TT virus
f) The SEN-V virus has been implicated in post-transfusion hepatitis but Professor Franklin indicated that he was not aware of any evidence of transmission to haemophiliacs.

---

[290] "Viral safety of haemophilia treatment products" by Teitel (Canada) Annals of Medicine, 32:7, 485-49, page 485
[291] MACK0001952

g) West Nile Virus (WNV) is said to have been transmitted by fresh blood components (i.e. red cell and platelet transfusions) but Professor Franklin indicated that he was not aware of transmission to haemophiliacs - there was evidence that modern processing methods would inactivate WNV but he stated that it could have been transmitted prior to these steps being introduced if it was present in the blood supply at that time (for example via untreated US plasma products).

4.37 In one article, "Clinical Perspectives of Emerging Pathogens in Bleeding Disorders"[292] a summary is presented of an interdisciplinary forum of clinicians who treat haemophilia, infectious-disease specialists, and epidemiologists that was convened at Washington University School of Medicine in St Louis, MO, USA, in June, 2004, to discuss infectious-disease risk management in patients with haemophilia. The forum had the following objectives: to review emerging blood-borne pathogens and their potential effects on therapeutic CFC; to discuss clinical issues related to viral infections in patients with haemophilia; and to review the safety of CFC in terms of transfusion transmissible infections. All of the pathogens discussed were transmissible by human plasma derived concentrates and also whole blood preparations. The article confirms that new pathogens are more likely to emerge in conjunction with opportunistic infections in highly immunosuppressed individuals, such as those with congenital immune defects, cancer, or AIDS. Immunosuppression, especially in xenotransplantation settings, might enable a poorly adapted virus to replicate and adapt to human beings and act as a bridge to subsequent infection of the healthy population. This may affect, in particular, those already infected with the recognised viruses.

4.38 The following additional pathogens appear to be worthy of the Inquiry's attention:

(a) <u>Human parvovirus</u>

[292] The Lancet, 367:252-61, January 21, 2006

4.39 There is a paper entitled "Towards a process for considering and prioritising actions to further reduce risk in transfusion", which is from June 2001.[293] This report was a draft interim paper for MSBT by request of the National Blood Service in light of the introduction of NAT testing by the Scottish National Blood Transfusion Service (SNBTS). The paper discusses measures which could still be taken at that time to minimise PT disease transmission risk. It includes some analysis of "other pathogens" and incidence of transmission. Amongst these is B19 parvovirus.

4.40 During the course of his evidence, there was some reference to a study undertaken by Professor Peter Collins & Ors and reported in 1998.[294] This study demonstrates that patients who were treated with 8Y did not develop HCV. 100% of the patients contracted parvovirus B19, as it is a nonenveloped virus which is thus resistant to the heat treatment procedure to which the 8Y was subjected, though no consideration appears to have been given the likely effects of this virus.

4.41 There is some literature on the likelihood that B19 parvovirus would be transmitted by recombinant products and the likely effects of that. Previous B19 infection was associated with ROM limitations in very young male patients with haemophilia. It concluded that virus inactivation techniques effective against B19 and other nonenveloped viruses are needed.[295] A Dutch study looked at the overall prevalence of B19 IgG in the haemophilia patients and found it to be 302/326, and in the controls 123/203. Below the age of 10, haemophilia patients had a higher prevalence of B19 IgG (76%) than the controls (23%). In those below the age of 5 who had been treated exclusively with monoclonally purified concentrate, it made no difference whether the product was pasteurized or solvent-detergent treated. There was significantly lower incidence in patients who were rarely treated. The conclusion was that parvovirus B19 was frequently transmitted in blood products and that then existing virus-inactivating methods do not prevent transmission.[296]

---

[293] NHBT0008156

[294] WITN4029008

[295] Human parvovirus B19 in young male patients with hemophilia A: associations with treatment product exposure and joint range-of-motion limitation Transfusion 2004 Aug;44(8):1179-85

[296] HIGH PREVALENCE OF PARVOVIRUS B19 IGG ANTIBODIES AMONG DUTCH HEMOPHILIA PATIENTS VOX SANG1998;74(4):225

4.42 The incidence of B19 viraemia in blood donations is considerably less than 1 % but this is still sufficient to contaminate plasma pools used to prepare therapeutic concentrates. It is generally thought to result in mild of sub-clinical disease and is not associated with a chronic carrier state.[297] Parvovirus B19 most commonly causes fifth disease, a mild rash illness that usually affects children. Adults can get infected with parvovirus B19 resulting in fifth disease too. Less common symptoms of parvovirus B19 infection include painful or swollen joints (polyarthropathy syndrome), which is more common in adults, and severe anaemia (a condition in which the body doesn't have enough healthy red blood cells). In rare cases, some of these symptoms can persist for a long time.[298]

4.43 A study of the effects of infection with B19 parvovirus transmitted by blood or blood products concluded that concern has been raised following the identification of the new parvoviruses, human parvovirus 4 (PARV4) and new genotypes of parvovirus B19, in blood products. It found that parvoviruses may cause clinical manifestations, especially in immunosuppressed patients.[299] The article notes that infection may cause the disease *Erythema infectiosum* (EI), fifth disease or 'slapped cheek', and arthritis among adults. The active disease forms related to PARV4 detection were rash and exacerbation of hepatitis. The concentrates involved were plasma-derived and had undergone S/D treatment and dry or wet heating processes. Thus, there does appear to be some evidence creating a clear link between plasma derived products and the development of parvovirus infection. Indeed, the evidence appears to be that this was a virus which was not eliminated by heat treatment regimes and may continue to have been transmitted in recombinant products, along with prions.

Epstein-Barr virus

---

[297] "Viral safety of haemophilia treatment products" by Teitel (Canada) Annals of Medicine, 32:7, 485-49, page 486

[298] https://www.cdc.gov/parvovirusb19/about-parvovirus.html

[299] "Parvovirus transmission by blood products – a cause for concern?" by Makris & Ors British Journal of Haematology, 2012, 159, 385–393

4.44 Epstein-Barr virus ("EBV") is a herpes virus. It can be linked with serious conditions such as rupture of the spleen, anaemia, low platelet count (thrombocytopenia), hepatitis (presumably due to the association between EBV and liver inflammation[300]), myocarditis and conditions affecting the nervous system, including encephalitis, meningitis, and Guillain-Barre syndrome as well as certain cancers (Nasopharyngeal cancers, Burkitt's lymphoma, Hodgkin's lymphoma and Gastric adenocarcinoma (stomach cancer)) and autoimmune conditions such as lupus. The association with these conditions is said to be one of increased risk and a further study is referred to which postulates a link between this and various other conditions. The association with these other conditions is said to be more likely in those with poor immune systems. However, in the recently circulated paper by Makris and Ors[301], it was claimed that haemophiliacs had no greater risk to the transmission of herpes virus than the normal population as they are transmitted by white cells and not plasma, though this would still be a risk for those who had received non-leukodepleted blood transfusions.

4.45 It remains possible that these viruses could cause immune-suppression and thus render the effects of other viral exposure worse. Thus, their presence in the normal course of events could render infection with HCV, for example, worse. At the Penrose Inquiry, Professor Hann said that in 1982 (in the context of the emerging knowledge about AIDS:

> *"[A]lthough we knew some viruses, like Epstein Barr virus, the glandular fever virus, other Herpes viruses like cytomegalovirus, could cause immune deficiencies, nothing remotely like this had ever happened before."*[302]

---

[300] See footnote 36 at page 593 of and para 14.67 the Penrose final report as well as the reported association between jaundice and EBV, CMV the Coxcaskie virus and adenovirus at para 18.74

[301] "Viral hepatitis in haemophilia: historical perspective and current management" British Journal of Haematology, 2021, 195, 174–185 by Makris & Ors – pages 1 – 2

[302] See Penrose final report para 11.8 and Penrose Inquiry transcript for Day 21, pages 43–44

Cytomegalovirus

4.46 Cytomegalovirus ("CMV") is a herpes virus. Similar comments about its significance in the current context apply as apply to the analysis of EBV above. Plentiful online information is available about the virus.[303] For people who have weakened immune systems, CMV infection can be fatal. If the immune system is weakened, serious problems can affect the eyes, lungs, liver, oesophagus, stomach, intestines or brain. In particular, it can be associated in those with a weakened immune system with (a) vision loss, due to inflammation of the light-sensing layer of the eye (retinitis) (b) digestive system problems, including inflammation of the colon (colitis), oesophagus (esophagitis) and liver (hepatitis) (c) nervous system problems, including brain inflammation (encephalitis) and (d) pneumonia.

4.47 Alison Richardson in Edinburgh cared for a patient who had acquired HIV from a blood transfusion and was also infected with CMV, which caused her to go blind. The patient eventually died.[304]

4.48 One witness from Aberdeen was infected with CMV as a result of a blood transfusion in 1991.[305] The system had no protection against the transmission of such infections at that time. This witness has gone on to become blind as a result of his infection. CMV is generally transmitted via the white cells. Leucodepletion of whole blood would have minimised the risk of such transmission. This happened when the risk of vCJD transmission occurred in 1999, even though it was not known that the disease would be transmitted via white cells. In the case of this patient, he had had a number of medical problems which resulted in him requiring to have chemotherapy, as a result of which he became immuno-suppressed.[306] The blood which was given to him which caused his infection ought to have been leukodepleted at that time. The techniques had been available for many years

[303] Such as at https://www.mayoclinic.org/diseases-conditions/cmv/symptoms-causes/syc-20355358
[304] PRSE0001055 @ para 12 (statement of Alison Richardson)
[305] WITN5274001 (first written statement of William Stafford)
[306] WITN5274001 @ para 5 (first written statement of William Stafford)

before that time.[307] Had it been, he would not have been infected and would not have suffered the life-changing consequences of that infection. For those infected with CMV, mechanisms should be made available to provide State support as is submitted as part of our submission on financial recommendations below.

Other herpes viruses

4.49 Other herpes viruses which may be transmitted by blood include human herpesviruses 6 and 8 (HHV-6 and 8). They are known to have been transmitted by white cells and so are not transmitted by blood products routinely used in the treatment of haemophilia.

Enteroviruses

4.50 These small non-lipid-enveloped viruses form a separate genus within the picornavirus family. Viruses such as these without lipid envelopes tend to be less susceptible than lipid-enveloped viruses to inactivation methods because they are typically smaller in size and are likely to have greater resistance to heat, irradiation, and solvent detergent treatment. Emerging non lipid-enveloped viruses could therefore have posed the greatest threat to the recipients of plasma-derived concentrates.[308]

4.51 Some of the enteroviruses can spread through the blood to other parts of the body, including the central nervous system. The resulting diseases can be severe, partly depending on the specific enterovirus serotype. Enteroviruses that undergo viraemic phases in their life cycle and are associated with substantial morbidity (eg, enteroviruses 70 and 71) could be particular threats to blood products.

---

[307] "Leukoreduced blood components: Advantages and strategies for its implementation in developing countries", Sharma et al Asian J Transfus Sci. 2010 Jan; 4(1): 3–8

[308] Ludlam et al (supra) from page 8

Enterovirus 70 was the causative agent of epidemics of acute haemorrhagic conjunctivitis in Africa, Asia, India, and Europe. This feature, in combination with their resistance to inactivation, makes them a potential threat to blood and concentrate supplies.

4.52 In a study in Scotland, 0.024% of blood donations showed evidence of enterovirus viraemia.[309] This proportion predicts about 1,000 enterovirus contaminated transfusions per year in the UK. A wide range of viral loads and enterovirus serotypes were detected, including enterovirus 71, coxsackieviruses A2, A5, A10, A16, B2, B3, B4, and B5, and echoviruses 11, 13, 18, and 30. In the light of the numbers of potential infected donations, initiation of screening methods for enteroviruses was recommended in the Ludlam et al article in 2006 to exclude the possibility of blood-transfusion associated transmission of potentially pathogenic variants such as enteroviruses 70 and 71.

Circoviruses

4.53 Human circoviruses include torque-tenovirus (TTV)[310] and torque-tenominivirus (TTMV), two related viruses with highly divergent sequences. Each has a vast number of distinct genotypes. Importantly for blood products, these extremely small and stable non-lipid-enveloped viruses cannot be removed easily by nanofiltration They are likely to be highly resistant to heat and other viral inactivation protocols used in manufacture of blood products. There are no known human diseases associated with circoviruses, but the Ludlam et al article counselled that some may pose a risk.

Q fever

---

[309] Welch J, Maclaran K, Jordan T, Simmonds P. Frequency, viral loads, and serotype identification of enterovirus infections in Scottish blood donors. Transfusion 2003; 43: 1060–66.

[310] TTV is listed in the Franklin letter in 2004 of as being a virus which has been known to be transmitted to people with haemophilia (MACK0001952)

4.54 Q fever is listed in the Franklin letter in 2004 of as being a virus which has been known to be transmitted by whole blood transfusions (like the herpes viruses).[311] It is a bacterial infection. Chronic Q fever can lead to serious heart problems like endocarditis. As Q fever is bacterial it is susceptible to antibiotic treatment.[312]

Recombinant products

4.55 There is a possibility that the cell line used in the production of the recombinant products could be infected with and propagate, a pathological prion.[313] The first-generation recombinant concentrates were manufactured from cultures that contained animal and human proteins. Human albumin was also added as an excipient to the final preparation.[314]

vCJD

4.56 vCJD was first reported in 1996 following the review of 10 patients in the UK who had exhibited a novel neuropathological profile. The cases were remarkable for the young age of onset, the clinical findings, and the absence of electroencephalogram findings that would ordinarily be seen in 'classical' CJD. The overwhelming majority of cases identified since 1996 have been within the UK, and are considered to be causally linked with BSE. That has been the subject of a separate Inquiry. The relevance of the disease for this Inquiry is the fact that, since 2000, studies in sheep demonstrated "*the efficient transmission of BSE by*

---

[311] MACK0001952
[312] https://www.nhs.uk/conditions/q-fever/
[313] Vorberg I, Raines A, Story B, Priola SA. Susceptibility of common fibroblast cell lines to transmissible spongiform encephalopathy agents. J Infect Dis 2004; 189: 431–39.
[314] Ludlam et al (supra) from page 16

intravenous transfusion of labile blood components including red blood cells, platelets, and plasma",[315] and the fact that, as is explored elsewhere in this submission, the response of the UK blood services to the emerging threat of the disease can be considered to have been very different to the response to other blood-borne transmissible infections.

4.57 There have been four cases in which the transmission of the disease via transfusion has been considered probable, and one case in which a patient with haemophilia was found to have abnormal prion proteins in his spleen which indicated infection with vCJD (although the patient did not exhibit symptoms of the disease prior to his death); studies concluded the most likely source of his infection was the receipt of UK plasma products.[316] Of the 4 transfusion recipients who developed vCJD, 2 had received red cells from a single donor who subsequently developed vCJD themselves approximately 2 years after making the donation[317]. Since 2017, there have been no further reported infections of vCJD in blood/ blood component recipients. However, there are known to be at least 32 blood donors who subsequently developed the disease. Of the recipients of components from those donations traced, 53 had died prior to 2019, and 14 were alive at that time.[318]

4.58 The disease is invariably fatal, there are no treatments beyond symptom control/ management, and there is no test available that demonstrates conclusively whether someone will develop the disease. Testing is available in patients showing symptoms of the disease where vCJD is a potential diagnosis but the sensitivity of the test is unknown, such that it is not offered to patients who do not exhibit any symptoms.[319] Techniques have been developed which are considered by those who have given evidence to this Inquiry to have potential to be developed into

---

[315] WITN7034001, para 8(a)(ii) (Professor James Ironside)

[316] HCDO0000799

[317] IBI transcript for 17/05/22: 33 (Professor James Ironside)

[318] Ibid, 35

[319] WITN3093002, para 15 (Professor John Collinge)

assays for testing, but the evidence in the Inquiry suggests that these techniques have not been so developed.[320]

4.59 In Scotland, two donors were identified who subsequently developed vCJD. One of those donor's donations were pooled to created plasma products including factor VIII, DEFIX, albumin, and IM immunoglobulin. The other donated 2 blood components. The former's donations were given in the period 1987-89[321].

4.60 Currently, the impact of plasma processing technologies on the infectivity of vCJD via pooled plasma products is unknown. It may be the case that there are a variety of factors that affect the likelihood of infection that relate to both issues relating to the donor pool, and the susceptibility of the recipient[322].

4.61 In the confirmed cases seen in the UK to date, there is a significant incubation period between infection and the development of symptoms associated with the disease. There is evidence to suggest that the incubation period may differ depending upon the genotype of the individual infected with the disease[323]. Although the relevant haemophilia directors of the recipients of the 'implicated batches' were notified, it appears they did not notify their patients of the fact at that time[324].

4.62 In 2003 an assessment of risk of exposure to vCJD in infectivity in blood and blood products was carried out (as an update to an earlier assessment in 1999)[325]. The assessment concluded that there was a small group of individuals who had potentially been exposed to vCJD at a level that warranted public health action; the recommendation was that these patients were contacted and informed of their exposure so they could ensure they did not give blood or organs, and they

---

[320] IBI transcript for 17/05/11: 117 to 118 (Professor James Ironside)

[321] JPAC0000086_019

[322] WITN7034001, para 8(a)(x)

[323] IBI transcript for 17/05/22: 23 to 24 (Professor James Ironside)

[324] JPAC0000086_019_003

[325] DHSC0020839_003

could notify any healthcare provider of the potential risks. Various plasma products were assessed regarding their considered infectivity risk. The UKHCDO recommended that an 'umbrella' approach should be taken to notifying all patients with bleeding disorders that they might be at risk if they received treatment between 1980 and 2001, irrespective of the extent of their treatment with relevant products. That notification process commenced in 2004. Subsequently, many patients were 'de-notified' as the period of exposure was shortened.

4.63 Given the nature of prion disease, there are concerns that surgical instruments used on patients with vCJD could be a vector for cross-contamination and infection of others. Although there are no known cases of transmission of vCJD via surgical instruments, there are cases of transmission via that route of classical CJD. Those who were notified as high risk patients for public health purposes were treated differently in surgical and dentistry settings in light of that notification. Some were unable to access medical care as a result of the possible risk. [326]Professor Collinge, in his evidence to this Inquiry, spoke of research he undertook to develop new sterilisation techniques to account for the risks posed by vCJD. Although he developed technology which he considered to have a high level of decontamination of the stainless steel surgical instruments, and that technology was adapted by a commercial chemical company into a product that could be sold to the NHS, the NHS did not purchase it. Professor Collinge suggested that, whilst public health precautions would still require to be undertaken in certain regards, had the technology been adopted by the NHS, issues surrounding decontamination of surgical instruments might have been avoided. However, he accepted that there were significant practical impediments to the introduction of such a product in the decontamination process ordinarily undertaken in hospitals; solutions to those impediments do not appear to have been pursued by the company with the rights to the intellectual property of the product.[327]

---

[326] IBI transcript for 13/05/22: 72 (Professor Collinge)

[327] Ibid, 78

5. General

5.1 The Inquiry should take account of the importance of the circumstances in which the infections were suffered:

(a) All patients who were infected were vulnerable either as a result of a chronic condition or more acute need for medical intervention;

(b) The chronic nature of some of the conditions leading to harm being caused to the developing body when the infected individual was a child. There is a need for better understanding and research of the consequences of that;

(c) In some case of those treated with pooled products or the multiply transfused, multiplicity of exposure to harmful agent (repeat infection with HCV/ HCV etc). There is a need for better understanding/ research on that;

(d) Those with haemophilia having acquired the condition through their mother's genes, mothers having been the people who infected them. This has caused deep seated psychological trauma.

6. Psychological consequences

6.1 The Inquiry has heard copious evidence about the psychological effects of both the infections themselves and the treatment regimes on the infected and affected communities. As explored within this submission, the infections almost invariably impacted many facets of the personal and public lives of those impacted by the contaminated blood disaster, with consequential psychological and psychiatric effects.

6.2 The psychological aspects of the infections are multi-faceted and complex. Some arise from the fact of the infection itself, some from the way in which people were told (or not told for extended periods of time), some arise from the manifestations of the illnesses themselves with organic effects on the brain, and some arise from

the effect of treatments. Additionally, the fact and effect of infection and/ or treatment has resulted in significant lifestyle effects for many, with consequential psychological impacts.

6.3 The psychological effects on the affected community are explored further below.

6.4 The psychosocial expert group have considered a variety of the elements of the response of the community to the disaster from a psychological point of view. They note the impact of loss of employment on a family unit or individual, with the consequential financial and emotional results.

6.5 The expert group notes that *"a lack of adequate psychological support has a negative effect on various psychological outcomes, including adherence to treatment regimens."*[328] Despite this, the majority of witnesses explained in their evidence that, particularly when they were told of their infections or underwent early treatments, little or no psychological care was provided. Some were told of their infections in the absence of partners or family members who might have been in a position to offer emotional support.

6.6 An anonymous witness talks in his statement regarding the psychological impact of his HIV and HCV infections, explaining that he suffered from addiction and depression, and felt that he *"slipped through the cracks of the system*[329]*"*. He notes that he felt his symptoms should have resulted in admission to rehab or a mental health institute, but instead he was left to manage without such support.

6.7 A number of individuals have had suicidal thoughts or attempted suicide following their diagnosis or treatment for their infection[330].

6.8 As a result of the ways in which people were treated, or as a result of the genetic cause of their bleeding disorder, many of those with bleeding disorders saw their friends and relatives die, particularly of HIV. A witness who gave oral evidence to this Inquiry recalled the horrifying experience of being a child in a ward with another boy who had HIV with whom he had become friends. He told the Inquiry that one night, he saw his friend die, and be taken away by porters who treated

---

[328] EXPG0000003_0030.
[329] WITN2149001, para 22
[330] WITN2148001, IBI transcript for 02/07/19: 88 (anonymous, Mr R)

the body callously, making jokes, and expressing no empathy either to the deceased, or to the witness[331].

7. Treatment for infection

7.1 Many core participants have spoken of the horrific side effects of their treatments for their infections. As the psychosocial expert group reported, *"early treatments of HIV and hepatitis C led to very severe and multiple physical and mental side effects[332]"*. For some, the treatment seemed 'worse than the disease'. We submit that, not only were the treatment themselves difficult (which we explore in more detail below), but for some, the discussions that patients underwent with their treating clinicians, served to compound the harms. Many core participants, for example, were repeatedly told of the cost of their treatment, with the effect that some felt increased levels of guilt and stigma, irrespective of the fact that the need for their treatment arose as a result of an infection caused by the state. For some, the references to the costs appears to have been linked to the fact that treating clinicians were perhaps sceptical of the source of their infection, or were used to treating patients who had contracted their infection through other routes. Infected individuals were made to feel that they had to 'justify' their treatment in these circumstances.

7.2 The various treatments over the years had enormous and long-term impacts on a significant number of the core participants who are represented in this submission. Some lost their jobs as a result of the impact of the treatment, either never able to return to the workplace thereafter, or losing the opportunities that might have been available to them in the year or more of treatment that they had to endure. Jobs were lost, promotions opportunities were missed, and employment prospects were, in many cases, irretrievably diminished. Many of

[331] IBI transcript for 31/10/19; 44 to 45 (Myles Hutchison)
[332] EXPG0000003_0004

those affected by the disaster have told the Inquiry that the treatments were worse than the disease in terms of the side effects at the time, and indeed the long term sequelae.

7.3 The early treatments in particular had considerable effects on many recipients' mental health, with wide-ranging consequences for every facet of their lives. For some, those mental health issues persisted long after the treatment had concluded, even where a sustained virological response was achieved. Ribavirin and interferon treatment caused physical and psychiatric side effects in a significant proportion of those who took it. Many were unable to complete the course as a result of those side effects. An anonymous haemophiliac witness who was co-infected with HCV and HIV noted that the ribavirin and interferon treatment caused a reaction that necessitated the prescription of diazepam and his admission to a psychiatric hospital for treatment.[333]

7.4 An anonymous oral witness who gave evidence to the Inquiry said that, whilst he had been warned that the side effects of the proposed HCV treatment were "very severe and brutal[334]", the treatments were "*completely inconsistent with what [he had] been told to expect [...]*". He suffered a broad range of considerable side effects, including significant mood changes, suicidal thoughts, boils and blisters[335]. He gave the Inquiry distressing evidence that during and after the treatment, his mental health was affected particularly badly, commenting that *"the whole issue was the kind of homicidal and suicidal thoughts. I felt the world was against me. I just wanted to – I felt like ripping heads off of people that I came across that irritated me a bit and I tried to sort of rationalise those kind of feelings and thoughts, because I'm not an aggressive person but, you know, you turned into something that was just horrific. I didn't like myself much, and I thought I was putting through – putting my family through hell. So I went back on a sort of programme of how best to kill myself[336]"*. The treatment did not clear the virus, and the witness had to undergo 2 further courses of treatment over the following

---

[333] WITN2149001, para 28 (anonymous)
[334] WITN2137001, para 20 (anonymous)
[335] IBI transcript for 10/07/19: 12 to 15 (anonymous, Mr X)
[336] IBI transcript for 10/07/19: 14 to 15 (anonymous, "Mr X")

years before the virus cleared. The second round of treatment felt, to Mr X, *"like Dante's hell circle -first circle of limbo[337]"*. Although cleared of the virus, the witness has cirrhosis, and significant other medical effects of the virus and treatments.

7.5 An anonymous witness with severe haemophilia A who was co-infected with HCV and HIV who gave oral evidence to the Inquiry ("Mr Z") that, when treated in 2005 with pegylated interferon and ribavirin that he *"wouldn't have wished that treatment on [his] worst enemy"*. He noted the difficulty with having to self-inject his treatment not knowing how severe the side-effects might be; he suffered a broad range of severe effects which culminated in an emergency admission to hospital with a period of unconsciousness and concerns as to whether he would survive. His medication regime was changed, and his condition improved, but he was left with considerable health issues, including the development of type II diabetes. [338]

7.6 Others saw their family lives severely affected, in some cases to the extent of destruction. Relationships broke down in circumstances where the treatments caused physical, mental, and emotional difficulties and changes. An anonymous witness giving oral evidence to this Inquiry spoke of the fact that he *"knew [he] wasn't the same person on it, once [he started on these, because [he] was irritable, [he] was annoying [...] [his] partner at the time said you could cause a fight in an empty house[339]"*. After 3 rounds of treatment, the witness cleared the HCV infection in 2017. He gave oral evidence in 2019, but passed away in June 2020.

7.7 GRO-D

GRO-D Many others experienced the breakdown of relationships as

[337] Ibid: 17
[338] IBI transcript for 10/07/19: 171 to 174 (anonymous, Mr "Z")
[339] IBI transcript for 22/07/19: 84 to 86 (anonymous, Mr R)
[340] GRO-D

a result of their treatment. Others experienced considerable tensions in their relationships with partners and other members of their close family.

7.8 For those infected with HCV, the mixed success with treatment regimes also meant that, in some case, despite the difficulties that some infected endured, their hopes of recovery were dashed when the treatment failed. Even for those whose treatment was 'successful', there have been life changing consequences in many cases, both as a direct consequence of the treatment, and as a result of the wholly understandable concerns and fears that the disease may return. The psychosocial expert group recognised that these fears have *"resulted in ruminative thoughts and surveillance of body symptoms, both of which can have detrimental effects on emotional well-being*[341]*"*. Elsewhere in this submission, we have submitted that this Inquiry recommends that those who have been found to have 'cleared' the virus are nevertheless offered ongoing monitoring of their liver status for this very reason[342].

7.9 A widow of a mild haemophilia A patient who contracted HCV following the administration of Factor VIII concentrates in 1977 states that *"initially there had been no noticeable impact from Hepatitis C to Dave. Dave was a fit man and enjoyed playing sports like cricket and volleyball. It was not until he started taking the treatment that he became very ill. Physically he became exhausted. He started having aching joints and cramps that made him jump out of bed at night... the initial effects of the treatment with interferon were only made worse with the knowledge it was unsuccessful and discontinued*[343]*"*.

7.10 Another anonymous witness giving evidence regarding her and her late husband's experiences of his infection with HCV gave emotional testimony regarding the effects the treatments he had had on him and his family. She noted that, following notification in 2004 that another round of treatment had not worked, left the family home and drank alcohol heavily. Her husband did not want people to know about his infection; the witness told the Inquiry that she let people believe that his alcoholism was the cause of their relationship breaking up, but she *"wanted to*

---

[341] EXPG0000003_0004
[342] See non-financial recommendations below
[343] WITN1500001, para 18 (Lorna Rusling)

scream that we were no longer together because of the hepatitis C and that [her husband] had become an alcoholic because of the hepatitis C"[344]. Her husband died in 2010. She stressed in her evidence, that it was not the HCV itself which killed him, but the treatment[345].

7.11 In addition to the psychological responses, the early treatments for HCV caused considerable physical effects.

7.12 One witness who gave oral evidence to this Inquiry with her family, gave detailed and emotional evidence about the particular effects her treatment for HCV had. Her son noted that it dominated their lives in all aspects; they had to plan their lives to take account of when the treatment was being taken, and as a result of the side effects his mother was bed-ridden and asleep, such that she was not able to participate in family life. After a second course of treatment, the witness developed an autoimmune disorder, systemic lupus erythematosus which causes her severe photosensitivity. As a result of that disorder, the family were required to alter their lifestyle to avoid light as far as possible.[346]

7.13 For those infected with HIV (who of course also frequently underwent HCV treatment), the early AZT treatments caused numerous and extreme side effects, resulting in anxiety, insomnia, and paranoia[347].

7.14 The widow of a haemophiliac treated in Edinburgh and co-infected with HIV and HCV (although he was never told of the latter infection) describes that he was told by Dr Ludlam that he was a candidate for AZT, and was reassured by Dr Ludlam that, in the trial, he would be given "the right drug". Within a month of commencing the trial, he was forced to stop as a result of the side effects[348]. The witness' husband subsequently developed lymphoma, and his HIV progressed to AIDS.

7.15 The stepson of an individual who contracted HIV following a blood transfusion writes in his statement that his "*mum was always on different drugs. You could tell*

---

[344] IBI transcript for 10/07/19: 90 to 95 (anonymous, Ms Y)
[345] Ibid: 110
[346] IBI transcript for 03/07/19: 154 to 162 (Gill, Stanley, Rory Fyffe and Lucy Parham)
[347] WITN2149001, para 27 (anonymous)
[348] WITN2665001, para 19 (Linda Grigor)

that a new drug she was trying was making her ill... she was gaunt, grey and ill, she would spend days in bed. She was a fighter, so you could tell she was having a bad reaction when it meant she had to stay in bed"[349]

7.16 Notwithstanding the very significant emotional and mental toll that the treatments were known to have on those undergoing them, many witnesses have provided evidence to this Inquiry that they found it difficult or impossible to access counselling or other assistance, with many noting that they were never offered such treatment.

8. Consequences of infection on social, personal and working lives

Employment

8.1 Many of those impacted by the blood contamination disaster have experienced a significant and permanent impact on their employment and/ or career prospects. The effects of such lost job security and opportunities have been broad-ranging and long-lasting, not only on the infected, but the affected as well. Such problems have been further compounded by difficulties faced by the community in securing life insurance in connection with mortgages, increased premiums for travel insurance (if such insurance were even available), as well as the increased cost of living generally associated with the effects of the infections. Some lost their houses as a result of their inability to pay their mortgages following the effect of the infection or the treatment[350]. In many cases, the fact and effect of an infection within the family had a ripple effect across the generations, e.g. with children of those infected seeing their own primary, secondary, and tertiary education affected by worries for their relatives, lost opportunities as a result of financial difficulties at home directly or indirectly caused by the infections, and the need to care for their infected relatives.

---

[349] WITN2103001, para 19

[350] IBI transcript for 02/07/19:87 (anonymous, Mr R)

8.2 The expert group on HIV note that, *"For younger people, school and educational attainment and achievement may have been negatively affected. HIV-related health issues had a direct impact on employment and career opportunities, because of absence from work due to ill health or due to stigmatising workplaces reducing employment opportunities. Challenge to employment resulted in financial hardship often borne by partners. HIV had an impact on travel due to ill health or because of visa restrictions. Property was unattainable because mortgages and health insurance were restricted*[351]*".*

8.3 An anonymous oral witness in this Inquiry who was infected with HIV and HCV as a child notes in his statement that, although he had had a successful career, working full time in corporate finance, he stopped work permanently in 2018 as a result of the effects of his illness. He notes in his statement that there was considerable cost associated simply with attending the hospital regularly, and a very significant effect on his income, his employment opportunities, and his pension as a consequence of those effects. He was unable to take up opportunities at other potential employers due to the effects of his infection.[352]

Family lives

8.4 Many core participants have given evidence about the significant impact on their family lives as a result of the infections. Many refer to the fundamental physical and personality changes to both the infected and to their relatives arising from the fact of their infection, the symptoms caused by their illnesses, the stigma associated with the illnesses, the effects of the treatments, the impact on employment and income, and the caring responsibilities for relatives.

8.5 Many core participants, both infected and affected, have given harrowing evidence about the fear, anxiety, and guilt they experienced when they realised that the infection they or their loved one was carrying could potentially be passed

[351] EXPG0000004_0033
[352] WITN2223001, para 35-36 (anonymous)

to other family members[353]. An oral witness told the Inquiry that, upon receiving a letter from the SNBTS advising her that she might have contracted a blood-borne infection, she realised her children might be infected, and her *"world just fell apart".*[354]

8.6 For some, the suggestion that their relatives should undergo tests to confirm whether they might have contracted the infection caused particular stress and anxiety. Many have given evidence about their concerns of being in physical contact with their relatives, and their avoidance of social gatherings. As time has passed, and those involved have grown older, many have grandchildren or other relatives who they are fearful to touch[355]; in some cases, their children harbour anxieties about the possibility of their own children being infected such that they place restrictions on contact between their infected parent or parent in law and their children.

8.7 The widow of a bleeding disorder patient treated by Dr Ludlam who contracted HIV records in her statement that, through lawyers, the couple were able to obtain evidence that her husband had been found to be HIV positive in 1984, but only told of his infection in December 1986. She notes that her husband was *"so very very angry that he was not told about his HIV diagnosis. He was angry about the fact that he could have infected both me and our son. We were his main priority and he was very upset that the thought he could have harmed us."*. The witness comments that she did not feel it was her husband that had put her and their son at risk, but the doctors who did not advise them of the infection[356]

8.8 Some core participants have given evidence that the fact of their infection has limited their family plans, with individuals deciding not to have children given their concerns about the risks associated, either in passing the infection on to loved ones, or the impact on their own health and response to the infection. One oral witness gave evidence that, having cleared the virus, she was *"very very scared*

---

[353] WITN2840001 @ paragraph 13,
[354] IBI transcript for 03/07/19: 126 (Gill Fyffe)
[355] IBI transcript for 08/07/19: 10(20) to 11(7) (Maria Armour)
[356] WITN2202001, para 19-20 (anonymous)

that a subsequent pregnancy could have led to the virus returning" and accordingly she decided not to have any more children[357].

8.9 An anonymous core participant writes in his witness statement that, due to the treatment he was taking for HCV when his wife was pregnant, they were advised to terminate the pregnancy as a result of possible complications for the baby arising from that treatment. As a result of the termination, and the witness' own ill-health, the couple decided not to have any more children[358].

8.10 For others, the infections had a significant impact on their intimate sex lives with their partners, whether as a result of fear of transmitting the infection[359], or as a direct effect of the physical and mental effects of the infections[360]. Core participants have given evidence that they did not feel able to enter into relationships as a result of their infections for fear of passing the infection on, or out of a desire to keep their condition secret, or both[361]. The psychosocial group provide details of studies that demonstrate that anxiety linked with sexual intercourse has a significant effect on an individual's enjoyment of their sex lives.[362]

8.11 The infected and affected have seen impacts on their ability to attend social groups or to practice their religion as a result of their illness, the effects of their treatment, and/ or the stigma associated with their infections.

8.12 As a result of his infections with HIV and HCV and the complications that arose with them, an anonymous witness in this Inquiry wrote in his witness statement that he had to tell his then 8 year old daughter that he might only have days to live[363]. He and his wife (Mr and Mrs Z) gave emotional evidence about the impact that his illness had on their family life; he spent considerable periods in hospital as a result of numerous medical complications, and his young daughter would frequently wake up at home in the morning to find her father was being taken into

---

[357] IBI transcript for 10/07/19: 126 to 127 (Pauline Reid)
[358] WITN2200001 (anonymous)
[359] WITN2203001 (anonymous)
[360] WITN2677001, para 30 (Agnes McNeish)
[361] WITN2071001, para 20
[362] EXPG0000042_007
[363] WITN2223001, para 29

hospital via ambulance. Mrs Z took extended leave from work to care for her husband.

8.13 Many witnesses talk in their evidence about the fact that their loved ones had to give up their own work to care for them. This had a compounding effect on the household finances, increased feelings of helplessness and guilt, and frequently led to greater isolation of the family both as a result of the loss of contact with others, and the financial effects. Those issues have, in many cases, been compounded by the stigma experienced by the community.

8.14 Those infected have, in some instances, been unable to obtain travel or life insurance, such that they have been unable to go on holiday, or buy a house. Others, as a result of effects on their employment, lost their homes and fell into considerable debt.

8.15 As the psychosocial group recognise, *"strained relationships and tensions between partners often reflected the multiple social impacts involving financial problems, housing problems, worries about the future, and the demands of care"*[364].

9. Stigma

9.1 This Inquiry has heard copious evidence of the stigma associated with infections contracted via the administration of blood and blood products. The stigma has been wide-reaching and deeply impactful on the lives of very many of those on whose behalf this submission is presented. It encroaches into private lives, public experiences, and health care. It is striking that, even now, many witnesses have chosen to give their evidence to this Inquiry anonymously, giving evidence that they have not told even close members of their family of the fact of their infection or their involvement in this Inquiry.

9.2 The stigma has traversed all aspects of many infected and affected lives and has been both personal and political. Individually, the infected and affected have suffered, and as communities there has been deep-seated stigma regarding

[364] EXPG0000003_0010

matters such as the route of infection, the nature of infection, and the risks posed to others. For some, perhaps particularly within the bleeding disorder community, the very fact of that underlying disorder has led to assumptions regarding their infections, GRO-D GRO-D Many, perhaps particularly in the transfusion community, have given evidence that they told very few members of their family about their infections, with some not feeling able to tell their children or other closed loved ones for fear of the information causing further stigma, or for fears for their relatives' own potential for stigmatisation. Some were advised by their doctors not to tell anyone because of the stigma[366]. As a result, many infected individuals have carried the burden of the knowledge of their infection with little emotional support from others.

9.3 Many witnesses have given evidence about being treated for their infection in difficult circumstances. A witness who gave oral evidence to this Inquiry noted that, when she was being treated at the liver clinic, most of those attending were drug users; she would attend the clinic with her children and was fearful for herself and her children. She confronted one of the nurses at the clinic regarding the nurse's preconceptions about how she had contracted her infection, and the nurse admitted that they assumed it was a result of drug addiction[367].

9.4 An anonymous haemophiliac writes of assumptions being made as to the source of his infection by doctors and nurses in hospital, noting that they frequently assumed he was infected as a result of IVDU or sexual misconduct. He had to repeatedly correct them *"and gain acknowledgment from these medical professionals that [he] was a victim of infected blood"*. He writes that this caused him to be reluctant to reveal the fact of his infection to others, resulting in feelings of isolation. He notes that he only recently revealed his infection to close friends as a result of the media coverage of the contaminated blood disaster[368]. Initially,

---

[365] GRO-D
[366] WITN2157001 para 9
[367] WITN2103001, para 22
[368] WITN2118001, para 7 (anonymous)

though, he felt the need to lie when questions were asked of him given his haemophilia status in response to the media coverage[369].

9.5 An affected representative gives a harrowing account of the stigma experienced by his stepmother and family as a result of her infections with HIV and HCV following a blood transfusion. He notes that the letters 'HIV' were written on the front of his mother's medical records and repeatedly reinstated despite efforts to remove such details from the front cover of the records. He notes that, at her funeral, *"her coffin was covered in a tarp. The flowers were used to hold it down. I thought my dad was going to have a heart attack that day. He had to tell the funeral director to take it off before everyone arrived"* and describes the impact of her infections as *"devastating[370]"*. He notes that his father lost his job as a result of his wife's story being made public, and that his family *"imploded"*.

9.6 An anonymous oral witness told the Inquiry that, following her husband's death with HIV/AIDS, she told the undertaker of her husband's infection and he refused to continue with the funeral arrangements. Instead, she told the Inquiry, her 24 year old son "*had to put his dad in a body bag*"[371].

9.7 An anonymous witness' statement regarding her mother who died in 2021 as a result of the effects of her infection with HCV, notes that when she was being treated at Gartnavel Hospital in Glasgow, she would be treated in the same clinic as drug addicts and alcoholics, and was *"treated like an addict[372]"*.

9.8 The Inquiry is aware that some recipients of blood and blood products received notification of their potential exposure to vCJD; the evidence suggests that the purpose of such notification was not for those who received the letter to undergo any screening or assessment, but to ensure that they were taking "public health precautions". Understandably, many who received the letter were very anxious. They also found that, in some cases, they were treated differently from other patients when undergoing medical treatment. That different treatment included only being offered limited appointments or spots on surgical lists, seeing their

---

[369] Ibid, para 28
[370] WITN2103001, paras 22-23
[371] IBI transcript for 11/07/19: 108 to 109 (anonymous, Ms AD)
[372] WITN5733001, para 30

treating clinicians take enhanced precautions with respect of infection control, and being told that surgical equipment that was used in any procedure was kept separately from other equipment out of concern that standard cleaning techniques would not eradicate the prions responsible for the disease. There is very little evidence of any support or education being provided to individuals receiving such notification, and it is clear that their 'notification for public health reasons' gave rise to further stigma. There seems to have been little recognition of the 'thin skull' effect that those who received the notification might have suffered from as a result of their pre-existing infections caused by the administration of blood or blood products, and no attempt to engage with individuals on a personal level.

10. Consequential effects of the impact

10.1 The infected community were those who perhaps most needed the medical profession, given their infections and potential other conditions, but were left with feelings of mistrust of the profession. This manifested itself in numerous ways, each compounding the harms that the communities have suffered.

10.2 For some, their doctors seemed unwilling to accept or believe that their infections (or symptoms arising from those infections) were a result of the administration of blood or blood products. As considered above, many were informed of the fact of their infection in accusatory language. Professor Hayes stated in his evidence to the Penrose Inquiry that it still remained common even in 2011 that people who had abnormal liver tests were referred up to the clinic and "they have had a good telling off from their GP about drinking too much alcohol when they insist that they are almost tee-total[373]. Such disbelief contributed to many feeling abandoned by their doctors, such that they would avoid seeking treatment for other matters.

10.3 The psychosocial expert group noted that there a range of negative emotional and behavioural reactions towards both individual healthcare providers, and the

[373] Penrose Inquiry transcript for 14/12/2011 (day 78); 104 (Professor Hayes); PRSE0006078_0104

institutions themselves, and the fact that these reactions were exacerbated by the lack of accountability of the clinicians and institutions. In such circumstances, they note that studies demonstrate that the issues tend to result in reduced quality of care, reduced trust in clinicians and a range of negative outcomes including PTSD reactions, financial hardship, and permanent disability.[374]

10.4 Our submission deals elsewhere in greater detail about the circumstances in which many learned of the fact of their infection; for some there is clear evidence that their treating clinicians withheld the fact of their infections from them and their loved ones, in some cases for many years. For others, their doctors refused to believe the source of their infection, with clinicians repeatedly challenging them as to the cause or making assumptions in that regard. Many were given their diagnosis with HCV as 'good news' in that it was not HIV, and very few were given any or any meaningful information about what their diagnoses meant. The psychosocial group notes that the manner in which patients are told of medical error plays a "pivotal role" in determining some of the effects of that error, and that denial of proper explanations and recognition of the wrongs caused results in additional distress[375]

10.5 Some of those with bleeding disorders recall in their statements that their distrust of the medical profession would mean they were not open with their clinicians regarding their bleeding issues or other medical concerns[376].

10.6 Some witnesses have expressed concern and frustration that they were not told of their infection at the time of receiving the blood or blood products. We accept that prior to the discovery of the relevant viruses, these witnesses could not have been formally diagnosed with that infection (although, in some cases, their symptomology ought to have been recognised and, where relevant, the potential reasons for those symptoms properly explained), but the failure of the medical profession to explain the position clearly when diagnostic tests were finally introduced gave rise to reasonable concerns on the part of patients that the information had been improperly kept from them, or tests could have been carried

---

[374] EXPG0000003_0006-7
[375] Supra, _0011
[376] WITN2188001, para 22 (anonymous)

out that were worse. We say it was incumbent on all those involved in advising patients of their infections to ensure that they were given all relevant information (accepting that, in some instances, this information would necessarily have to be imparted as knowledge grew), that they had understood all the relevant information, and that they felt able to ask questions and engage with medical professionals about their options, prognosis, and any other queries that they may have. All too often, information was provided in too abrupt a manner for individuals, particularly those who had just been given shocking and scary news, to take in and process, if information was given at all. Many were left to seek information from other sources, often feeling isolated and abandoned by the medical profession just when they needed them most. Where those providing news of the infections did not have the answers to hand, they could and should have sought guidance from colleagues to ensure that they were sufficiently knowledgeable to counsel those who were receiving the news of their infection and to respond properly to their questions. Although some thought seems to have been given to ensuring that counselling provision was in place at SEBTS when the 'pilot study' lookback commenced, the absence of consistent approaches on the part of medical practitioners in the main lookback programme would, we say, appear to demonstrate that insufficient thought was put into ensuring that primary care doctors would have sufficient knowledge and expertise to be involved in difficult discussions. There was ample opportunity for such matters to be considered and implemented.

10.7 Those who were warned that they had been exposed to vCJD experienced further fear and concern as a result of the notification. The notification itself also gave rise to further issues regarding stigma (as set out above). The warning letters and the denotification letters came to individuals who were already distrustful of medics given the circumstances of their infections. To be told that they had been potentially exposed to another disease was to compound the harms already being suffered by a community which had repeatedly been told that the 'products were safe' or the effects of hepatitis would be limited or nothing to worry about as many in the bleeding disorder community in particular were. For those who had been promised safety in the past, attempts at reassurance regarding the possible risks

associated with yet another serious infection rang hollow, and those who were 'de-warned' of the risk, having had many years of fear and anxiety associated with the earlier notification of risk were unlikely to have had those fears assuaged.

10.8 As a result of delays in diagnosis, or being informed of a positive test for infection, those who had contracted the infections were, unknowingly, risking the health of others. Some were blood donors in the period between their own infection and the introduction of testing, and express guilt and concern that they may have unknowingly passed on their infection to others in that way.

10.9 Amongst the Thompsons' clients are a small number of individuals who unknowingly infected relatives and partners[377], and 'secondary' victims of the disaster, having contracted their infection as a result of contact with a relative who was infected by blood or blood products.

Access to other medical services

10.10 As a result of their infections, some core participants have given evidence that they have experienced difficulties accessing other medical treatments. Access to dental treatments has, in particular, been a matter regularly raised by those on whose behalf this submission is provided and is explored further below. However, access to other treatments have been affected by virtue of an individual's infection history. One anonymous witness wrote of being refused treatment at the time of an appointment for varicose veins as a result of her HCV infection[378]. Another has written that her surgery for a shoulder injury had to carried out at the end of the surgical list because the hospital would have to *"scrub the place"* following that surgery. The witness writes that, *"once again, this made me feel like a leper, unclean and dirty. This is exactly the same reason I did not tell my family or friends of my infected status[379]"*

---

[377] WITN2276001 (Geraldine Todd)
[378] WITN2098001 @ paragraph 21
[379] WITN2156001 @ paragraph 23 (anonymous)

10.11 Many witnesses have given evidence about the difficulties experienced in obtaining dental treatment as a result of their infections. Some have been told that they must have their treatment at the end of the day for infection-control purposes. Others have been unable to obtain dental treatment. In some cases, individuals have attributed deterioration in their dental health to the treatment they were having in response to their infection, only to find that they were unable to access a dentist to have their concerns dealt with[380].

10.12 For some, relatives of those infected with HCV have had difficulties accessing dentistry services; an anonymous core participant gave oral evidence that, although he himself had no issues in this regard, his wife and children were required by their dentist to have their appointments at the end of the day. The witness noted that he had in fact been campaigning for greater recognition of dentists as a source of infection given the nature of the work they undertake[381].

11. Impact on the affected

11.1 The impact on the affected community has been extensive and varied.

11.2 As set out above, there were broad-ranging and deeply felt impacts for those infected on their family lives and their employment; the affected community are part of that same experience. The evidence demonstrates that they too were frequently stigmatised, and their lives deeply affected by the fact of their loved ones' infection. Relationships were strained, and in some cases completely broken. Families were torn apart by the effect of the infections and treatments. The affected too experienced stigma, isolation, and health issues.

11.3 In addition to the shared experiences of the infected and affected communities, there are harms experienced more particularly by those affected, rather than

[380] WITN2251001 @ paragraph 26 (Helen Rice)
[381] IBI transcript for 10/07/19 (Anonymous, Mr X)

infected, just as there are harms experienced by the infected that cannot, by definition, have been directly experienced by the affected. However, just because someone who is not infected cannot feel the pain or experience the mental health issues arising from the infections and treatments, does not meant that they do not experience their own traumas watching their loved ones go through such issues.

11.4 Many people have seen loved ones die in painful and harrowing circumstances. Due to the genetic nature of bleeding disorders, some have seen more than one close relative die in short periods of time.

11.5 In some cases, parents died in circumstances where children were too young to necessarily understand or comprehend what was happening. Similarly, because so many infected individuals were told to keep the fact of their infection secret, some family members were not told of their relative's infection and therefore could not understand the reason for their ill-health or lifestyles that were perhaps different from 'the norm'. In some cases, close family members were told of the infection, but were instructed to keep the knowledge 'secret' to avoid stigmatisation outside the home.

11.6 Where an infection resulted from treatment for a genetic condition or in response to a medical emergency connected with the involvement of others such as in obstetric care, the relative involved in that care often was left with feelings of guilt for their involvement and perceived 'blameworthiness' for the infection.

11.7 In many cases, affected individuals experience similar emotions as the infected individual regarding the cause of the infection. . An oral witness who was involved in discussions surrounding his wife's treatment following obstetric complications told the Inquiry that he and his wife felt conned, tricked, and forced into agreeing to the transfusion, despite both of them being reluctant to pursue that treatment approach.[382]

12. Campaigning

[382] IBI transcript for 03/07/19: 112 to 113 (Stanley Fyffe)

12.1 Some comment is made above of the particular impacts of campaigning. We consider below the response of the State to the disaster. In the context of impact on the community, we submit it has compounded the harms yet further. The refusal to hold a public inquiry and to recognise the unique harms caused to this community has impacted on multiple facets of individuals' lives. It has given rise to greater stigma, because the facts of the cause of these infections have been hidden and because the State itself was responsible for media campaigns that sought to link AIDS to risky or undesirable practices, such that many who contracted HIV from contaminated blood were considered to have been responsible for their own infection. As the psychosocial expert group identifies, there were no such campaigns in respect of HCV, with the effect that public knowledge about that infection was very limited. Accordingly, many people drew only on their knowledge of the HIV public health campaigns, misunderstanding the nature, cause, and implications of the disease.

12.2 As is explored above, those responsible for providing care often stigmatised their patients in the way they spoke with and treated them. Even within the medical community there seems to have been insufficient recognition of the fact that the medical community administered the blood and blood products that caused so many infections and destroyed so many lives. In part, at least, that is, we say, a result of the failure on the part of the government to respond to the calls for an inquiry, and to provide clear, open, understandable and meaningful explanations as to how the disaster came to be.

12.3 The State's response to the disaster has therefore considerably compounded the harms suffered by those who were infected and affected as a result of their medical treatment under the NHS. There have been numerous witnesses who have given evidence that have resulted in involuntary outcries from those watching that evidence. The impact on the community continues even now; the delays in the institution of a full and open public inquiry have further ingrained that impact.

13. Conclusions

13.1 It is clear that the extensive and complex harms caused to these communities have been consistently under-estimated by those who have, belatedly, attempted to provide some recognition of the effect of the disaster.

13.2 The harms suffered by the community have been consistently reinforced, exacerbated and compounded by the response of the medical community and governments to the plight of the infected and affected. This aspect of the blood contamination disaster and its aftermath (which continues to this day) is examined in more detail in section L below ("The Response to the Disaster") where it will be submitted that the inappropriate, inconsiderate and uncompassionate response of the NHS and government has (a) constituted a serious of separate harmful acts perpetrated upon the infected and affected community and (b) has increased the suffering of that community manyfold.

E. KNOWLEDGE ABOUT THE RISKS OF INFECTION FROM BLOOD AND BLOOD PRODUCTS

1. General

1.1 A number of themes arise from an assessment of the way that the State went about assessing risk of infection, as follows:

(a) Risk versus incidence. The number of cases of AIDS does not equal the risk in light of known patterns in the way that the disease spreads. To approach the risk in that way was unscientific and irresponsible.

(b) Knowledge arising in different branches of the medical community and the availability of the best information to the people who needed it, including the appropriateness of the sources of information provided to government and other decision makers

(c) Sharing of information between agencies. The sharing of information with patients addressed separately below

(d) Accessing up to date information and the rigidity of medical disciplines and the poor systems in place for ensuring that the best and most up to date medical information was out in the hands of those with the need to have it in order to advise fully about the risks of blood and blood products.

1.2 There was, across the board, a lack of proper consideration of public health implications of giving patients blood or blood products which were at risk of being infected. Potentially infected recipients of blood and blood products were vectors for the disease. Broadly speaking, there appeared to be a lack of epidemiological input in relation to these matters, in particular the prediction of the risk of onward spread of disease from allowing recipient of blood or blood products to be exposed to risk of the kind now commonplace since the COVID pandemic. In his evidence of the public health role of the DoH, which one might have expected to have taken the lead in that regard, Lord Fowler (Secretary of State for health over much of the 1980s) said that though public health was "an important area" it was not always recognised as such in internal debates. He claimed that public health was about predicting something and so it was much easier to have a debate about something like waiting lists which you could see.[383]

1.3 Communication and availability of information, within the medical profession and between the medical profession and government was lacking. Thu, access to research/ information, including pre-publication was lacking. Availability of that information to the wider public was often not achieved by government. The press required to playa. role in disseminating information to the public and was apparently often the best source of information to the government.

2. <u>The emergence of the threat of viral contamination from blood and blood products</u>

[383] IBI transcript for 21/09/21; 28 (Lord Fowler)

General

2.1 The transmission of infection from blood and plasma was known from the outset of their use in World War Two. The industrialisation of the production of products derived from blood and, in particular plasma, was well known from that time.[384] As a result the British Pharmacopoeia (1973) recommended that dried plasma should state on its label that it was derived from pools of not more than 10 donations.[385]

The knowledge of HBV as a threat

2.2 This section concentrates on the threat of viral transmission from blood and blood products associated primarily with HBV in the period from WW2 until around 1981 when the threat from AIDS started to become apparent. There is an inevitable overlap between the emergence and development of knowledge about the risk of HBV and the emergence of knowledge about the risk of another hepatitis which appeared to be transmitted by an organism contained in blood or blood products and was initially a diagnosis of exclusion, namely NANB hepatitis. Once again, it is emphasised in this context that although these threats are viewed for the purposes of this submission as separate threats, their aggregated risk should be viewed cumulatively. It was indeed an apparent failure of analysis at the time that they were viewed as separate and not as cumulative risks, as they all derived from the same transfusion or product.

2.3 It cannot be claimed by those responsible for the collection of blood, the production of blood productions, transfusion of blood or the administration of blood products that their use in the 1970s and 1980s did not come against a clearly understood background of the general risk associated with these activities. It was clearly known

---

[384] As was set out in the historical analysis by Dr John Wallace in 1977 in "Blood Transfusion for Clinicians" - PRSE0002052_0005 to 0006 which makes clear that even on the basis of fractionated products which might be produced from 500 donation pools the number of recipients who would be exposed to an infected product would be far greater than with10 donation pools

[385] PRSE0002052_0006

that blood and the risk of serious infectious disease went hand in hand. It therefore needed to be part of the thinking of all of these individuals at every stage of the process. It simply cannot be said that disease transmission was something that took those with responsibility in this area unaware. The risk of the transmission of serious disease from the use of blood and the massively increased risk of disease transmission as a result of exposure to pooled products was known from at least World War 2, when the knowledge of the use of blood and plasma and the transmission of disease as a result became greater due to the need to treat battlefield injury and maintain a fit fighting force. Widespread infections caused by yellow fever vaccine shows the threat of serious disease from the industrialised production of products derived from plasma or blood. These infections created important general context to the risk of serious disease transmission and the possibility of mass infections at a population level. Given that vaccinations against yellow fever had been given to large parts of the population who had served in the military, it created or should have created an awareness about the likely prevalence of disease in the donor population and the need to manage the risk which blood transfusion could cause to the public health. As so many people had been exposed to yellow fever vaccine, there would have been many unwitting carriers of serum hepatitis in the donor population prior to screening in 1972. The risk posed by particular populations should also have been understood and acted on against this background. Military personnel were studied and could be seen as posing a risk to the recipients of blood and blood products due to their exposure to vaccination as well as service abroad creating a risk of them being exposed to dangerous foreign pathogens.[386] Despite this, military and ex-military personnel continued to be used as donors in the UK system. They should not have been.

2.4 The risk that HBV infection could be a fatal condition caused to those exposed to infected blood was well known. The fatal outbreak of viral hepatitis in Edinburgh was alluded to as being one of a number of such incidents internationally in the 1973 WHO

---

[386] See "Epidemiology of Acute Hepatitis in the Royal Air Force" (AJ Zuckerman, Brit J prev soc med (1964), 18, 183-188); and "Mortality and Morbidity Among Military Personnel and Civilians During the 1930s and World War II From Transmission of Hepatitis During Yellow Fever Vaccination: Systematic Review" Am J Public Health, 2013 March; 103(3): e16–e29.

report on viral hepatitis.[387] In the context of discussing risks to staff from infection with hepatitis caused by exposure to blood, it noted that the outbreak had resulted in staff mortality of 33%. Hepatitis mortality globally in patients in haemodialysis units was noted to be between 6% and 28%. Furthermore, the report noted that those suffering from HBV infection constituted an increasingly diverse group (which was thought possibly to be associated with IVDU), with the result that the risks of infected people becoming part of the donor population had increased.[388] Professor Cash spoke at the Penrose Inquiry of the fatal outbreak of hepatitis at the renal dialysis unit in Edinburgh in 1969–70 having, once Hepatitis C tests became available, been shown to have been caused by both Hepatitis B and Hepatitis C. The combination of HBV and NANB infection may explain the virulence of the 1969 outbreak.[389] HBV was known to be sexually transmissible, meaning that unwitting transmission to blood donors who had had sexual contact with someone exhibiting no signs of the disease was a further route by which the virus could enter the donor pool.

2.5 The argument is often raised that few people seemed to get ill and that there was a high clearance rate of the disease. That is hard to reconcile with the significant time and effort put into the investigation of the disease which had caused issue with the war efforts and been known to cause fatality.

2.6 Along with the developed knowledge about the transmissibility of serious disease from blood and blood products emerged information about the fact that collecting blood from certain groups would increase the risk of disease transmission, as those groups were known to be associated with higher incidence of disease. These groups included prisoners and those serving in the military. The former group were known to have an association with intra-venous drug use ("IVDU") whereas the latter were likely to have been exposed to foreign pathogens on military service abroad and were more likely to have been so exposed by sexual contact, including via prostitution as well as

---

[387] PRSE0001968_0017

[388] PRSE0001968_0010

[389] Penrose Inquiry transcript Wednesday 23 March 2011 (day 19); 102 to 103; [PRSE0006010_0102 to _1013]; and PRSE0000271 - "Dialysis-associated Hepatitis in Edinburgh; 1969-1978" published in Reviews of Infectious Diseases (1982) Vol 4 No 3 May-June 1982

via the vaccinations which had caused military outbreaks of "serum hepatitis" (diagnosed not by testing but by the appearance of jaundice) from WW2 onwards.

2.7 Alongside the emergence of knowledge about the risks addressed above was the knowledge of the fact that HBV was a viral disease which was transmissible relatively easily in the community on the basis that it was sexually transmissible. Furthermore, research was done and available from at least the 1970s into the actual effects of this disease on the community. The public health implications of infecting individuals with such a disease by administration of blood or blood products ought to have been viewed as considerable. Thinking that the administration of blood products led to the infection of a single haemophiliac was short sighted. In fact, the infection of that single haemophiliac (in particular in light of their propensity to bleeding incidents) was in fact the creation of a risk of infection of the entire community around that individual haemophiliac who might come into contact with his blood or into sexual contact with him. The community spread of HBV was a subject of significant concern to certain academic writers in the 1970s. That the State was knowingly creating a source of that spread via its administration to patients of blood and blood products appeared not to be a matter of particular moment or concern.

2.8 The World in Action documentary is examined in more detail below. It shows that the risks inherent in commercial products were not hidden or the province of expert, finely balance clinical judgement. They were well known and out in the open. They were the reason why by the late 1970s and early 1980s, parents at the Yorkhill parents' group were taking questions about the safety of imported products to the hospital.[390] They were the reason why one parent there on seeing an article about HTLV III in 1982 immediately knew that his son was at risk from the commercial treatment he was receiving there.[391] They were the reason why standard practice in Scotland was to avoid their use at all costs. They were the reason, or at least part of the reason, why Professor Ludlam sent patients away on holiday with a letter telling other units not to give them foreign products. The dangers were not secret. They were plain for all to see.

---

[390] Witness statement of John McDougall (WITN2850001), para 23
[391] Witness statement of John McDougall (WITN2850001), para 25

2.9 The risks of commercial products were known before the 1975 World in Action documentary and before their licensing started in the UK in 1973. A 1972 article was written about plasma being purchased from impoverished Haiti for the US market.[392] This was before licensing of US products in the UK. It was not surprising that commercial products were made according to the rule of the market. The companies which would survive according to the rule of the market were those which could keep their profits high, inter alia by keeping their cost low, which in this industry meant sourcing blood from impoverished countries, with cost the most important principle. This is entirely inconsistent with the principles of the National Health service and the voluntary principle of blood donation. It is incomprehensible why these principles appear to have been abandoned in a situation whereby the UK could produce products for the treatment of bleeding disorder patients and could do so much more cheaply as the raw material was donated for free.

2.10 The economics of blood collection and the importation and production of blood products has played a significant part in the blood contamination disaster. As early as 1968, in a letter called "Price of Blood", Professor Arie Zuckermann, in a plea to avoid the importation of blood due to the high incidence of post transfusion hepatitis in foreign blood, made an economic argument against the proposed practice.[393] He pointed out that the future treatment costs for those who contracted icteric and anicteric hepatitis as a result of treatment with foreign blood would outweigh the short term economic advantages of purchasing blood from blood abroad. The article's main premise that there would be an increased rate of transmission if blood/ blood products were purchased from abroad based on the lower incidence of transmission as a result of the voluntary donor system in the UK. That may have been the case in 1968. This was of course no longer the case by the early 1980s at the earliest by which time the transmission rates from concentrates had been brought to same level by the value of the voluntary donor system having been lost. The failure to appreciate that the voluntary system was not a magic bullet and its efficacy in protecting recipients against transmission needed to be monitored is addressed elsewhere in this

[392] WITN1055181

[393] RLIT0000072_0002

submission. However, the economic argument made by Professor Zuckermann was prophetic insofar as it applied to the way that government spending would work in the following years. Only 5 years later, commercial concentrates started to be licensed, as opposed to sustained investment being made in a safe and sustainable domestic system of blood product production. The annual budgetary system within government gravitated against capital investment and there was a short termism about funding which clearly contributed towards the eventual occurrence of the disaster. By the early 1980s, these messages had been completely lost. The order of the day was short tome finance and not these longer term implications of causing damage to public health. In his evidence, Dr McClelland described there being a strong political influence in his dealings with SHHD, that if those higher up did not want something to happen it did not and that the priority was the current cost of factor concentrates, which was enormous.[394] The context in which he made these observations was a 1981 meeting amongst the SHHD, SNBTS and the haemophilia directors. It had not even met since 1977 at that time. The enormous cost was not well managed.

Governmental response to the emerging threat of HBV

2.11 Even by 1983, as report from Edinburgh relating to period 1971 to 1979 showed that patients were still being infected at a rate of 7% and 9.5% from SNBTS products despite the introduction of HBsAg testing of blood donors. HBV continued to be transmitted and remained an issue in blood transfusion.[395]

2.12 The significance of the threat of HBV infection through blood was acted upon by the government. A Group chaired by Lord Rosenheim was set up to undertake an

[394] IBI transcript for 27/01/22; 57 to 58 (Dr McClelland)

[395] PRSE0002188 - Abstract of article by Stirling, Murray, Mackay, Black, Peutherer & Ludlam: 'Incidence of Infection With Hepatitis B Virus in 56 Patients With Haemophilia A 1971-1979' (1983)

examination outbreaks of hepatitis in haemodialysis units in the UK, such was the threat from these outbreaks thought to be.[396]

2.13 Despite the recommendations of this group having included a recommendation that there should be a system of notification of infections with Australia antigen, the system for notification of disease remained poor.[397] This was a contributory factor to the State-wide failure to deal with the emerging threat of viral contamination of blood and blood products in the UK. Notification of the occurrence of disease was clearly an essential element of allowing those with an interest and speciality in its study to develop a more in depth knowledge of the disease, its transmissibility (including by potential blood donors), its severity and thus was an essential part of the fight against this disease but in developing robust systems for the prevention of viral threats more generally. The fact that HBV was transmissible not only parenterally but also by close contact was certainly known by the time of the Wallace text in 1977.[398] That text drew attention to the limited nature of the information about the prevalence in the UK of viral hepatitis. It referred to the MRC study from 1974 which suggested that the incidence of post transfusion viral hepatitis was low at only 1% in the UK but clearly doubted the accuracy of the testing methods (regarding the exclusion of possible case as explained by other infection routes, the dearth of cases before becoming detected by the study, the lack of willingness to be involved in a study or the cuts offs used for diagnosis). The discrepancy with the far higher rates in other countries was not understood.[399] Wallace hoped that codes of practice in renal dialysis units (of which he had some evidence) would be extended to use in other parts of the hospital service, in particular in light of the need to avoid the possibility of transmitting infection with HBV to immunosuppressed patients.[400] The Inquiry has heard no evidence that any such codes of practice were implemented or adhered to despite calls of this nature being made in the mid to late 1970s. Further, the need to protect immunosuppressed

---

[396] LOTH0000111_013 (1972)
[397] LOTH0000111_013_0049 – paras 11.2 and 11.3 which recommended that greater efforts needed to be made to promote the reporting of outbreaks of viral hepatitis in the dialysis setting and also that the statutory reporting systems for viral hepatitis required to be overhauled to create a more effective basis for understanding the extent of transmissible hepatitis in the community (1972)
[398] PRSE0002052_0041 (1977)
[399] PRSE0002052_0041 - 0042 (1977)
[400] PRSE0002052_0048 (1977)

patients from potential exposure to both HBV and the risk of NANBH was not realised or, if it was, not acted upon. In fact, many of the most vulnerable immunosuppressed patients continued to be those who were exposed to the greatest risk of infection – haemophiliacs whose immune systems were rendered weaker by frequent exposure to proteins in their treatment, increasing exponentially with the advent of factor concentrates, renal dialysis patients, leukaemia patients in need of transfusion etc.

Notification of disease

2.14 One of the issues which appears to have had a significant effect on the appreciation amongst practitioners involved in the collection of blood but also in the use of blood or products made from it (for blood transfusion, in particular) was the defective system for the notification of disease which created an erroneous impression of the prevalence of viral hepatitis, both in the general population (and hence potentially in the donor population) and in the population of the recipients of blood or blood products. Retrospective studies from America and modelling studies from France, in addition to data and studies from the health protection agencies, showed that, in Western countries generally and in Scotland in particular, the rate of growth of NANB Hepatitis/HCV infection accelerated through the 1970s and 1980s, largely related to intravenous drug use.[401]

2.15 Under the Public Health (Infectious Diseases) (Scotland) Regulations 1975 a medical practitioner, on becoming aware that a patient was suffering from a notifiable disease, had a legal obligation to inform the chief administrative medical officer for the area health board 'forthwith' using a particular certificate.[402] This was the system whereby the public health was thought to be protected by the awareness of infectious disease and its prevalence generally and in particular parts of the medical world was to be maintained. The regulations were not fit for this purpose. They required only basic details of incidents of disease to be given and did not require information about the

[401] Penrose Inquiry transcript for 16/03/2011 (day 6); 20 (12 to 20) (Dr Gillon); PRSE0006006_0020
[402] Public Health (Infectious Diseases) (Scotland) Regulations 1975, Regulation 3

possible or likely means by which the disease had been contracted to be communicated.[403] The information which would be necessary to understand the means by which the disease was being spread was therefore not to be provided. A chief administrative medical officer for each Health Board had an obligation to send the CSA a return of the number of cases of each notifiable disease intimated to them during that week.[404] They had an obligation to report any serious outbreak of any infectious disease which, to their knowledge, had occurred in their area to the CMO immediately.[405] This system was not well suited to diseases such as HBV or HCV which has long prodromal periods, or indeed AIDS whose prodromal period could allow transmission before symptoms emerged as well. In practice, notification and the monitoring of compliance with these obligations was poor. Evidence which was heard at the Penrose Inquiry by those responsible for the collection of such data now gave evidence to the fact that the information notified and collected on hepatitis transmission in Scotland was not reliable.[406] The fact that the regulations require the reporting of "viral hepatitis" also seems problematic as this it was not a specific disease.[407] The result of this was that reporting was in fact rare in Scotland.[408] The system for keeping abreast of information which would assist with the public health monitoring of infectious disease was not effective. Assumptions made from it about the limited incidence of disease was misguided.

2.16 The existence of the notification system appeared to give misplaced comfort to those involved in the collection and production of labile blood products across the UK. There was no recognition that the system was unfit for purpose, but some regional transfusion directors placed faith in the fact that they were not receiving a large number of notifications as justification that the system for collecting blood was safe and/ or that there was little or no need for concern in respect of NANBH[409].

---

[403] Regulation 2
[404] Regulation 4
[405] Regulation 7
[406] Penrose Inquiry transcript for 16/03/2011 (day 6); 103 to 104 (Professor Goldberg); PRSE0006006_0103 to _0104
[407] Despite this, "viral hepatitis" remained in the scheduled list of notifiable infectious diseases under the Public Health (Notification of Infectious Diseases) (Scotland) Regulations 1988
[408] Penrose Inquiry transcript for 16/03/2011 (day 6); 103 (Professor Goldberg); PRSE0006006_0103
[409] IBI Transcript for 30/11/21: 85 to 88 (Dr Napier)

Furthermore, the system relied on record keeping standards sufficient to allow the components to be traced; in many cases this was impossible either because there was no record of the transfusion being administered at all, or because there was insufficient information to permit the full history of that donation to be traced. In 1953, the World Health Organisation, in the Expert Committee on Hepatitis' first report, had recommended compulsory reporting on a national level of notifiable disease as a method of acquiring adequate data on the prevalence of it with a view to planning satisfactory control measures. It also noted the benefit of instigating a 'simple follow up system' for those who had received blood and blood products, whereby each patient could be given a card explaining that jaundice might occur as a late complication of the administration of blood or blood products. The card would set out the need for the patient to report to his or her doctor or hospital if such a complication arose within 160 days of treatment. The WHO considered such an approach would "detect an appreciable number of cases which would otherwise be missed" and recommended studies as to the feasibility of introducing such a programme on a large scale. It was thought that the system, when coupled with proper record keeping would "make it possible to withdraw an icterogencic blood-product at the earliest possible moment"[410]. The Inquiry has not heard any evidence of such a scheme being introduced in Scotland. As the knowledge of the existence of NANBH increased, such schemes should have been revisited.

2.17 Whilst dealing with the subject of notification of disease, the same issues can be said to have applied to the notification of instances of HTLV-III/ AIDS cases. AIDS was also not a notifiable disease. The surveys undertaken by Dr Craske of instances within the haemophilia community are discussed elsewhere in this submission. He appears to have had incomplete and inconsistent information from haemophilia centres. Given the reliance within government (also discussed elsewhere) of relying on information about incidence as opposed to risk, this limited information is likely to have led to an underestimate within government about the dangers posed to this community at the time.

---

[410] RLIT0000215_0020

Conclusions

2.18 There was a lack of recognition of the risk of HBV being transmitted by blood and products derived from blood/ blood components – there was an ongoing threat of a fatal condition. There was the emergence of the "golden interval". The period which was so described (eg Dr Mark Winter) was a dangerous period for the exposure of patients to unnecessary risk in the bleeding disorder community. The period was characterised by a number of false assumptions or understandings, which were the basis for the exposure of patients to the ongoing risk of hepatitis but also to the inevitable emergence of other pathogens, as follows:

(a) The assumption was made over this period by those involved in the treatment of patients with bleeding disorders that the risks of the potentially fatal HBV had been resolved by the advent of donor screening for the presence of the virus in the early 1970s. This was an inaccurate assumption as the early screening was of limited success and so the threat of this condition had not disappeared;

(b) The assumption was also made that the supposed eradication of HBV from the products which were used in the treatment of patient with bleeding disorders were now virtually free from risk. This assumption ignores the most significant element of the treatment of patients with bleeding disorders and the risk which was present for them, namely that (i) it was now only known conditions that one had to take into account in assessing risk but the known unknown conditions which stemmed from the inevitability that new viral risks would emerge in blood derived products and (ii) the use of pooling coupled with the frequent treatments given to patients with bleeding disorders meant that they were the "canaries" who would inevitably become exposed to these new pathogens before other patients. This, of course, meant that they were of significant research value into merging new diseases. It also meant that they required to have every reasonable step taken to minimise the risk of them being exposed to those risks sand contracting new diseases as a result of their treatment.

(c) These assumptions led to an inaccurate further assumption that it would be safe to go ahead with a huge expansion of the use of factor concentrates in the treatment of bleeding disorders. It was apparent that there were advantages in the use of factor concentrates in the treatment of bleeding disorder patients. However, these advantages needed to be understood in the context of the limitations of the UK system being dependent as it was on the altruism of voluntary donors and not on the apparently limitless supplies of plasma, the raw material for the manufacture of these products, available on the open market. This is discussed in more detail in the section below relating to the treatment of bleeding disorders.

2.19 We say that the risks were cumulative, and should not be viewed in isolation, as they often were. The inevitability of new pathogens emerging meant that from the outset of the expansion of the treatment regimes involved in the treatment of patients with bleeding disorders, a precautionary approach to the treatments was mandated. Over-reaching the boundaries of what was safe in light of the known and unknown (but inevitable) risks unleashed a juggernaut of treatment based on the use of dangerous factor concentrates which got out of control as it has not been launched with sufficient safety mechanisms in place.

3. NANB hepatitis

The emergence of knowledge about the parenteral transmissibility of a new form of hepatitis

3.1 As noted above, it was clear from the 1970s at least that there was a new form of hepatitis (not HAV or HBV) which was being transmitted by transfusion which was not hepatitis B.

3.2 It appears clear that the real essence of the dispute with which the Inquiry must concern itself is not to do with the transmissibility of a new form of viral hepatitis

which was not HAV and not HBV but instead to do with its potential severity. It was known from the mid 1970s that NANB hepatitis was transmitted by factor concentrates, in fact by all factor concentrates.[411] This is an important part of the analysis as it mandated a subjective judgement about whether the risks of a potentially severe disease were worth taking. These were subjective decisions which could only be taken by patients or their guardians/ representatives. They required to be explained and discussed.

3.3 Assumptions were made about the likely clinical course of NANB hepatitis being similar to that of HBV were ill founded and unscientific. In any event, the potential dangers of HBV had been significant enough to have prompted significant research and investment in testing and later in vaccines. The presence of another hepatotoxic vital threat in the already weakened immune system of those in receipt of pooled factor concentrates was like to be dangerous. In any event, a precautionary approach and one arrived at after consultation with the patient was mandated.

<u>The emergence of knowledge about the severity of NANB hepatitis – the 1970s</u>

3.4 In a paper by Mannucci and Ors published Journal of Clinical Pathology on 10 February 1975 data from a study of 91 multi-transfused severe haemophiliacs was presented which suggested that repeated and prolonged contact with the agents responsible for post transfusion hepatitis may cause chronic liver damage not associated with overt illness.[412] All 91 patients were asymptomatic but there was a high incidence of abnormal liver function tests showing damage to the liver. The incidence of abnormal liver function tests tended to increase with age. It was not possible to establish a link with any particular type of product as the 91 patients had received the full range of haemophilia treatment.

---

[411] Dr Charles Rizza in "HIV the Myth" published in 1989 and quoted in Carol Grayson's third witness statement WITN1055004 @ para 35

[412] PRSE0000240

3.5 In "Non-A, Non-B hepatitis" by Purcell, Alter and Ors (published in the Yale Journal of Biology and Medicine on 26 February 1976)[413], it was noted that, generally, NANB hepatitis had been associated with less severe acute illness than hepatitis B. However, judged by frequency of jaundice and magnitude of SGBT elevations it was observed that the prognosis for the two diseases may be similar. Further, for 3 patients in whom transaminase elevations were documented at the NIH over a period of several years and who had a liver biopsy, 2 had histopathologic changes in the liver compatible with chronic active hepatitis and the other was diagnosed as having chronic persistent hepatitis. It was concluded that chronic NANB hepatitis was not necessarily a benign infection and may be the cause of a significant proportion of chronic hepatitis not identifiable as hepatitis B.

3.6 Dr Rosemary Biggs, the director of the Oxford Haemophilia Centre, published the 2nd edition of "The Treatment of Haemophilia A and B and von Willebrand's Disease" in 1978.[414] One of the four complications that was said to arise from treatment with plasma fractions was the transmission of an infective organism, in particular hepatitis, to the patient.[415] It was suggested that mildly affected patients who had never or rarely been transfused should not receive large pool commercial concentrates. Instead, they should be given cryoprecipitate or small pool concentrates. There was no overt mention of NANB Hepatitis in the book, though it can be assumed that she was talking about NANB hepatitis due to the fact that hepatitis B testing had been instituted by this stage. The text indicated an awareness that haemophiliacs in the UK may have long incubation hepatitis for which no causative agent had yet been identified.[416] Small pool products were being recommended for mild patients in the 1970s based not on the fact that their bleeds were less severe but on the fact that they carried a lesser risk of transmitting NANB hepatitis. This was clearly understood in 1978 as was the need for such action to be taken.

---

[413] PRSE0000381
[414] Penrose Inquiry preliminary report, para 6.62
[415] Pages 181–2
[416] Page 181

3.7 In an important paper by Preston & Ors entitled "Percutaneous liver biopsy and chronic liver disease in haemophiliacs" (published in the Lancet on 16 September 1978), data from the screening of 47 haemophiliacs in Sheffield showed that 77% of them had abnormal liver function tests with a tendency for those abnormalities to persist.[417] Importantly, a liver biopsy was carried out on 8 symptom free patients who had had abnormal liver function for 6 months or more in order to elucidate the importance of the abnormal liver function tests. These biopsies demonstrated a wide range of chronic liver disease including chronic aggressive hepatitis and cirrhosis. It was observed that the hope that the incidence of liver disease amongst haemophiliacs would fall after the introduction of hepatitis B testing had been unduly optimistic.[418] Further, it was concluded that the high incidence of chronic liver disease was probably related to factor concentrate replacement therapy. 4 of the 8 patients had indications that their liver disease was not caused by HBV but by NANB hepatitis.[419] As a result, it was also suggested that patients with mild haemophilia may possibly benefit from the newly developed DDAVP treatment against a background of it being discovered that two mildly affected patients who only required occasional transfusion with factor VIII had cirrhosis.[420]

3.8 This was an important paper in the developing understanding of the severity of post transfusion hepatitis in the UK. The findings of the study were clearly connected by its authors to the increasing use of factor concentrates in the treatment of the patients and the move away from the use of single donor cryoprecipitate.[421] The increased pool size of clearly linked to the increased risk of adverse outcome for the patients. A range of severity of liver damage was demonstrated but this included permanent damage in the form of cirrhosis in 2 of the 8 who underwent biopsy. That other less severe liver damage was apparent in some appears only to demonstrate that some were more advanced in the

---

[417] PRSE0003622
[418] PRSE0003622_0003
[419] PRSE0003622_0003
[420] PRSE0003622_0003
[421] PRSE0003622_0003

progression of the disease than others. Given that the authors so clearly linked the use of concentrates with the damage apparent on the biopsies would tend to suggest that future greater exposure would result in progression of the disease in the less severely impacted patients as well. The fact that all of the patients who underwent the biopsy procedure were symptom free would tend to suggest that the comfort which certain haemophilia treaters took from the fact that their patients were "clinically well" despite the known risk of hepatitis transmission was misplaced. It is also worthy of note that of the 8 patients who underwent the biopsy, 2 were over 40 and 2 over 50. Given that these patients are unlikely to have benefited greatly from factor concentrate therapy (given its relatively recent advent in the UK by the time of the article's publication in 1978), the assumption that patients would die before reaching their 40s without significant concentrate use appears not to be supported by the sample in this study. It is of significance to note that when asked about this paper in his evidence, experienced haemophilia clinicians and later transfusionist Dr Boulton stated that the implications of the paper were underestimated by the haemophilia treating community, an approach which he described as "self-denial" and that patients should have been informed of these risks.[422]

3.9 An article entitled "Progression of hepatitis non-A, non-B to chronic active hepatitis" by Iwarson and Ors (Journal of Clinical Pathology, 25 September 1978)[423] contained details of a follow up of 2 cases with no hepatitis A or hepatitis B markers, assumed to be NANB patients). They progressed to chronic liver disease (one from a blood transfusion). One of the patients had died and the other was still alive 8 years after follow up. The article concludes that NANB hepatitis may progress to chronic liver disease in certain cases and refers to a study by Knodell et al (1977) reporting 10 cases of chronic liver disease amongst 44 patients with NANB hepatitis.

3.10 In light of this evidence, there certainly seems to have been a clear lack of attention not only to the known risks of HBV but also the clearly emerging risks of

---

[422] IBI transcript for 04/02/22; 54 to 58 (Dr Frank Boulton)
[423] PRSE0002174

NANB hepatitis in the treatment of patients with blood and blood products. This was the case based on evidence available at the time but certainly in hindsight. The predominant attitude appeared to be wilful blindness tom the risk. In his 1977 text, Dr John Wallace, in what would be a fatal portent of the similar attitude adopted in many quarters to the risk of the aetiological agent of AIDS entering the donor pool in the UK, appeared to dismiss evidence of long incubation "hepatitis C" as a foreign problem.[424] The very fact that this attitude was being expressed to a disease which was known to have a long incubation period (and which based on the evidence referred to above could have significant morbidity and/ or prove fatal) was foolhardy in the extreme and illustrative of an attitude that it was acceptable to turn a blind eye to a problem, however serious, in the face of the evidence of the nature of the condition until it had been medically proven to be transmissible domestically, by which time by the known nature of the disease it would inevitably be too late. In analysing this important text in his evidence to the Penrose Inquiry, Dr Brian McClelland accepted that the text was contradictory and reflected a confused attitude to the ongoing risks of post transfusion hepatitis. He stated that the extent of the problem in the 1970s was clearly underplayed and referred to the only large scale prospective study of post transfusion hepatitis (the 1974 MRC study), as follows

> *"actually interpreted as saying that it wasn't a problem apart from Hepatitis B. Non-A non-B hepatitis wasn't a problem but actually, if you look at the data for five minutes, it actually clearly is a problem and that, you know, coming from a group of eminent academics seems – again, I had real difficulty understanding that when I looked at it again. It does seem to me that there must have been a very strong received belief that somehow non-A non-B hepatitis just wasn't a problem in the UK sufficient to cause highly intelligent people doing research study to actually really ignore their own findings and interpret them quite*

[424] PRSE0002052_0022 and _0042 (under reference to the Prince paper of 1974) (1977)

inappropriately, in my view. So I think that sort of attitude, the power of that sort of attitude must underlie this statement of Dr Wallace. It's speculation."[425]

3.11 The Lancet published a paper by Robert Galbraith et al on an outbreak of HBsAg negative hepatitis in a renal unit at the Fulham Hospital, London, in 1968–70, in May 1979.[426] The outbreak was reminiscent of the outbreak in the renal unit in Edinburgh which (amongst other outbreaks) had prompted the Lord Rosenheim review (see above). As regards the understanding of the prominence of the postulated non A non B virus as a cause of post transfusion hepatitis, it was commented that more and more data pointed to this as the cause of a substantial proportion of cases of post-transfusion hepatitis negative for HBsAg. The article pointed to its role in the subsequent development of chronic liver disease, concluding that it may be related to a high frequency of persistent hepatic dysfunction. As would happen with a re-assessment of the aetiology of the Edinburgh outbreak when testing for HCV became available many years later, in the late 1970s, there seemed to be a re-assessment of the role of a new aetiological element in the causation of the fatal outbreak in London[427], as an earlier article about its causation had not postulated anything other than HBV as the cause.[428] These were fatal or at least very serious outbreaks of viral hepatitis. At least by 1979, the London outbreak was associated with a viral agent which the screening programmes for HBsAg stood no prospect of combatting. The London outbreak was thus a clear example of the force and severity of NANB hepatitis, against which the recipients of blood and blood products had no screening protection. In assessing the risks of this new threat (at a crucial time in the expansion in particular of concentrate therapy for bleeding disorder patients) this

---

[425] Penrose Inquiry transcript for 22/03/11 (day 9); 44 – 45 (Dr Brian McClelland); [PRSE0006011_0044 to PRSE0006011_0045]

[426] PRSE0002202

[427] Penrose Inquiry transcript for 23/03/11 (day 10); 102 – 103 (Professor John Cash); [PRSE0006010 _0102 to PRSE0006009 _0103]

[428] PRSE0002060 (8 November 1975) – the article does however detail the significant hepatocellular consequences which had been experienced by a number of those infected, some of whom had already been exposed to a similar outbreak in the same unit a few years earlier

evidence was, it would appear, simply ignored or at least underplayed in reaching the view that the condition caused by the new agent (known to have a long incubation period) was mild or benign. The evidence in this paper would also seem to add to the evidence from the haemophilia studies referred to above such as the Preston paper, which appear to have been discounted by certain doctors as irrelevant to the question of the potential transmission and severity of viral hepatitis caused by the non A non B agent. Evidence of serious outcomes associated with transfusion (albeit frequent transfusion) was apparent. The fact that the considerable scientific efforts made to isolate the Australia antigen and the development of tests which had some role in combatting its impact were followed so closely by the emergence of a new threat seems to have given rise to a sense of disbelief or wishful thinking and a form of paralysis in acting against it. The same attitude prevailed when the next fatal viral threat was to emerge a few years later in the form of AIDS/ HTLV III, which is discussed further elsewhere in this submission.

3.12 A further paper of interest in the Scottish context was which provided a somewhat retrospective look at the emerging knowledge of the prevalence of NANB hepatitis in the local community was published in 1979.[429] Included in the study were three male haemophiliacs and a female patient with Christmas disease. These four patients and also two drug addicts with hepatitis had no evidence of HBV infection, nor of HAV infection nor of infection with CMV or EBV and were thought to have NANBH. The article stated that evidence from other countries suggested that a virus (or viruses) may be associated with this type of hepatitis and that a carrier state was possible. With laboratory tests now permitting definitive diagnosis of hepatitis A virus infection, as well as hepatitis B, in 1979 it was anticipated that it would be possible to determine the prevalence of NANB hepatitis in the general population in West Scotland.[430]

3.13 As regards the risk of transmission from blood in the local context, a 1980 article from Edinburgh looked at the fact that they had previously rejected donors with

---

[429] PRSE0000592 - Chaudhuri et al – "Viral hepatitis in Glasgow 1976-1977"
[430] PRSE0000592_0003

history of jaundice in SNBTS and that that policy had recently changed in last 12 months. The paper concluded from testing that there was little correlation between HBV and jaundice and so concluded that NANB was a significant cause of jaundice in the region[431]

The emergence of knowledge about the severity of NANB hepatitis – the 1980s

3.14 The evidence seen and heard by the Inquiry makes it clear that by the late 1970s and early 1980s, the accumulated knowledge about NANB hepatitis was to the effect that (a) the condition was potentially very severe and possibly even fatal in the longer term and (b) that the rates of transmission of past transfusion hepatitis of this nature had not eradicated by the introduction of routine HBsAg testing, as had been hoped early in the 1970s. This is demonstrated by papers in circulation at the time. For example, within government, Dr Diana Walford's understanding in 1980 that viral hepatitis caused by NANB could be "rapidly fatal", as described by her in a 1980 memo about the possible commercial takeover of BPL.[432] In that memo she also appears to have appreciated the possibility that infection with NANBH could result in a chronic carrier state. She argued that the introduction of NANBH into the pool of haemophiliacs as a result of a greater amount of imported plasma being mixed in with the plasma collected in the UK would also result in there being a greater amount of this potentially harmful virus circulating in the wider community. The irony of this memo is considerable. In arguing against the commercial takeover of plasma fractionation in the UK by commercial entities from the US, based on a fear that UK plasma would become mixed with and thus contaminated by US plasma which would be shipped in to the UK by these entities for fractionation, no regard appears to be given to the fact that this potentially lethal threat from the very same plasma from the US had for some years already

[431] PRSE0000271 – Lancet 15 March 1980. "Blood donors with a history of jaundice" (McClelland et al, Edinburgh).
[432] PRSE0001306 – 15 September 1980

been introduced into the treatment of haemophilia patients and thus into the wider community by the use of imported products, licensed for use in the UK by the very same government to which Dr Walford was now providing this cautionary advice. In arguing that the Department had a "moral obligation" not to go down this route and thus to avoid increasing the risk both to the haemophilia community and the rest of society as a whole, Dr Walford is in essence admitting that that moral obligation was being breached by the government at that very time given (a) the considerable extent of the use of imported products which had been going on in the UK for some years and (b) the use of domestic factor concentrates which by this time were also a significant source of the transmission of NANB hepatitis to haemophiliacs and the wider community.[433]

3.15 Some analysis of the recommendations of the Lord Rosenheim group were given above, including the need, expressed in 1972, for greater efforts to be made to promote the reporting of outbreaks of viral hepatitis in the dialysis setting and also that the statutory reporting systems for viral hepatitis required to be overhauled to create a more effective basis for understanding the extent of transmissible hepatitis in the community.[434] The emergence of clear scientific evidence for the additional threat of NANBH as a cause of viral hepatitis reinforced the need for there to be scientific study of the prevalence of viral hepatitis in society, its prevalence amongst blood donors and its severity (interpreted in light of it being a disease of ling incubation). Certain isolated studies of this nature were undertaken. For example, work on identifying the extent of NANB Hepatitis in the west of Scotland, begun in the late 1979 as part of a PHD undertaken by Dr Brian Dow, was continued by a team at the University of Glasgow. This study was made possible by the emergence of reagents for HAV in 1978 which enabled cases of NANBH to be assessed by exclusion.[435] A full prospective study on the significance of the disease was not undertaken due to cost restrictions though limited unsuccessful attempts at a prospective study were made.[436] In the period from

---

[433] As revealed by the Fletcher et al paper published only shortly thereafter - PRSE0002154
[434] LOTH0000111_013_0049 – paras 11.2 and 11.3
[435] PRSE0001312_0004 and _0005 (statement by Dr Brian Dow)
[436] PRSE0001312_0006

1980–1985, Dr Dow carried out ALT testing on prison sessions, as prisoners had already been shown to have a high incidence of Hepatitis B and NANB Hepatitis was also thought to be blood-borne. People with haemophilia, intravenous drug users and renal dialysis patients were also obvious populations.[437] The very fact that efforts were being made at the instigation of the RTD in the west of Scotland, Dr Mitchell to undertake an examination of the extent and nature of NANBH indicates that there was reason for concern about the condition and its implications for the recipients of blood and blood products. The lack of any impetus to take any action as a consequence of that concern, including discussing the concerns with the recipients who were at risk as a result appears not to have occurred.

3.16 The Dow and Follet study into NANBJ in the west of Scotland was clearly limited in scope. Only nine cases of NANBH were identified in the study, which was an issue with the reporting of the disease. Four haemophilia patients who had been multiply transfused with Scottish and imported blood products were excluded from consideration. The fact that all patients treated with concentrates would likely have been infected shows the limitation of the study's ability to find infected patients. The report also contained an examination of ALT levels, and the results of other serological tests, of 10,655 blood donations. They found elevated ALT levels in 367 individuals (3.4%), and markedly elevated levels in 96 cases (0.89%).[438] However, there was no follow-up of the 10,655 blood donations. No valid conclusions could be drawn as to the frequency of post-transfusion NANB Hepatitis. Drs Follett and Dow concluded, however, that on the basis of the nine reported clinical cases, NANB Hepatitis was very rare in the region. The authors recognised that sub-clinical forms of post-transfusion hepatitis probably occurred but were not notified. Like previous studies based on reported incidents, this work probably missed the vast majority of cases of post-transfusion NANBH. The sub-clinical forms of infection were noted but not taken into account, although it later transpired that they were the dominant component in the actual pattern of

[437] Penrose Inquiry transcript for 17/03/11 (day 8); 149 - 150 (Dr Brian Dow)
[438] PRSE0002577

transmitted infection. The limitations in these findings in which appears to have been a poorly funded study did, however, it would appear continue to influence the thinking amongst those within SHHD that NANBH was not a problem which should cause great concern and certainly that ALT testing as a form of surrogate testing for NANBH should not be instituted in Scotland.

3.17 It was, however, not until the start of the 1980s despite the known limitations of screening which had been instituted after the Rosenheim report in preventing post transfusion hepatitis caused by HBV and otherwise) that any action was taken even to start to move such a project forward. Even then, the lack of a full scale study on these matters seriously impeded progress being made in the understanding of the extent of the threat from the post transfusion hepatitis, in spite of the clear views expressed by Dr Walford. The setting of an advisory committee on hepatitis indicates that there was some limited impetus to take action but the start of the advisory process would mean that any action would inevitably take time to achieve.[439] By this time NANBH was described as already being a major cause concern. The proposal of merely setting up an expert group is characteristic if the lack of alarm with which the threat was treated. Furthermore, the threat of NANBH is considered in the context of a recognition that HBV was still a major problem. No recognition appears to be given to the emerging knowledge that blood and blood products were a source of multiple viral threats and that a major reconsideration of the ability of the system to react to new threats. A familiar plan was being proposed – an expert advisory group, set up when the problem was already a major cause for concern to public health. There was no reason to think that this plan would give rise to anything other than a familiar pattern involving lethargic response, scientific toing and froing, lack of action until consensus or conclusive proof were reached and government reaction by the time it was inevitably too late, when the process had started (in any event late in the day) with a recognition that the threat and the reality of threat being realised already existed. The UK Working Party on Transfusion Associated

[439] PRSE0004529 - DHSS note 'Advisory Group on Hepatitis' (undated but possibly around the time of Dr Walford's comments above, around the start of the 1980s)

Hepatitis first met on 27 September 1982 – there was some agreement that there should be some co-ordination between this and the DHSS Advisory group, though the overlap did not seem to create much likelihood of urgent action.[440] In addition, there was also the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody (known as the Maycock group) which had first met on 5 October 1970.[441] This group had been intimately involved in recommendations around the instruction and improvement of HBV testing in the 1970s. By the time of its third report in 1981, it was also expressing concern about NANBH infection which it said was common in haemophiliacs as a result of commercial concentrate administration and occasionally UK concentrates (which is an apparently significant underestimate of the risk of the latter in light of the Fletcher et al report published in the following year).[442] All that that group could propose was again that research into the extent and severity of NANBH be commissioned and that hospital haematologists should be encouraged to report cases due to this putative agent.[443] This appears to represent little more than the message which had been applied to viral hepatitis for a decade by this point, with little more than a recommendation that more research and notification would be of use. By the latter part of the 1980s, when measures attention turned back to the risks of viral hepatitis after heat treatment of factor concentrates to combat HIV (December 1984 and April 1985 at PFC and BPL respectively) and after screening of blood donations for HIV (October 1985 in the UK) the failures to take action as a result of these earlier repeated recommendations for further notification requirements and prospective study had the effect of undermining the knowledge base upon which action could have been taken to improve safety. The sequence of recommendations from various committees and the lack of any funding or action as a result shows that there was a systemic failure in the UK in the 1970s and early 1980s prior to the emergence of AIDS in 1982. These failures not only led to unnecessary infections with HBV and HCV but also with HIV. Had

---

[440] PRSE0001047_0002
[441] PRSE0000190
[442] PRSE0000862
[443] PRSE0000862_0009

these measures been taken earlier, an opportunity would have been realised both to gain further knowledge of the broad viral threat of blood and blood products, which could have prompted the setting up of a system was more capable of speedy reaction to new viral threat but also for treatment and safety decisions to be taken to prevent viral hepatitis which would also have prevented HIV infection, given the diseases similar transmission routes. At that very meeting, for example, discussion was undertaken about the possibility that anti-HBc testing could result in the prevention of certain undetected cases of HBV transmission. Further study of HBsAg and anti-HBs negative though anti-HBc positive donors was recommended, again avoiding a decision being taken.[444] As is discussed below, the possibility of what would turn out to be a possible surrogate test for AIDS (anti-HBc testing) was missed due to the familiar pattern of simply recommending more research. The possibility that anti-HBc testing may also act as a surrogate test for NANBH infection (also thought to be blood borne) appears not to have been considered by the group. A more precautionary approach which appreciated the known risks and potential consequences of viral hepatitis could have led to the use of all testing measures available to minimise the risk of infection from all of these parenteral viruses. Similarly, the possibility of ALT testing for the exclusion of potentially risky donors was considered by this influential group which advised the government. ALT testing was rejected on the basis that they would require confirmatory ALT testing and may cause worry and inconvenience to donors. 3% of the blood supply would be lost. As a result, the proposal was rejected summarily.[445] There would seem to have been no reason (other than cost) who confirmatory ALT tests could not have been undertaken. It would seem likely that donors would be assisted by knowing that they had raised ALT levels which may be indicative of viral hepatitis or other causes of ill health affecting the liver. They could be given the option to find out about the results which could have significant medical advantage to them. These opportunities were not taken. They should have been. The assumption that the natural history of NANB Hepatitis as mild or benign was misplaced. The

[444] PRSE0000862_0009 and _0010
[445] PRSE0000862

continual cycle of research (recommended or otherwise) not being undertaken which was used as the justification for action not being taken based on lack of sufficient knowledge represents a serious failure of the system in its obligation to protection of NHS patients in receipt of blood and blood product and the wider public health, a systemic failure which would also be repeated in the AIDS crisis and beyond. It is important to realise that the systemic inadequacies which led to the AIDS crisis in the recipients of blood and blood products was not, as some would have the Inquiry believe, caused by the unexpected nature of the virus. The roots of the failures around AIDS lay in earlier opportunities not being taken to understand and combat similarly transmitted viral diseases.

3.18 An event which attracted particular prominence in the evidence of Professor Lowe was an event which took place in Glasgow in 1980. In an article which he wrote in the Journal of the Royal College of Physicians of Edinburgh (volume 50, issue 3, September 2020), he stated that:

"During the 1980 Annual General Meeting of UK Haemophilia Centre, Directors at the Royal College of Physicians and Surgeons of Glasgow, Forbes and Prentice organised its first scientific open meeting. International speakers highlighted growing areas of haemophilia care and research, including increasing awareness of non-A non-B hepatitis."

3.19 Dr Craske delivered a paper at this International Symposium held on 1 and 2 October 1980 at the Royal College of Physicians, Glasgow, on "Unsolved Problems in Haemophilia".[446] He highlighted that despite screening for HBV significant amount of symptomatic HBV associated with commercial and NHS concentrate.[447] He expressed the view that there was a high risk that patients would contract NANB from factor VIII or IX and there was a 20 – 30% chance of chronic hepatitis.

---

[446] PRSE0003209

[447] PRSE0003209_0002

He recommended cryo or small pool products for mild patients.[448] This is significant in the decision which was about to be taken in the west of Scotland to abandon its capacity to produce freeze dried cryoprecipitate despite these expert warnings.

3.20 In a further article entitled "Long term follow up of acute and chronic NANB post transfusion hepatitis: evidence of progression to liver cirrhosis" by Realdi and Ors (GUT, 10 September 1981)[449] the long-term development of NANB hepatitis was studied in the cases of 21 patients who developed the condition after open heart surgery. The histological chronic sequelae were documented in 13 patients over 5 years. The progression to the chronic state was in most cases symptomless but 5 developed cirrhosis and one had died.

3.21 A paper entitled "Clinical and histological features of a group of patients with sporadic NANBH" by, among others, Professor Thomas and Dame Sheila Sherlock (1981) also related to the issue of the severity of the consequences of the disease.[450] Professor Thomas gave evidence about this study to the Penrose Inquiry.[451] This was a study of non-haemophilia patients. The results constituted an affirmation of what was seen in the 1978 Preston paper where there was one patient with cirrhosis. Half of the patients in this study had chronic active hepatitis (which had a poor prognosis according to Professor Thomas)[452]. Professor Thomas summed this up by saying that the study was a confirmation of the message from the Preston paper and other groups (in particular in Italy).[453] The condition was one where the effects took time to emerge. In light of this clear pattern, the evidence of starting to see patients whose disease was progressing ought to have resulted in a swift departure from the false reassurance which had been taken from the lack of symptoms in patients whose condition was in its early stages.

---

[448] PRSE0003209_0008

[449] PRSE0001451

[450] PRSE0004118

[451] Penrose Inquiry transcript for 11/10/11 (day 52); 123 to 124 (Professor Thomas); [PRSE0006052_0123 to 0124]

[452] Penrose Inquiry transcript for 11/10/11 (day 52); 128 (22 to 23) (Professor Thomas); [PRSE0006052_0128]

[453] Penrose Inquiry transcript for 11/10/11 (day 52); 129 (7 to 10) (Professor Thomas); [PRSE0006052_0129]

3.22 In an article entitled "Blood product concentrates and chronic liver disease" by Preston & Ors (The Lancet, 6 March 1982)[454] it was noted that the presence of chronic liver disease in patients with post transfusion NANB hepatitis was now well established but that the rate or likelihood of progression was unknown. The article gave details of one patient (infected from a single infusion) showing significant progression in the disease after 2 years but with no symptoms.

3.23 A further article entitled "Non A, non B post transfusion hepatitis: Disaster after decades" by Koretz and Ors, UCLA Medical school (Hepatology, 1982)[455] 35 - 53% of patients (66) with post transfusion NANB hepatitis had chronic liver disease. 6% had cirrhosis (after between 4 and 9 years of follow up). It was concluded that the disease developed in a clinically silent fashion and recommended that patients with post transfusion NANB hepatitis should be followed for many years. In his evidence to the Penrose Inquiry, Professor Thomas noted that this was one of the bigger studies into this subject at the time.[456] One would have expected that it would have permeated the medical profession in the UK and that those in charge of the treatment of patients who were at risk of contracting liver disease (including those with bleeding disorders, who were being constantly monitored and studied for these conditions and those responsible for transfusion) would have taken account of the results and the warning.

3.24 In the period after this, it is clear from the evidence available to the Inquiry that loss of focus on NANBH due to AIDS becoming the focus of attention in the period from late 1982 until early 1985. It is submitted that the loss of focus on the risks from hepatitis was misplaced. Focussing on single viruses failed to appreciate that blood and, in particular blood products, presented cumulative risk of AIDS, NANBH and also HBV which had not in any way been eradicated by screening methods in the period before 1985. However, despite this general shift of focus, evidence continued to emerge which supported the reality that NANBH was more prevalent and hence likely to be transmitted by blood or blood products and of a greater potential severity over this period.

---

[454] PRSE0000384
[455] PRSE0000499
[456] Penrose Inquiry transcript for 11/10/11 (day 52); 131 (18) (Professor Thomas); [PRSE0006052_0131]

3.25 The minutes of UKHCDO centre directors meeting on 13 September 1982 contain reference to a report from the chairman of Hepatitis Working Party (Dr Craske) which had not met for 6 months. The report points to interesting results from a study involving mildly affected or seldomly transfused patients and hepatitis being undertaken in Oxford and records which was being prepared for publication at that time.[457] A separate note of the same meeting records the Oxford data as showing that the risk of contracting hepatitis from large pool NHS concentrates was unexpectedly high.[458]

3.26 The UKHCDO Hepatitis Working Party report for the year 1982/83[459] refers to the Oxford study, started in 1981, of hepatitis in infrequently treated haemophilia patients. It was noted that the study appeared to demonstrate that the risk of contracting NANB Hepatitis from Factor VIII concentrates was 100% on first exposure, whether of NHS or commercial origin. It was noted that the problem of AIDS had overshadowed these developments – as noted above they appear not to have been viewed as predating a cumulative risk despite the known immuno-suppressant effects of AIDS which would render the ability fight the NANBH infection less.

3.27 The Oxford research by Fletcher, Craske & Ors was published in the British Medical Journal under the title "NANB hepatitis after transfusion of factor VIII in infrequently treated patients" (10 December 1983).[460] All nine of the patients who had not had factor VIII concentrate (whether NHS or commercial) before contracted NANB hepatitis. It was stated that the pool size of NHS concentrates had increased to the point where the benefit conferred by using plasma from volunteer donors had been lost. In his evidence to the Penrose Inquiry, Professor Thomas confirmed that what was taken from this study was that there was a very high rate of development of NANB hepatitis in people given concentrates for the first time whether of NHS or commercial origin.[461] Professor Lowe (who became a

---

[457] PRSE0004807_0010
[458] PRSE0002638_0002
[459] PRSE0001160 (dated 28 September 1983)
[460] PRSE0002154
[461] Penrose Inquiry transcript for 11/10/11 (day 52); 86 (25) (Professor Thomas); [PRSE0006052_0086]

consultant at the GRI in October 1985 but who had experience of working in the haemophilia unit before that) told the Penrose Inquiry that the studies between 1983 and 1985 resulted in it being very much on people's mind that there was a virtually 100% risk of contracting NANB hepatitis from concentrates at that time.[462] He accepted that it was known from 1985, one would have thought that the SNBTS concentrates were equally 100% infective with NANB hepatitis.[463] There is no reason why this position should not have been reached by 1983 at the latest.

3.28 Similar research was being done in Scotland by 1983. At a meeting of the Scottish Haemophilia & Blood Transfusion Working Group on 14 November 1983[464] Professor Cash reminded those in attendance about collection of data of liver function tests of virgin haemophiliacs. He raised a question about the number of virgin haemophiliac patients in Scotland. Dr Forbes responded that 'there were not enough virgin patients in Scotland' and that he was writing up his experience of hepatitis in 12 mild cases treated with PFC factor VIII concentrates. In a letter to Dr Forbes dated 28 March 1984, Professor Cash pointed out that he was beginning to 'plan ahead with regard to getting our product put into SHS 'virgin' haemophilia A patients'. He asked Dr Forbes for his data about the incidence of hepatitis in his patients which he had indicated to the working party was identical to the Oxford data and was needed for use as retrospective controls.[465] This would appear to suggest that the results in Scotland at this time had also indicated a 100% transmission rate from PFC concentrates. In a talk given by Dr Brian McClelland at the International Society for Blood Transfusion Congress in Munich on 22 July 1984 he indicated that present day coagulation factor concentrates had a very high risk of transmitting NANB hepatitis.[466] The evidence all pointed towards there having been since around 1981 at least a clear basis upon which the prevalence of NANBH in the donor population had risen to such a level that the pooling of concentrates rendered all of them infective. In addition, this prevalence

---

[462] Penrose Inquiry transcript for 13/10/11 (day 54); 22 (2 to 8) (Professor Lowe); [PRSE0006054_0022]
[463] Penrose Inquiry transcript for 13/10/11 (day 54); 32 (19) to 33 (1) (Professor Lowe); [PRSE0006054_0032]
[464] PRSE0002581
[465] PRSE0003749
[466] PRSE0000470

will also have resulted in many more infective blood and blood component donations.

3.29 In a further article entitled "Liver disease in haemophiliacs - an overstated problem?" by Stevens, Craske and others (British Journal of Haematology, January 1983)[467] the significance of the disease was questioned after liver biopsy had been performed of 12 multi-transfused patients in Manchester. It was found that only one had chronic active hepatitis with progression towards cirrhosis and that 4 had mild chronic active hepatitis but 7 had signs of good prognosis from chronic persistent hepatitis. It was noted that the incidence of chronic active hepatitis/cirrhosis may be around 16% (consistent with other worldwide studies). In our submission, even the content of this article is perhaps not as reassuring as its title might suggest. The content of the article was summed up in his evidence by Professor Thomas when he gave evidence to the Penrose Inquiry and said that "there are some worrying things in there but in the main most of that histology is encouraging".[468] Further, Professor Thomas noted that most of the studies available at that time were small and so one needed to look at the overall picture.[469] Though this small study was relatively reassuring, in its context it would have been foolhardy to have relied upon its results as justifying the cavalier approach to treatment of the day.

Further developments in the knowledge of the transmissibility, frequency and severity in the period from 1985

3.30 In Scotland, this period was significant as from December 1984 an HIV free factor VIII concentrate was available in Scotland (NY) and from October 1985 routine anti-HIV testing was effective in limiting spread of the disease through transfusion. By the time of these innovations, science had found a way to deal with the threat

[467] PRSE0002564
[468] Penrose Inquiry transcript for 11/10/11 (day 52); 145 (14 to 16) (Professor Thomas); [PRSE0006052_0145]
[469] Penrose Inquiry transcript for 11/10/11 (day 52); 133 (from 17) (Professor Thomas); [PRSE0006052_0133]

from AIDS being transmitted through blood and blood products (though not completely, as is addressed elsewhere in this submission). It was important (as the threat from NANBH in particular from blood and blood products remained) that the focus turn at that point to the protection of those who were at risk of becoming infected with viral hepatitis. The treatment of patient so exposed is addressed elsewhere in this submission. The position as far as haemophiliacs were concerned remained as it had been in the Fletcher paper. There was no reason to think that anything had been done to render it anything less than likely that NANBH would be transmitted to the recipient of a factor concentrate of any origin on first infusion. Indeed, evidence of the transmissibility, prevalence and potential severity of such transmission grew to make this a more serious problem over this period.

3.31 In an article by Kernoff, Thomas and Ors published in the British Journal of Haematology in July 1985[470], it was reported that 9 out of 9 UK patients developed NANB hepatitis after first transfusion of commercial factor VIII concentrate. Further, 10 out of 12 UK patients developed NANB hepatitis after first transfusion of NHS factor VIII concentrate and 4 out of 4 UK patients developed NANB hepatitis after first transfusion of NHS factor IX concentrate. It was concluded that whether prepared from volunteer or commercial donor plasma, clotting factor concentrates carried a very high risk of acute NANB hepatitis in first exposure recipients.[471] Given that this was a collaboration between Professor Thomas and haemophilia clinicians, one would have expected the haemophilia treating community to have been aware of it.

3.32 In his evidence to the Penrose Inquiry, Professor Thomas expressed the view that between 1970 and 1990 the prevalence of HCV in the UK blood donating general community was around 0.5%.[472] He accepted that the levels were found to be lower than that in blood tested in the first 6 months to a year after anti-HCV screening was introduced and pointed out that the level had fallen to around

---

[470] PRSE0003439

[471] PRSE0003439_0009

[472] Penrose Inquiry transcript for 11/10/11; (day 52); 78 (21 to 23) under reference to his report (Professor Thomas); [PRSE0006052_0078]

0.01%. However, he observed that that (even using that prevalence) still meant that one in 10,000 donors would be positive at that prevalence level meaning that one would still expect to see "some carry over into a factor VIII concentrate if its derived from 30,000 donors".[473] Professor Thomas explained that the figure he had been using was derived from a paper by Minor[474] (whom he thought would be privy to the accurate figures) which reported "a frequency of 0.4% consistent with previously reported figures" in the plasma from UK donors used to make factor concentrates.[475] As was accepted by Professor Thomas, this demonstrates that the UK donor plasma, although it had a smaller amount of the virus than the equivalent US plasma, had more than the critical level of infection at which the vast majority of recipients would be infected with hepatitis C.[476] This explains the epidemiological basis upon which factor concentrates available over this period were nearly always infective for NANB hepatitis. As far as the then available Scottish product was concerned (NY, heated to 68 degrees for 24 hours) the PFC did not receive regular reports of apparent infections as it was assumed that most patients, if not all patients, who received concentrate prior to 1987 became infected with NANB hepatitis.[477]

3.33 By around 1983 (and hence thereafter), it was or should have been known on the basis of the evidence which had been accumulated over a number of years that it was almost certain that a patient who was not infected with NANB hepatitis would contract the disease on first infusion with a factor concentrate of any origin. This inevitability should have featured highly in the treatment decisions made for patients who were unlikely to have been infected with the disease at the time when the treatment under consideration was received – ie those who were untreated or had been minimally treated before, in particular in light of the evidence mentioned above that the disease had the potential to become serious

---

[473] Penrose Inquiry transcript for 11/10/11 (day 52); from 79 (Professor Thomas); [PRSE0006052_0079]
[474] PRSE0000390
[475] Penrose Inquiry transcript for 11/10/11 (day 52); 113 (Professor Thomas); [PRSE0006052_0113]
[476] Penrose Inquiry transcript for 11/10/11 (day 52); 115 (2 to 9) (Professor Thomas); [PRSE0006052_0115]
[477] Penrose Inquiry transcript for 7/12/11 (day 74); 61 (8 to 16) (Dr Perry); [PRSE0006074_0061]

and even fatal. The clinical treatment of patients thereafter is considered in more detail below.

3.34 By 1985 by a further paper from the Sheffield group entitled "Progressive liver disease in haemophilia - an understated problem" by Hay, Preston and Ors (The Lancet 29 June 1985) was published.[478] The paper presented data from an 8 year study of 79 haemophiliacs in Sheffield who had received concentrates which showed that 21% of them had chronic progressive liver disease (8 had chronic active hepatitis and 9 had cirrhosis). There was therefore evidence of cirrhosis in 12% of patients. The histological evidence showed that NANB hepatitis was mainly responsible. Liver biopsies (done on 34 of the patients) showed progression from chronic persistent hepatitis to chronic active hepatitis within 6 years (suggesting that chronic persistent hepatitis was not as benign as had been hitherto thought by some). It was noted that symptoms and abnormal physical signs were uncommon in these patients and it was anticipated as a result of this protracted study that liver disease in haemophiliacs would become an increasing problem in future.

3.35 The UKHCDO Hepatitis working party report 1984/85 referred to the results of this Sheffield research and the fact that previous reports may have seriously underestimated the risk of serious chronic liver disease resulting from infection with NANB hepatitis amongst haemophiliacs.[479] There can be no doubt that the Preston/Hay research was communicated to the haemophilia directors. In his evidence at Penrose, Professor Thomas described this paper as the turning point in the understanding of the severity of the disease which came to light when Dame Sheila Sherlock was writing the 8th edition of her textbook.[480] Professor Ludlam pointed out that it was the progressive nature of the disease which was not understood adequately before this paper.[481] It is submitted that these comments should be taken in the context of the identity of the scientists who spoke them.

---

[478] PRSE0004229
[479] PRSE0002382
[480] Penrose Inquiry transcript for 11/10/11 (day 52); 146 (21 to 24) (Professor Thomas); [PRSE0006052_0146]
[481] Penrose Inquiry transcript for 13/10/11 (day 54); 85 (25) to 86 (2) (Professor Ludlam); [PRSE0006054_0085 to 0086]

By this point, it was clear and inescapable that this was a progressive disease which would be likely to show increasingly severe sequelae going forward. It was already apparent on a reasonable, patient-orientated approach to the previous data analysed above that this pattern had been emerging for some years.

3.36 In "A study of liver biopsies and liver disease among haemophiliacs (Blood, 66, 367 – 372) by Aledort & Ors dated August 1985 biopsy and autopsy results from 155 haemophiliacs were examined in order to study the relationship between severity of liver disease and treatment history.[482] The article noted that published results on increasing numbers of liver biopsy studies being conducted around the world which had stressed (a) the severity of the pathologic lesions observed and (b) the safety of the biopsy procedure. The incidence of cirrhosis was found to be 15%. This was less than had been previously reported in other studies but still represented a significant marker of the potential severity of the disease.

3.37 In a letter from Dr Schimpf and others in The Lancet (8 February 1986) [483] 16% of patients were found to have chronic active hepatitis and a further 13% had cirrhosis in his centre. The authors aligned themselves with the Sheffield study to the effect that the progressive nature of liver disease in haemophiliac was deemed to be an understated problem. The lead author was described as a very distinguished haemophilia treater by Professor Ludlam in his Penrose evidence.[484]

3.38 From the late 1970s and into the early years of the 1980s, evidence became gradually clearer that the frequency of transmission of NANBH to patients in receipt of blood and blood products of any origin was becoming ever greater and that the consequences of those transmissions may well, in time, become irreversible (in terms of the damage to the liver) or even fatal. The disease was clearly progressive. Sub-cirrhotic damage to the liver could only be deemed to represent the position as a snapshot in time, which could become permanent. No treatment or cure was available to prevent that progression. Liver damage and *a fortiori* permanent damage to the liver, one of the major organs of the body, could reasonably have been anticipated to lead to some significant degree of physical

---

[482] PRSE0003089
[483] PRSE0000149
[484] Penrose Inquiry transcript for 13/10/11 (day 54); 92 (21 to 22) (Professor Ludlam); [PRSE0006054_0092]

and psychological co-morbidity, with inevitable economic, social, emotional and developmental consequences. It could reasonably have been anticipated that if these conditions were emerging in adult patient who had contracted the infection, the damage to the developing livers of children would be likely to be exponentially worse, over time. In muti-transfused patients or patients in receipts of blood products derived from multiple infected donors, it could reasonably have been anticipated that the cumulative effects of multiple viral loads, with multiple re-infections could only have increased the likelihood damage and decreased the chance of clearing the virus naturally.

3.39 In light of that knowledge (actual or constructive), it was not reckless and certainly not in the best interests of patients for treatment to be continued as it had been, without any apparent regard to the potential consequences of infection based simply in the fact that the precise aetiology of symptoms attributable to infection was unclear or death rates as a result remained unclear or unproven. The progressive nature of the disease meant that it was predictable that the serious consequences of it would emerge some period into the future.[485] In his Penrose evidence, Professor Thomas agreed that the approach of haemophilia clinicians (whose patients were known to be inevitably exposed to this infection) was perhaps based on an underestimation of the severity of NANB hepatitis based on the fact that screening techniques had minimised infections with hepatitis B by 1981.[486] This was a reckless, dangerous and wilfully blind approach. It can reasonably be inferred that it led to the infection of many patients, the exposure of many already infected patients to further harmful viral load and its consequences and the exposure of many more to the another fatal pathogen, namely HIV.

3.40 As was the position of Professor Thomas in his Penrose evidence, it became increasingly clear from 1978 that NANB hepatitis was a more serious disease.[487]

---

[485] Penrose Inquiry transcript for 11/10/11 (day 52); 144 (2 to 4) (Professor Thomas); [PRSE0006052_0144]
[486] Penrose Inquiry transcript for 11/10/11 (day 52); 143 (18) to 144 (2) (Professor Thomas); [PRSE0006052_0143 to 0144]
[487] Penrose Inquiry transcript for 12/10/11 (day 53); 82 (Professor Thomas) [PRSE0006053_0082] - under reference to the development between the 6th and 8th editions of the textbook by Dame Sheila Sherlock which

Early assessments about the likely severity of the progression of the disease were based on what transpired to be erroneous assumptions about the likelihood of similarities between the progression of hepatitis C and hepatitis B[488] as well as problems, in particular with haemophiliacs, of evaluating the progression of the disease based on uncertainties about the date of infection[489] . The advent of the liver biopsy allowed a more accurate picture of the disease and its likely progression to be evaluated.[490] It was the position of Professor Thomas in his Penrose evidence that the view of the disease changed (as reflected in the Sherlock text) on the basis of the study in which he was involved and which was reported in the Journal of Clinical Pathology.[491] Even in the sixth edition of the Sherlock textbook the position had been stated as being unclear as the disease was referred to as "probably benign".[492] The development of the understanding that the disease was more severe, Professor Thomas stated in evidence, was the result of this article which, in itself was a confirmation of the results of the Preston paper published in 1978.[493] Professor Thomas accepted that once this data started to become available, one would not take what comfort existed in the sixth edition of the Sherlock text.[494] The view expressed in the eighth edition of the Sherlock text (which was prepared in the 2 or 3 years prior to its publication in 1989[495]) was that evidence suggested that the disease was potentially very serious. Professor Thomas's evidence supports the contention that this was an accurate statement of the known position based the overall picture emanating from the papers published resulting from the liver biopsies, the results of which were published in 1978 and 1981/82.[496]

---

was referred to by Professor Thomas as approaching the status of "absolute truth" on 11/10/11; 122(20); [PRSE0006052_0122]

[488] Penrose Inquiry transcript for 11/10/11 (day 52); 119 (3 to 7); [PRSE0006052_0119]

[489] Penrose Inquiry transcript for 11/10/11 (day 52); 119 (19 to 24); [PRSE0006052_0119]

[490] Penrose Inquiry transcript for 11/10/11 (day 52); 118 (15 to 22) (Professor Thomas); [PRSE0006052_0118]

[491] PRSE0004118 and PRSE0004640_0009

[492] Penrose Inquiry transcript for 11/10/11 (day 52); 129 (25) (Professor Thomas); [PRSE0006052_0129]

[493] Penrose Inquiry transcript for 11/10/11 (day 52); 129 (7 to 8) (Professor Thomas); [PRSE0006052_0129]

[494] Penrose Inquiry transcript for 11/10/11 (day 52); 139 (4 to 9) (Professor Thomas); [PRSE0006052_0139]

[495] Penrose Inquiry transcript for11/10/11 (day 52); 130 (5 to 6) (Professor Thomas); [PRSE0006052_0130]

[496] Including PRSE0000499 also referred to by Professor Thomas on 11/10/11 (day 52); 131; 11/10/11; 133 (25); [PRSE0006052_0131; 0133]

3.41 These were the publication dates of studies which had gone on before and so the results of which had been known to the medical profession for some time before that. Professor Thomas pointed out to Penrose that information would be exchanged between haemophilia centre directors around a year before it would be published in a journal.[497] On this basis, it can be assumed that this information could have been exchanged between directors even earlier than the dates of publication, if not at the date of publication at the latest. A key issue which arises from this related to the extent to which there was any or an effective system for action to be taken when this information was disseminated (either formally or informally prior to that). The UKHCDO appears to have been one forum which at least afforded the opportunity for informed discussion about this emerging evidence. The regular internal SNBTS RTDs meetings and joint meetings between them and the haemophilia directors (attended by medically qualified representatives of the SHHD) were fora a which afforded similar opportunity for information sharing, analysis and decision making, one would have imagined in the best interests of patients. In his evidence to the Penrose Inquiry Professor Ludlam (a UKHCDO reference centre director) made it clear that he had no managerial responsibility for any other of the haemophilia centres and that it was not until the factor VIII working party was established in 1988 that there was a forum for a regular exchange of views.[498] Thus, it appears that this information simply hung in the air for polite medical debate as opposed to be subjected to scrutiny with a view to action.

3.42 Further, there is a separate issue about how this information was disseminated internally within hospitals to those who might be at the coal face and interacting with patients. in his evidence to Penrose, Professor Lowe stated that information from Dr Forbes (who attended the UKHCDO meetings) came more frequently to him once he became a consultant than when he was a junior doctor, suggesting that as a junior was not fully updated.[499] At that time, Professor Ludlam felt that it should have been a matter of medical policy for information and guidance to be

---

[497] Penrose Inquiry transcript for 11/10/11 (day 52); 43 (21 to 24) (Professor Thomas); [PRSE0006052_0043]
[498] Penrose Inquiry transcript for 14/10/11 (day 55); 61(3 to 8) (Professor Ludlam); [PRSE0006055_0061]
[499] Penrose Inquiry transcript for 13/10/11 (day 54); 37 (4 to 11) (Professor Lowe); [PRSE0006054_0037]

circulated, referring in particular to the 1984 – 1987 this period. The evidence tends to suggest that there were no clear lines of responsibility, discussion of communication to enable medical wisdom which required precipitate action to be acted upon in the NHS in Scotland.[500]

Inconsistent government medical advice on NANBH

3.43 One of the main issues in this area appears to have been the inconsistency of the approach to the potential severity of NANBH in advice given to the UK government (as examined in the advice of Dr Walford from the beginning of the decade above) and the prevailing medical advice being expressed within the SHHD. In August 1988, Dr Forrester (medical advisor to the SHHD) was still expressing the view that NANB was "so benign at least in the short term that evidence of transmission had to be specially sought, the patient not being ill in the ordinary sense".[501] The context of this memo was the controversy surrounding the use of Alpha's Profilate in Scotland in 1988 as a result of a failure in the supply of the Scottish Z8 factor VIII concentrate, the circumstances of which are discussed elsewhere in this submission. Dr Forrester appears to be aware of the evidence of the severity of the disease obtained by the liver biopsy study, which it presumably what he meant by evidence of the disease needing to be "specially sought" in the absence of overt signs of illness. The focus on the short term nature of the disease is notable. It was of course well established by this point (and had been for many years) that this long incubation hepatitis meant that focussing on the short term was not really the problem. In trying to downplay the risks of the disease which had clearly been expressed by others, Dr Forrester was clearly misrepresenting the true position. That this remained his impression of the disease and its potential threats in late 1988 provides important context to government decision making about efforts

[500] Penrose Inquiry transcript for 14/10/11 (day 55); 62(20 to 21) (Professor Ludlam); [PRSE0006055_0062]
[501] See PRSE0003962_0002 (30 August 1988 memo by Dr Forrester)

which might have been made to limit the spread of the disease over the late 1980s and early 1990s.

3.44 The importance of seeking to undertake a proper assessment of the threat of NANBH in the blood and blood products recipients was not appreciated by government. Despite advice to this effect from 1981 by Dr McClelland a Scottish or UK study similar to the US TTV study was not undertaken. This was an early and important example of the government, who at other time claimed to rely on and follow medical advice to doing so when it required action and cost. This would prove to be an important error of judgement later in the decade.

Conclusions

3.45 There is clear evidence over this period of the emergence of considerable troubling knowledge that there was a threat of potentially very serious, even fatal disease from blood and blood products blood and blood products. These caused a significant public health risk. The failures to act on this knowledge was a fatal were errors of judgement. Given the history as set out above, there required to be a precautionary approach taken to the use of blood and blood products. Action was mandated for that to be implemented in practice in the discharge of the State's responsibility to the health of patients and the wider public health.

3.46 Subsequent infections with HCV/ NANB hepatitis were avoidable. As is argued below, transmission of HCV by commercial concentrate ought not to have occurred in Scotland as these products ought never to have been used in light of the unacceptable increased risk of HBV from these products and the emerging threat of NANB hepatitis of which there was also a known increased risk due to the use of high risk donors, whose donations would not have been accepted in the UK.

3.47 The differing prominence of HCV when compared to HIV in the UK donor population meant that the likelihood of infection with these two viruses differed considerably. Whereas HIV transmission was very rare based on its relatively low prevalence in the donor population, HCV prevalence and hence transmissibility via concentrates was much greater.

3.48 It is not possible to know with any degree of certainty about the extent to which infection rates with HCV could and would have been reduced by the measures which it is submitted ought to have been taken as part of a more precautionary/ patient orientated approach. The best that can be said is that the continuance of unsafe practices identified elsewhere in his submission materially contributed to the danger of the transmission of hepatitis C.

3.49 The line of argument advanced against this argument is that all products which were produced by the NHS in Scotland were infective for HCV before April 1987 and so even on first exposure to a concentrate or on first treatment of any magnitude with cryoprecipitate a patient would have become infected. Though it is contended that this argument is not made out on the evidence which has been heard by this Inquiry, even of this is correct, it is tantamount to an admission that all products provided by the NHS in Scotland were infective. That is an argument which, it is submitted, hardly reduced and indeed significantly increases the culpability of the NHS in Scotland – even the safer products were not safe.

3.50 In any event, the treatment regimes and the blood collection practices of the period before April 1987 increased the amount and variety of viral load to which all patients were exposed and patient ought to have been advised of the risks and of the best ways of manging their infections such as moderating their alcohol intake.

3.51 The avoidability of HCV infection in mild and moderate patients was achievable in any event by a reduction in the treatment regimes and proper advice about the risks for these patients, given their lesser treatment requirements.

4. HTLV-III/ HIV/ AIDS

Background to knowledge about AIDS emerging – hepatitis risk

4.1 It is submitted that it was clear by the start of the 1980s that there was a risk of viral transmission through blood and blood products. It was known that there were a number of potentially harmful viruses which could be transmitted parenterally, including hepatitis B, cytomegalovirus, Epstein-Barr virus and NANB hepatitis. It was known that these viruses could be transmitted after exposure to blood or blood products.[502] In his evidence to the Penrose Inquiry, Professor Lever also mentioned parvovirus.[503] A list of viruses transmitted by blood and blood products as at October 1984 is contained in an article by virologists Tedder and Barbara of that date.[504] Many of these were known about at the start of the 1980s. in this context, it was clear known not only that certain pathogens were so transmitted but that there was a considerable risk that new pathogens would emerge. Despite this, the prevailing culture appears to be one of a lack of acknowledgement that pathogens could be so transmitted until high scientific standards of proof had been satisfied. Koch's postulates represented the extent to which a viral threat had to be proven to be taken seriously. The past proof of the propensity of blood and blood products to transmit viruses and the known risk to the recipients of pooled products as the patients likely to be the first exposed meant that a culture of precaution should have prevailed and a reactive culture to emerging threats be facilitated. The actual approach taken to risk assessment and management by the medical community was the opposite and went on to inform the "conclusive proof" approach to AIDS transmission which prevailed in government thinking (discussed below).

4.2 Even as early as the 1960s, the need to avoid transfusions was recognised because of the threat of viral diseases. In an SHHD document dated 16 December 1964 setting out the responsibilities of the SNBTA, it had been pointed out that serum hepatitis was transmitted in 0.5% of infusions with blood or small pool plasma and

---

[502] Penrose Inquiry transcript for 11/10/11 (day 52); 19 (5 to 17) (Professor Thomas); [PRSE0006052_0019]
[503] Penrose Inquiry transcript for 18/05/11 (day 27); 22 (5 to 9) (Professor Lever); [PRSE0006027_0022]
[504] PRSE0003183_0002

that, consequently, "no transfusion should be undertaken unless the benefits outweigh the risks of hepatitis" and the products "should only be used where there is a clear clinical necessity".[505] This shows a clear recognition of the risks of viral infection from blood products for many years before the 1980s such that the policy was that blood and blood products should only be used where clinically necessary. This message applied *a fortiori* to the use of factor concentrates, given that even a single infusion constituted exposure to many more potentially infected donors than the products in use in the 1964 paper. Despite these general risks having been well known since the advent of blood product use in the United Kingdom, the overall use of blood products grew dramatically between 1969 and 1991 in the UK, with cryoprecipitate being used much less in favour of factor VIII concentrate (as is submitted in detail elsewhere in this submission).[506] The massive increased usage of concentrates from 1980 onwards to the virtual exclusion of products made from smaller pools such as cryoprecipitate lost sight of these early warnings about the risk of viral transmission and the consequent need to use these products only where absolutely clinically necessary.

4.3 Before the AIDS crisis emerged, it was known that blood products transmitted numerous potentially harmful viruses. The presence and transmission of new viruses was discovered periodically. It was understood that the risk of viral transmission was increased by the use of concentrates rather than products made from smaller donor pools. That this had been evident for some time at the start of the 1980s is exemplified by the content of the 1975 World in Action film viewed during the course of the oral hearings.[507] Professor Cash's reference to the film in the BMJ demonstrates that it was known that hepatitis B was a "potentially lethal virus".[508] Professor Cash referred to the importation of foreign concentrates as an unequivocal means to increasing the level of this virus in the whole community.

---

[505] PRSE0000157_0003

[506] See the overall UK factor VIII concentrate, cryoprecipitate and plasma usage in PRSE0002965 and the overall increase in the usage of factor IX concentrate in PRSE0002545

[507] See, for example, PRSE0001802_0003 relating to an outbreak of hepatitis B and "non-B" hepatitis in Bournemouth in 1974 and the "pronounced increase in risk of post-transfusion hepatitis when some batched of commercial freeze dried concentrates are used"

[508] PRSE0004064

Thus, it was realised (and perhaps should have been more widely) that patients with bleeding disorders do not live in social isolation. The introduction of a potentially lethal virus into their community was a serious public health issue.

4.4 At the UK Haemophilia Directors' Annual Meeting in September 1982 hepatitis was being discussed as a potentially serious problem with risk reduction measures being proposed including, for infrequent users of concentrate, the use of small pool cryoprecipitate (discussed elsewhere in this submission) and, for regular users of concentrate improved donor screening and pool security.[509] At the dawn of the AIDS crisis the risks of viral transmission from blood products were known as was the need to reduce to a minimum the numbers of potentially infected donors, as was the need to make better use of treatments made from smaller donor pools. Despite this, AIDS arrived and was spread in these very communities as none of these measures had been taken.

The routes by which knowledge about AIDS emerged

4.5 Information about the existence of AIDS emerged in the UK via information from the US. The earliest reports emerged on certain communities, which ought from the outset to have alerted all medical practitioners and indeed the government to the fact that knowledge of the characteristics and risks of the disease could be obtained from a range, though a limited range of medical specialities, including genito-urinary medicine (who tended to deal with those presenting with symptoms in the homosexual community), haematology (who tended to deal with those presenting with symptoms in the bleeding community), as well as virology and infectious diseases.

4.6 AIDS was a disease which first emerged abroad. As a result, it was particularly important for the medical community, when at least broadly award of its existence and severity, to take stock of the best available international evidence of its

[509] PRSE0000185_0005 to PRSE0000185_0006

characteristics, transmissibility, risk and potential severity. In a medically advanced country likely the UK, there was no reason why such evidence could not have been as available to clinicians here as it was to those in the US, for example. Abundant evidence is available relating to the close connections between the medical fraternity in Scotland the US, Europe and beyond.[510] It was important that these channels were exploited to their fullest in order that pre-emptive steps could be taken in anticipation of the clear risk that the disease would eventually arrive in the UK and in the UK donor pool. The advantage which the UK medical community had was that it had the ability to anticipate take steps to prevent a fatal disease which had caught others unaware.

The emergence of knowledge about the parenteral and sexual transmissibility of AIDS

4.7 The earliest reports about AIDS liken its characteristics as a disease in terms of transmissibility to HBV. This meant that it should have been possible to use existing systems to try to mitigate the likely transmission of the new disease as existing protective measures ought to have been able to have had the dual benefit of preventing the transmission of both diseases by excluding harmful blood or plasma entering the system from donors exposed to the risk of both disease via the same transmission route or routes. As identified above, these systems were flawed and so the inbuilt ability of the system to resist this new threat was already more limited than it should have been.

4.8 The sexual transmissibility of AIDS was also known from the outset. Thus, it should have been appreciated that the introduction of the disease into the community of those in receipt of blood or blood products would create a new vector whereby the disease would spread through the community. Contemporaneous information about the nature of AIDS can be seen from the notes of the meeting which was held at Heathrow Airport on 24 January 1983.[511] The note was prepared by Dr

[510] The connections of Professor Forbes and Dr McClelland there are discussed elsewhere in this submission
[511] PRSE0002647

Boulton (who attended the meeting) who expressed the view in his Penrose Inquiry evidence that the handwritten annotations on it were likely to have been made by Dr McClelland. The meeting was thus well attended by key decision makers from Scotland (as well as Dr Ludlam). In particular, the 45% mortality rate reported in the 800 infections in the US by 10 December 1982 (reported by Dr Craske) has been underlined.[512] It is also marked that the incubation period of the disease (also reported by Dr Craske) appeared to be between 6 months and 2 years.[513] The fatal threat, the rate of spread in the US and the incubation period (which would affect detectability) were all well-known at that time.

4.9 The issue of the attitude taken to the possibility that AIDS would be spread to the bleeding disorder population in Scotland either (a) via products imported from abroad for use in Scotland or (b) via products made from blood/ plasma donations collected in Scotland and the response of the clinicians involved in the treatment of those patients is examined in more detail below but needs to be understood in this context.

4.10 Further, from the outset it was known or ought reasonably to have been known about AIDS that it had a latency period between "infection" or contraction of the disease by whatever route and the emergence of symptoms. This had a number of important sequelae. In the first instance, it meant that it was important not to base an assessment of the severity of the threat from the disease on cases of AIDS. The incidence of AIDS was not a reliable basis upon which to assess the number of people who might be infectious with it due to the acknowledged latency period. Further, this knowledge created a basis upon which it ought to have been realised that any assessment of the risk of an individual having the disease could not reliably be based on the appearance of symptoms. People were known to be infectious before these signs emerged. As a result (and the absence until 1984 of a clearly acknowledged aetiological agent for the causation of the disease), it should have been realised from the outset that it was necessary that an extreme

[512] PRSE0002647_0003
[513] PRSE0002647_0004

precautionary approach be taken due to the limitations which were likely to be exist in the identification of infected individuals.

4.11 Evidence emerged from the USA concerning the link between AIDS and haemophilia from the summer of 1982. The information emanating from the USA from that time should have been available to those responsible for the treatment of bleeding disorders in Scotland. It should have been influencing attitudes towards treatment. After all, there was general knowledge about the disease and its risks in this country and the risks of extensive use of imported US products

4.12 In his evidence to the Penrose Inquiry, Dr Boulton pointed out that the report in the MMWR on 16 July 1982[514] commenting on three cases of AIDS in heterosexual haemophiliac patients was well known to historians of HIV.[515] It was this first report which gave rise to the initial concern that AIDS might be caused by an agent transmissible in blood, as earlier reports had been restricted to the drug using and homosexual communities. The MMWR of July 1982 referred to the probability that AIDS was transmitted by a blood-borne infection. This information and opinion stemmed from the US Centers for Disease Control (CDC), the federal agency whose responsibility it was to investigate new infectious diseases.

4.13 In fact, there appeared to be evidence of an earlier infection in a haemophiliac under the care of Dr Ratnoff in 1981 but there is no evidence that this as known about widely, other than to Professor Forbes (director of the haemophilia centre in Glasgow at the time), who was contacted directly by Dr Ratnoff with whom he had worked previously. The case does not seem to have been reported until 1983.[516] It is interesting to note that Professor Forbes did not indicate in his evidence to the Penrose Inquiry that he had taken the opportunity to contact Professor Ratnoff over the crucial period during which news of greater number of infections amongst US haemophiliacs was emerging. One would have thought that this might have avoided the inevitable delay in the reporting of cases from the USA and allowed him to access information from the coal face about Dr Ratnoff's views about the severity of the disease, its transmissibility and the likelihood of its

[514] PRSE0000523
[515] PRSE0001296_0002
[516] PRSE0004542

spread to the UK. It seems likely, given his views, that Dr Ratnoff would have advised him that this was a very serious matter and that he should consider minimising the exposure of his patients to factor concentrates, in particular imported ones.

4.14 A Department of Health Memo dated 16 July 1982 entitled 'American Factor VIII' indicates that there was a knowledge within the department at that time that American factor VIII seemed to be transmitting a new virus, and that around 400 haemophiliacs there had become infected.[517] In his evidence to the Penrose Inquiry, Dr Winter was of the view that the author of the memo might have shown a bit more concern about this emerging picture.[518] He also suggested that the tone of it indicated a greater concern for the furore surrounding the emerging news than for the haemophiliacs in the UK who might have been similarly infected, though he did concede that this was very early in the emerging story.[519]

4.15 This emerging evidence of a fatal new threat was known to the relevant key individuals within the transfusion and haemophilia services in Scotland as it emerged. As they met regularly and had close contact with the SHHD, it was or ought to have been known to the key decision makers within the SHHD. The American articles available at the beginning of 1983 relating to AIDS were presented to a Joint meeting of the SNBTS and haemophilia directors by Professor Cash on 7 January 1983.[520] These joint meetings appear to be the only formal setting in which haemophilia directors came together at this time. Professor Ludlam told the Penrose Inquiry that no formal haemophilia directors' meetings took place until 1985 [521] and that before that the Scottish centres worked much more independently from each other as separate units.[522] No information about the precise nature of the information communicated on 7 January 1983 is minuted, no action is proposed and the entry about AIDS is surprisingly brief in light of the contemporaneous US material. Amongst that material is an article by

---

[517] PRSE0003007
[518] Penrose Inquiry transcript for 26/04/11 (day 15); 116 (15 to 16) (Dr Winter); [PRSE0006015_0116]
[519] Penrose Inquiry transcript for 26/04/11 (day 15); 117 (6 to 9) (Dr Winter); [PRSE0006015_0117]
[520] PRSE0001736_0007 (21 January 1983)
[521] Penrose Inquiry transcript for 03/05/2011 (day 18); 7 (4 to 5) (Professor Ludlam); [PRSE0006018_0007]
[522] Penrose Inquiry transcript for 03/05/2011 (day 18); 102 (18 to 23) (Professor Ludlam); [PRSE0006018_0102]

Dr Bruce Evatt.[523] In it he describes contemporaneous appreciation of scientists at the CDC in Atlanta that (a) it had been warned in a similar article in Science on 7 January 1982 that the CDC considered haemophiliacs to be at high risk of AIDS which may be transmitted by an agent in factor concentrates (b) AIDS was the second leading cause of death amongst the haemophiliac population in 1982 though it had only been discovered in the haemophiliac population in the summer of that year and (c) haemophilia clinician Dr Oscar Ratnoff had suggested that a way to minimise the risk for haemophiliacs would be to use cryoprecipitate rather than factor concentrates, a view which might have been explained and justified to Dr Forbes had he taken the trouble to seek it out.

4.16 Also amongst the material available from the US at the meeting in January 1983 would have been the MMWR article of 10 December 1982.[524] This was the article with the information about the infection of the baby in San Francisco as well as updates on the infections of other haemophiliac AIDS patients in the USA. The transmission of AIDS to the San Francisco baby via multiple platelet transfusions indicated that the disease was transmissible through blood and blood products whether multiple or single donor.[525] In his evidence to the Penrose Inquiry, Professor Lever stated that the material in this article was "very compelling data for an infection."[526] Despite this clear evidence being available in the UK at the start of 1983, it obvious implications appear not to have been taken on board. The clear implications were that blood was a transmission risk to a recipient who clearly could not have been infected by another one of the known transmission routes. The disease was clearly parenterally transmitted. That is was not only transmitted by those who had received factor concentrates meant that it was not as a result of the unique qualitied of such products that it was transmitted. If it could be transmitted to the San Francisco baby, all recipients of any blood or blood products were at risk. Dr Gillon conformed in his evidence that this evidence was

---

[523] PRSE0001370 - published in "Science" dated 21 January 1983 reporting the details of a workshop held at the Centre for Disease Control in Atlanta on 4 January 1983
[524] PRSE0003276
[525] PRSE0003276_0004 (10 December 1982) (MMWR)
[526] Penrose Inquiry transcript for 17/05/11 (day 26); 49 (5) (Professor Lever); [PRSE0006026_0049]

the point at which he thought that the disease would have implications for the transfusion system.[527] Unfortunately, others did not think the same way and he did not start to work in the transfusion service until 1985. Dr McClelland agreed that it was a serious problem and one that would be likely to have a profound effect on the transfusion services.[528] However, he stated that there were "*many other challenges*" pre-occupying transfusion personnel in early 1983 which resulted in most taking *"some time to realise the seriousness of* [AIDS]".[529] In light of the known threat, that pre-occupation elsewhere was unjustified. This is a particularly significant revelation, in our submission. The matters with which the transfusion personnel (including himself) were pre-occupied in 1983 were the issues which had arisen from the MI report. They required to deal with the many shortcomings which had been identified by the inspections due the disrepair of a system which was not fit for purpose. This must have applied to all of the transfusion personnel across the country, in particular the directors and staff at the PFC, all of whom had received scathing reports. What this admission amounted to on the part of Dr McClelland was that due to the disrepair of the system, they were unable to take adequate steps to deal with what he certainly realised was an imminent deadly threat. This caused infections and lives.

4.17 It is submitted that the system for the risk assessment of the implications of this information was deficient. Unfortunately in Scotland after the December 1982 MMWR article, the possibility of producing freeze dried cryoprecipitate was abandoned (see below).[530] The lack of consideration of the materials evident in the minutes of the joint meeting on 9 January 1983 is indicative of an attitude which prevailed in Scotland and the United Kingdom throughout this period of complacency that this was an American problem from which recipients of blood and blood products here would be protected due to the voluntary donor system.

---

[527] IBI transcript for 19/01/22; 142 (Dr Gillon)
[528] para 296 of Brian McClelland statement at WITN6666001
[529] para 279 of Brian McClelland statement at WITN6666001
[530] PRSE0001736 (21 January 1983)

The UK background to the emergence of the US evidence in 1982

4.18 It would be inaccurate for the impression to be gained that it was purely through American evidence that knowledge of the existence of a new disease (later called AIDS) emerged. Dr Winter, in his evidence to the Penrose Inquiry spoke of an "extraordinary event" (the publication in the Lancet of details of a case of a man with what turned out to be AIDS in 1981[531]) and there being "a lot of talk" about it.[532] He worked in London at that time. The man had been treated at the Brompton Hospital. Dr Winter notes that the theory prevalent at that time was that there was a link between the homosexual lifestyle and the immune function changes which were apparent in this patient. The article specifically links this case to the similar presentations of homosexual males with an unexplained respiratory illness in the US. Dr Winter talked of this being treated as a "new disease". He commented that the theory about the aetiology of the disease later changed as haemophilia and blood transfusion patients started to be described. The important thing to take from this is that, even in hospitals in the UK and in publications such as the Lancet, evidence of the emergence of a new disease was evident from 1981. It was therefore not out of the blue that similar cases emerged in the blood and blood product recipient communities in the US in 1982 and in the UK in spring 1983. Nor was the disease a uniquely American phenomenon from 1981. It is against this background that one requires to view the emerging evidence from the US of the three haemophiliac infections described by Dr Evatt. Far removed from the attitude demonstrated at the joint meeting in January 1983, Dr Winter took the view these cases made viral aetiology very much more likely than the previously favoured theories.[533]

---

[531] PRSE0000426 (12 December 1981)
[532] Penrose Inquiry transcript for 26/04/11 (day 15); 110 (25) to 111 (21) (Dr Winter); [PRSE0006015_0110 to PRSE0006015_0111]
[533] Penrose Inquiry transcript for 26/04/11 (day 15); 114 (13 to 17) (Dr Winter); [PRSE0006015_0114]

Further emerging evidence - 1983

4.19 Articles began to be published in the Lancet in early 1983 with the details of AIDS-like disease in haemophiliacs. One of these concluded that transmission of an infectious agent in blood products seemed likely.[534] A further such article in the Lancet reported steps being taken as a result of infections amongst the haemophiliac community in the US involving (a) the cancellation of elective surgical procedures (b) the reduction of exposure to concentrates and (c) where possible, the switching of patients to cryoprecipitate rather than factor concentrate treatment. [535] The reaction of the author of this article was typically non-urgent, suggesting that the available evidence merited further monitoring of patients and did not constitute a strong argument for treatment policy. No consideration is given here to the temporal coincidence between the rise of AIDS in the homosexual and drug using populations and the emergence of an apparently similar disease in the blood and blood product recipient population.

4.20 A useful marker of internationally available evidence and a clear indicator of the evidence available to the Scottish medical community can be seen in the report written by Peter Foster for Mr John Watt of the PFC relating to matter which had been discussed at the WFH and ICTH conferences which he had attended in 1983. He wrote to Mr Watt on 13 July 1983 on T cell abnormalities in haemophiliacs which had been reported in Scotland, which just be the research referred to below in Edinburgh and Glasgow.[536] Interestingly, criticisms were made of the Ludlam et al research by north American colleagues at the WFH and ICTH conferences. Dr Foster expressed the view that did some of the scientific criticisms of the T cell situation not make sense to him It seems that there was some dubiety about the antigen overload theory attached to the results by Dr Ludlam in light of the emerging picture of AIDS from the US. Dr Foster's report draws on the evidence which was presented by the AIDS pioneer Dr Bruce Evatt of the CDC and merits

[534] PRSE0001916 (29 January 1983)
[535] PRSE0002723 (2 April 1983)
[536] PRSE0002014 (13 July 1983 memo from Foster to Watt)

close scrutiny of the state of medical knowledge about the disease by the date of the conferences, prior to July 1983.[537] As regards the transmissibility of the condition, the assessment of the conference made by Dr Foster was to the following effect:

- June 1983 figures from the US CDC showed that the total number of USA confirmed marginally higher than would be predicted from an exponential growth. This was analysed by Dr Foster as being consistent with the view that AIDS is a transmissible agent. There were also thought to be over 1,000 AIDS cases in Haiti – evidence of rapid growth. Epidemiological assessment strongly suggested a transmissible agent given that AIDS had been found in spouses, male & female, siblings, etc. This cutting edge evidence of how the AIDS epidemic had grown in the nations in which it had emerged was clear evidence from the first half of 1983 that AIDS was caused by a transmissible agent and was a clear warning from the foremost experts on the planet about its potential to spread. This evidence is the kind of epidemiological assessment which seems absent from the contemporary medical and official government assessment of the nature and risks of the disease. The government response was characterised by a focus on incidence of the disease rather than the risk of its spread and appeared devoid of any consideration of epidemiological projections of the likely impact of the epidemic, based on evidence from other places which were ahead of the UK in the process.[538]
- He reported that AIDS is still located mainly in key urban areas in the USA (New York, San Francisco, Los Angeles) however the haemophilia cases were generally located in non-AIDS areas, which he took to be strong evidence of transmission by factor VIII

---

[537] PRSE0004071 (15 July 1983)

[538] Epidemiological analysis appears to have been undertaken by Dr Craske and others in the aftermath of the outbreaks of HTLV III infection in the haemophilia community in the UK (HCDO0000273_066_0001) and by Drs McClelland and Perry in Edinburgh in similar circumstances. By contrast, there was a distinct lack of predictive epidemiological input or at least it appears to have been given no prominence in the thinking which was based on incidence of AIDS over risk of HTLV III infection.

- Further epidemiological evidence derived from the gay male population strongly suggests three stages to the disease (a) a latent period of up to 1 year with no symptoms (b) a period with various early symptoms which are not themselves specific for AIDS: this can be from 1 - 2 years and (c) full blown AIDS, 2 - 3 years after the initial contact. By this point this epidemiological assessment of the natural history of the disease based on evidence created a strong impression (which had in fact been suspected before) that the disease had a latency period before symptoms would emerge. In addition, the those had the conferences had made clear that The AIDS victim is thought to be capable of transmitting the disease "from time 0 onwards". This was a very important element of the formulation of the response to detection – the rooting out of infected patients would require to rely in the early stages of the emergence of the disease in countries like the UK on methods other than the assessment of symptoms. Further the governmental focus on incidence of symptomatic AIDS (ie those in the third stage) would automatically be several years behind the true picture of the infected and infective population.
- He reported that haemophiliacs were in the group which develops opportunistic infections. There were 16 confirmed cases of AIDS amongst haemophiliacs in the USA (8 were dead) and 5 in Europe (3 in Spain, 1 Wales – the Cardiff case under Professor Bloom - and 1 in Canada). He also reported that other delegates seemed to think there were more cases than this outside the USA, "eg Canada, Germany, Israel, Sweden...it is possible that these have not yet been confirmed by CDC". Dr Foster indicated that "this is strong evidence for transmission by FVIII".[539] There appeared to be no suggestion that haemophiliacs' apparent AIDS like illness could be due to anything other than the same aetiological agent that had caused the fatal disease in the other at risk populations. Meanwhile, in Edinburgh Professor Ludlam and other like him in Scotland were still being influenced by his view that haemophiliacs deemed at the conferences to be so infected may in fact may simply have T cell abnormalities based on antigen overload similar to those in his patients.

---

[539] PRSE0004071_0002

- A combination of the relatively recent advent of the disease in the haemophilia community and the known period between infection and symptoms emerging that meant that "a number of delegates (mainly European) were clearly uneasy and felt that we may be still only seeing the tip of the iceberg". This epidemiological approach based on the emerging epidemic evidence and the known natural history of the disease is in strong contrast to the incidence over risk approach which seems to have permeated government and medical thinking – such an approach to a disease like this was bound to fail to prevent otherwise preventable infections.

4.21 Dr Foster expressed the view that the Dr Evatt presentation had been so persuasive to you in making it clear that haemophilia infections were caused by a blood borne agent but there was no abstract.[540] It seems hard to understand why that information with such clarity was not communicated to the Scottish haemophilia clinicians. Had it been it may have altered the interpretation of the seriousness of the position. Dr Foster further reported that it was thought that "For donor screening it was suggested that the presence of circulating immune complexes plus anti-HBc would identify 98.4% of AIDS cases." He estimated that "rejection on this basis would remove 10% of all the plasma pool". As is examined below, no progress was made in the UK with such a screening.

<u>The emergence of knowledge about the severity of AIDS</u>

4.22 From the outset, it was clear that AIDS was a very serious, likely fatal disease. The mantra of the medical community persists that it was thought that NANB hepatitis was thought on the available evidence to be a relatively benign condition. This statement is controversial and is addressed elsewhere in this submission.

[540] page 61, para (iv) of Peter Foster witness statement at WITN6914001

However, a similar argument could not reasonably be mounted by the medical community or the government in response to AIDS. It was always properly understood as a disease which would be likely to be fatal. This is clear from the evidence, not least from the material considered at the Heathrow airport meeting in January 1983 (see above).

4.23 In his evidence to the Penrose Inquiry, Professor Lever made it clear that one of the earliest details of AIDS which was known was that it was a disease which suppressed the immune system.[541] Given the known risks of transmission of other viruses through blood products, it should have been realised that an immuo-suppressant disease could have the effect of making

4.24 it less likely that recipients would be resistant to the other viruses to which it was known they were exposed. As Professor Lever accepted, the evidence of immuno-suppression and, in particular, evidence of death from immuno-suppression should have triggered a new analysis of the risk/benefit balance of using products which might transmit the virus.[542] In light of this, the "carry on as usual" approach adopted by haemophilia clinicians and advocated in correspondence by senior figures like Professor Bloom was unjustifiable, unreasonable and unsafe. The details of this approached are addressed in the section relating to bleeding disorder treatment below.

4.25 Again, the assessment presented by Dr Peter Foster to his colleague Dr John Watt at the PFC of the information gained at two international conferences in 1983 was instructive of what was known by those at the cutting edge of the disease in terms of its severity in the first half of 1983.[543] In this regard, he reported that:

- The form of AIDS fell into two categories; those who develop Karposi's sarcoma and those who develop opportunistic infections (haemophiliacs being in the latter group). Predicted mortality was 100% in 3 - 4 years for those with Karposi's

[541] Penrose Inquiry transcript for 18/05/11 (day 27); 25 (3 to 8) (Professor Lever); [PRSE0006027_0025]
[542] Penrose Inquiry transcript for 18/05/11 (day 27); 26 (17 to 21) (Professor Lever); [PRSE0006027_0026]
[543] PRSE0004071 (15 July 1983)

sarcoma and 100% in 25 months for those with opportunistic infections. The disease was inevitably fatal in a short space of time.

- Of the 16 USA haemophilia cases 1 was a mild haemophilia B case who also received 2 units of New York blood. Haemophilia A cases were amongst the mild, moderate and severe categories of the condition. The disease did not to discriminate between those who are likely to have received different treatments or different levels of treatment based on the severity of their haemophilia, indicating that its prevalence in the donor pool was not so rare as to spare those who had received less treatment. In the same vein as HCV in the UK which had by this time become so prevalent in the donor pool as to mean that domestic factor concentrates were thought likely to be infective for the condition on first infusion.

Governmental response to the emerging threat of AIDS

4.26 The government response to the AIDS crisis was characterised by lethargy, a confusion of risk and incidence of the disease, an apparent unwillingness or inability to see the disease not just as a foreign threat (and hence one which concerned only those exposed to that threat through the use of commercial concentrates, which in itself was woefully underestimated) but one which inevitably would enter the donor population in the UK, the selective and misplaced reliance on medical advice without questioning its context, source or thoroughness and a willingness unquestioningly to avoid action where inaction was recommended and only to question advice where action was recommended or mandated. It was made clear in subsequent investigations into the actions of the NHS from at least the time of the AIDS crisis onwards, that all decisions with regard to the way that products for the use in the treatment of those with bleeding disorders in Scotland was taken with the full knowledge of both the haemophilia

directors and the SHHD.[544] The planning of the system was thus supported and endorsed by all of the three major players – SNBTS, the haemophilia clinicians and the government.

4.27 The fact that the protections against hepatitis were inadequate and the decisions made around that exposed patients to any new threats was the starting point

4.28 The lack of involvement of epidemiologists was the source of looking at incidence over risk.

4.29 The fact that evidence appeared to emanate only from the haemophilia clinicians or that their views on matters seemed to be prioritised or given more prominence in government thinking than the views of others. This was the equivalent of looking only at one side of the argument. It was inevitable that those involved in the treatment of patients with bleeding disorders, being fully aware of the threat to which they had exposed their patients would seek to argue that the continued use of products was important. Their priority was the maintenance of what they considered to be the best treatment for the bleeding aspect of the patient. The government accepted that advice (a) to the apparent exclusion of other advice which would have tended to argue the opposite point of view meaning that the advice which the government took was unbalanced. Further, the response of government was to accept that advice (which naturally favoured the government's desired outcome of inaction which would lead to no additional cost) unquestioningly and unanalytically. No consideration appears to have been given to probing temporary responses to the imminent and emerging threat, such as those proposed in the treatment section below.[545]

Lack of appropriate reaction to advice

4.30 The inadequacy of the government response is illustrated by the lack of attention paid to the expert opinion expressed by Dr Spence Galbraith of the Public Health

[544] MACK0002319_001_0002
[545] Section H of this submission

Laboratory Service in 1983. In his letter to Dr Ian Field (department of health and social security) dated 7 May 1983, the author's current understanding of AIDS was set out.[546] The letter was sent the week after a case of AIDS in a haemophiliac patient in Cardiff was reported (the details of which are considered below). The attached paper recommended that all blood products made from blood donated in USA after 1978 should be withdrawn based *inter alia* on the current understanding that (a) the AIDS epidemic in the USA was probably due to a transmissible agent (b) the agent was probably transmissible through blood and blood products (c) AIDS had already spread to haemophiliacs (d) although number of cases was small, this did not indicate that the risk was small because there was known to be a long incubation period (e) there was no known way of ensuring that blood or blood products were free from AIDS and (f) the mortality rate of AIDS was 50% one year after diagnosis and was likely to rise to 70%.

4.31 In addition to illustrating the inadequacy of the government's response, it was clear from the evidence available to this Inquiry that the understanding of AIDS set out in this letter was largely unknown to those responsible for the treatment of patients with bleeding disorders at this time, in particle in Scotland. This was explained by Professor Ludlam by the fact that the matters discussed at the Committee on the Safety of Medicines were highly confidential due to the fact that they related to products and hence were commercially sensitive.[547] However, this was no excuse as to why these views (based on a factual understanding of the transmission and severity of AIDS which was available from other sources, as explained above) should not have permeated the risk assessment undertaken by clinicians. Professor Ludlam's explanation was merely an excuse to avoid facing the reality that the risks were or ought to have been known to him and the conclusions expressed by Dr Galbraith were conclusions which he and other like him ought to have drawn as well.

---

[546] PRSE0003286

[547] Penrose Inquiry transcript for 04/05/11 (day 19); 35 (23 to 24) and 36 (5 to 6) (Professor Ludlam); [PRSE0006019_0035 and PRSE0006019_0036]

4.32 In his evidence to the Penrose Inquiry, infectious diseases expert Professor Andrew Lever explained the culture which existed at the time as far as the medical discipline of infectious diseases was concerned. He considered the views expressed directly to the DoH by Dr Galbraith to be "understandable and rational". He also said that during the 1960s and 1970s infectious diseases practice had rather faded away. However, he made it clear that this was not due to the lack of new infectious diseases which come along every year.[548] He described a general reluctance in the medical profession to seek the advice of specialists in infectious diseases or a lack of such specialist advice being available in clinical practice in the 1980s.[549] This may account for the low level of attention paid to the possibility of new infectious diseases arising in the world of blood and blood products but does not excuse it. Professor Lever said that the possibility of an infectious aetiology was clearly known to senior haemophilia clinicians (whose advice was preferred by government to that of a public health expert like Dr Galbraith). However, they and hence the government, appear not to have taken enough notice of it or appreciated the level of the threat.[550]

4.33 In his statement to the Penrose Inquiry, Professor Lever stated that "in May 1983 [there was] much circumstantial evidence and consensus opinion in the majority of doctors that a transmissible agent, almost certainly a virus, is the most likely aetiology".[551] He told that Inquiry that this would have been the consensus opinion amongst doctors in different disciplines at that time.[552] He also commented that if he had been asked for his honest opinion at that time, without the requirement to reassure the audience, that he thought it was quite likely that AIDS was caused by an infectious agents transmitted by blood products.[553] He expanded upon his reasoning at the time by saying that he would have been persuaded by the

---

[548] Penrose Inquiry transcript for 17/05/11 (day 26); 78 (13) to 79 (10) (Professor Lever); [PRSE0006026_0078 to 0079]
[549] Penrose Inquiry transcript for 17/05/11 (day 26); 79 (19) to 80 (15) (Professor Lever); [PRSE0006026_0079 to 0080]
[550] Penrose Inquiry transcript for 17/05/11 (day 26); 82 (13) to 83 (1) (Professor Lever); [PRSE0006026_0082 to 0083]
[551] PRSE0000331_0005
[552] Penrose Inquiry transcript for 18/05/11 (day 27); 4 (20 to 22) (Professor Lever); [PRSE0006027_0004]
[553] Penrose Inquiry transcript for 18/05/11 (day 27); 2 (20 to 25) (Professor Lever); [PRSE0006027_0002]

infectious theory (as opposed to other prevalent aetiological theories, such as the antigen overload theory) based on (a) there was evidence that this disease caused lymphocyte dysfunction and there was experience of a retrovirus targeting lymphocytes in humans (HTLV-I) (b) there appeared to be clusters in particular geographic areas (c) sexual transmission of infectious diseases and transmission in blood were extremely well documented.[554] He was also of the view in May 1983 that the connection between AIDS and blood products, particularly (but not restricted to) commercial products made in the US was very strong.[555] It is submitted that the very real threat of AIDS to patients with bleeding disorders should have been realised and acted upon by those responsible for their care by the spring of 1983. That included the obligation to make government aware of this urgent state of affairs.

4.34 In his evidence to Penrose, Professor Lever contrasted the position being taken by Professor Bloom in his advice to the Haemophilia Society (see below) and that given by Dr Galbraith only a few days later from an infectious diseases point of view. He stated that the latter had a duty to apply a precautionary principle in the public interest.[556] This was the responsibility of government as well. That it was not acted upon was a clear failure in the government's responsibilities. Dr Galbraith's approach was contrasted with the position of Professor Bloom who came at the problem from a haemophilia clinician's perspective.[557] What was required was a precautionary approach based on the clear, evidence based, public health advice or at least a greater balance between the two extremes. It is interesting to note that, at that time, Professor Lever confirmed to the Penrose Inquiry that there would be consultant virologists in all large hospitals and access to virological advice in all hospitals in the UK.[558] Links through the requirement to treat chronic infections with diseases like hepatitis B would already have been

---

[554] Penrose Inquiry transcript for 18/05/11 (day 27); 3 (3 to 14) (Professor Lever); [PRSE0006027_0003]
[555] Penrose Inquiry transcript for 18/05/11 (day 27); 5 (9) to 6 (2) (Professor Lever); [PRSE0006027_0005 to 0006]
[556] Penrose Inquiry transcript for 18/05/11 (day 27); 12 (4 to 9) (Professor Lever); [PRSE0006027_0012]
[557] Penrose Inquiry transcript for 18/05/11 (day 27); 12 (12 to 17) (Professor Lever); [PRSE0006027_0012]
[558] Penrose Inquiry transcript for 18/05/11 (day 27); 15 (22) to 16 (12) (Professor Lever); [PRSE0006027_0015 to 0016]

established between haemophilia clinicians and virologists.[559] Such infectious diseases experts would have been likely to have had a broader perspective and a deeper understanding of the emerging infection at that time.[560] Haematologists giving evidence to this and the Penrose Inquiry seemed to be unaware of the Galbraith recommendations at the time. This suggests that the advice of virologists may not have been sought or, if sought, was not understood.

The response of government in Scotland

The context in which decisions were made

4.35 The government's commitment to achieving self-sufficiency in blood products had been its policy since 1974/ 75.[561] It is of interest to note that the policy appears to have been based on an understanding that AHG concentrate was the mainstay of treatment for haemophilia by 1974.[562] The evidence heard by the Inquiry is that this was not the case for Scotland. In Edinburgh, in particular, the mainstay of treatment continued to be cryoprecipitate for many years after that date.

4.36 This policy objective had not been achieved beyond Scotland by the time of the emergence of the AIDS crisis in 1982/ 83. By 1980, an update was given on behalf of the government in the House of Commons which estimated that improvements made to BPL would still mean that commercial products would be required in projections to the end of 1982.[563] The response on the position of BPL and the transfusion service more generally was given specifically for England and Wales only, responsibility for Scotland and Northern Ireland having been specifically

[559] Penrose Inquiry transcript for 18/05/11 (day 27); 17 (16) to 18 (2) (Professor Lever); [PRSE0006027_0017 to 0018]
[560] Penrose Inquiry transcript for 18/05/11 (day 27); 21 (4 to 10) (Professor Lever); [PRSE0006027_0021]
[561] BPLL0004847_0001, para 2 - letter from Mr Gidden to regional administrators dated 24 December 1974
[562] BPLL0004847_0001, para 1
[563] DHSC0000288_0003 (15 December 1980)

excluded.[564] Commercial imports were still the mainstay of the treatment of patient with bleeding disorders beyond Scotland by 1982/ 83.

The decision-making structures relating to the use of blood and blood products in Scotland

4.37 Within the Scottish Home and Health department, blood transfusion matters at this time appear to have been accorded a relatively low priority. Dr Archie McIntyre was the principal medical officer with responsibility for blood transfusion matters with it being only a very small part of his job.[565] The SHHD took a reactive rather than proactive approach to formulating guidance on how treatment should be planned to minimise the risk of HTLV III infection. Reliance was placed on the medical advisors with specialist knowledge of the area of medical speciality with which particular decisions were concerned. As at the UK level, this involved reliance primarily on the views of the haemophilia directors and the SNBTS as opposed to those with a more specialist interest in the area of virology or infectious diseases.

4.38 In addition, the relative paucity of resources available to the Scottish Office meant that there was a *de facto* reliance on information, knowledge and decision-making in the Department of Health. The political reality of the arrangement of government at that time was that consistency was key as both the Scottish Office and the Department of Health were headed by Secretaries of State who were part of the same cabinet and ministers who were part of the same government. The myth of the "administrative devolution" which existed at the time was that it was rarely possible for Scotland to take a different course on important issues like the public health response to the AIDS risk for political considerations, even when it would have been justified in doing so. The combination of these factors led at the time of the AIDS crisis to there being insufficient consideration of why Scotland

[564] DHSC0000288_0001 (15 December 1980)
[565] PRSE0004764_0002

was in a different position, what its options were and why taking a different course to the position in the rest of the UK was the correct option to choose.

4.39 Dr Walford had made it clear in her evidence that the position within the Department had been that it was likely that AIDS had a viral aetiology. That had resulted in a focus on the implications for the treatment of haemophiliacs and, in particular, the importation of products upon which there was considerable reliance in the rest of the UK, beyond Scotland. Her department (and Dr Walford, in particular given her particular knowledge of haematology) had access to the up to date information needed to respond with sufficient urgency to the emerging threat. Her capacity to do so was hampered by the reliance on commercial products. Her evidence was that she only very occasionally communicated directly with her Scottish office counterparts over this key period.[566] Scotland had the theoretical capacity to make decisions in the interests of patient safety which may not have been available elsewhere in the UK. The SHHD lacked the access to those with those with the key information and experience and they were politically bound to follow the decisions elsewhere in the UK, reached on a basis not factually applicable to Scotland. The system was not set up to serve the interest of public health or patient safety and was thus defective. Similar issues would become evident again in the political limitations imposed upon Scotland in decision-making around the threat of HCV in the second half of the decade (discussed below).

4.40 It was clear from the evidence of infectious diseases expert Professor Lever to the Penrose Inquiry that it was believed to be the case from early on in the emergence of HIV that it was sexually transmissible.[567] He also referred to the spouse of a haemophiliac becoming infected.[568] Other than the public health risks posed by the risk of bleeding incidents on the part of haemophiliacs who may be infected with HIV (which, in our submission, are highly significant in themselves) the knowledge that any such infected patients could transmit the disease sexually should, in our submission, have created a far greater degree of urgency about

---

[566] IBI transcript for 19/07/21; 65 (Diana Walford)
[567] Penrose Inquiry transcript for 18/05/11 (day 27); 35 (6 to 9) and 37 (7 to 8) (Professor Lever); [PRSE0006027_0035 and 0037]
[568] Penrose Inquiry transcript for 18/05/11 (day 27); 36 (17 to 19) (Professor Lever); [PRSE0006027_0036]

doing all that was possible to prevent them contracting the disease in the first place. In his evidence to that Inquiry, Professor Ludlam pointed out that his predecessor, Dr Davies, did not use commercial concentrates on the basis that he did not want to expose his patients to "novel" viruses from abroad.[569] Patients with bleeding disorders were, however, so exposed without much apparent consideration being given to the fact that they were effectively a medium or vector through which novel viruses could be spread throughout the Scottish population. We are not aware of any evidence of secondary infection by patients infected with HIV in Scotland. However, this state of affairs appears to be the result of luck rather than design on the part of those responsible for their treatment – all of the close contacts of those infected with viral hepatitis and HIV (in particular HBV and HIV which were known to be sexually transmissible) were exposed to the risk of contracting a fatal disease. Those responsible for the minimisation of the risks of sexual transmission at the treatment level were in the first place the haemophilia clinicians who had the power to minimise the chances of infection and also the government, in its capacity as protectors of the health of the public. It seems that the wider public health implications of creating a transmission route via the recipients of blood and blood products to the wider community with whom they came into contact was never properly appreciated or acted upon by government. HBV had been known to be sexually transmissible in at least the 1970s. That easy transmission route created an unnecessary widespread public health risk of which the human vectors for transmission were largely unaware.

The actual government response

4.41 On 13 July 1983, the meeting of the Sub Committee on Biological Products of the Committee on the Safety of Medicines was an important one in shaping the government's attitude to the issue of the emergence of the AIDS threat.[570] Though

[569] Penrose Inquiry transcript for 04/05/11 (day 19); 125 (10 to 12) (Professor Ludlam); [PRSE0006019_0125]
[570] ARCH0001710 (13 July 1983)

the minute of that meeting claims to have drawn on the advice of various experts to reach its conclusions, it was subsequently suggested in legal advice prepared in connection with the HIV litigation that the sub-committee had actually drawn on advice from the Chairman only, which in turn had been based only on advice from Dr Spence Galbraith and not the others mentioned in the sub-committee meeting minute.[571] That advice refers to this being apparent from a DoH memo dated 27 July 1983, which does not appear to be available to the Inquiry. The extent of the expert advice taken by the sub-committee and ultimately by the CSM (which accepted the sub-committee's recommendations[572]) appears to have been limited. The purported advice and papers on "instance and epidemiology" are certainly not listed or otherwise set out in the minutes. The significance of Dr Galbraith's advice is discussed below.

4.42 The advisory sub-committee of the CSM discussed possible reactions to AIDS in relation to licensed blood products on 13 July 1983.[573] It is significant that this discussion formed the basis of the government's position on the AIDS risk from blood at that time. The context of the meeting shows that consideration of these matters was limited to the scope of the CSM's operational sphere, namely licensed (ie imported) blood products. The system of Crown Immunity (discussed elsewhere in this submission) meant that this Committee was concerned neither with blood products produced in the UK at PFC or BPL, nor with the possibility of blood collected in the UK could be or become infective. Evidence analysed elsewhere in this submission shows clearly that the virus which caused AIDS was being transmitted by domestic blood and blood products from 1982 at the latest, ie well before this meeting took place. The government advice was therefore reliant on the advice of a sub-committee looking only at a limited aspect of the risk.

4.43 The agenda for the sub-committee meeting contained lists of possible responses to the AIDS threat in the approach to imported products, designed as a list of options to put to the Committee, although it is clear from the agenda that these

---

[571] ARCH0003115_0007 (11 December 1990)
[572] DHSC0001207 (27 July 1983)
[573] PRSE0002336

were subject to possibly significant revision at the meeting. The agenda does give an indication of the fact that an infectious aetiology for AIDS was thought likely by that stage.[574] This was agreed upon by the sub-committee at the meeting.[575] A number of proposed solutions were set out in the agenda with some preliminary commentary on the strength of each of the proposals. Withdrawal of factor VIII and IX concentrates was considered[576] but it was stated that "the perceived level of risk does not justify serious consideration of this solution" and this step "would involve a major rethink of UK policy for preparing blood products".[577] At the meeting, this proposal was rejected on the grounds of supply (ie the supply position in England and Wales and not in Scotland).[578] It is interesting to note that consideration was given to the option of using US blood products as sparingly as possible and modifying product licenses accordingly. This option was noted as being something which should be left to clinical judgement. The Inquiry heard evidence that decision making about licensed products was based in part at least on an assumption that because the product had been licensed it could be deemed to be safe to use without limitation. At this stage, it appears that this sub-committee was taking the view that decisions on safety were for the clinicians, at least as far as volume of use was concerned. The possibility of recommending the reduction of exposure to concentrates to the lowest level necessary (which would have helped with the overall aim of achieving self-sufficiency anyway and was in accordance with Recommendation R83(8)) appear to have been side stepped. Other possibilities such as avoidance of domestic concentrates or making more cryoprecipitate available appear not to have been considered based on the fact that this sub-committee was tasked with looking at imported product use only. Despite the fact that it was acknowledged that "recipients of clotting factor concentrates [generally] are at risk"[579], the withdrawal of US preparations was

[574] PRSE0002336
[575] ARCH0001710_0002
[576] ARCH0001710_0002
[577] PRSE0002336_0003
[578] ARCH0001710_0002
[579] PRSE0002336_0002

considered to have been impractical on grounds of supply.[580] The options were assessed on a national level, whilst not appearing to give any consideration to the fact that Scotland was nearer (or in fact had reached) self-sufficiency and therefore options such as stopping use of commercial products, ruled out here on grounds of supply, may have been more achievable.

4.44 In addition, despite Mr Watt having been in attendance at the 13 July 1983 meeting[581], and despite the fact that there was a wholly separate system for the production of blood products in Scotland (at the PFC), no separate consideration of the position in Scotland was undertaken within government at the time when there required to be a clear understanding of (a) the risks of AIDS being transmitted by blood or blood products and (b) the feasibility of the possible responses. The feasibility of the possible responses proceeded on the basis of an assumption that bleeding disorder patients would require to continue to be exposed to commercial products imported from the US as the policy ambition of self-sufficiency had not been realised. The fact of virtual self-sufficiency in Scotland was mentioned in an SHHD memo on 6 May 1983.[582] However, this does not appear to have resulted in action as far as strategy was concerned with regard to the continued use of commercial concentrates. Discussions at government level proceeded on the basis of an assumption that patients would be exposed to the more dangerous products as a matter of necessity. This assumption was false. It was certainly not the position in Scotland, which had been self-sufficient in factor IX for some time and was also by this time in a position to be self-sufficient in factor VIII, as a result of the surplus of blood products which had been built up at the PFC, as spoken to in evidence by Dr Robert Perry.[583]

4.45 The government evidence heard by the Inquiry in connection was illustrative of a system designed to achieve minimum accountability for decision making. One might naturally have thought that the minister of State or the Secretary of State within the DHSS in the period between 1983 and 1985 would have taken

---

[580] ARCH0001710_0002
[581] ARCH0001710_0002
[582] SCGV0000147_181
[583] See the submission on fractionation below, Section J

responsibility for the decisions taken or not taken within the department at that crucial time. In fact, the mainstay of their evidence was to distance themselves from such responsibility, instead stating that the junior minister within their department, Lord Glenarthur or the medical advisors were more suitably placed to be blamed for any shortcomings in the system. Such an approach is, unfortunately, redolent of the way in which a certain commentator has characterised the government's response to the recent COVID-19 crisis as being a situation whereby everyone in the room points at someone else to take responsibility.[584] The lack of clear structures of accountability and responsibility and the lack of clear roles within the advisory and decision making elements of the system clearly, it is submitted, contributed to the inadequacy of the government's response to the disaster.

Conclusive proof

4.46 The line adopted by the government over this period regarding AIDS appears to have been to state that there was no conclusive proof that AIDS was transmitted by blood or blood products.[585] Whilst technically correct, the government's own expert advisory CSM sub-committee had taken the view the day before Lord Glenarthur's statement that an infectious aetiology was likely and measures to prevent the spread to recipients of blood and blood products were actively under consideration.[586] As with the comments by Professor Bloom, the state of knowledge and medical opinion was deliberately portrayed more optimistically than the reality.

4.47 Later in the year, the Inquiry is aware that Lord Glenarthur became involved in correspondence with the ASTMS union regarding the risk of contracting AIDS from blood products. The absence of conclusive proof of the transmissibility of AIDS

[584] https://twitter.com/bbcpolitics/status/1397508054900432899?lang=en-GB
[585] See Lord Glenarthur on 14 July 1983 @ PRSE0001886_0002
[586] ARCH0001710

through blood products is again relied upon.[587] He denied complacency and referred to measures in place to facilitate reporting of the disease, rather than prevention of its occurrence.[588] By the time of a further such letter dated 5 January 1984, it was accepted that there was, in fact, strong circumstantial evidence that AIDS was transmitted by blood products and that conclusive proof could only be achieved when the transmissible causative agent had been identified.[589] It is interesting to note that Dr Foster was the source of the argument being presented by the union in this correspondence. He was well informed and had attended international conferences regarding the matter. That his identity was not known at the time suggests that he was free to express his views without fear of professional reprisal. This, in our submission, makes the contemporaneous opinions expressed in these letters valuable evidence from an informed source of the known risks at that time. He confirmed in his evidence to the Penrose Inquiry that he told nobody about this other than Dr Perry who was also a member of the union.[590] It was known, for example, at this time that the long incubation period of the disease meant that the numbers of actual infections could not be taken as indicative of the number of known infections at any given time, both in the donor and the recipient population.[591] Further, it is interesting to note that Dr Foster considered there to be an air of fatalism about the Glenarthur correspondence.[592] Just because there was not conclusive proof was no reason to do nothing. Ultimately, Dr McClelland describe the line as "verging on a lie".[593]

4.48 The then Secretary of State for Health, The Rt. Hon Kenneth Clarke stated in answer to a parliamentary question on 14 November 1983 that "There is no conclusive evidence that AIDS is transmitted by blood products".[594] As is covered elsewhere in this submission, the evidence that AIDS had been contracted by recipients of blood products with no other risk factors, even in the United

---

[587] PRSE0004408
[588] PRSE0004408_0002
[589] PRSE0001727
[590] Penrose Inquiry transcript for 11/05/11 (day 23); 26 (22) to 27 (5) (Dr Foster); [PRSE0006023_0026 to 0027]
[591] PRSE0001259_0050
[592] PRSE0001259_0068
[593] IBI transcript for 28/01/22; 21 (Dr McClelland)
[594] PRSE0000886

Kingdom, was readily available. The extent of the real concern within the government is demonstrated by the fact that Dr Diana Walford attended the UKHCDO reference centre directors meeting on 19 September 1983, specifically due to the Department of Health's interest in AIDS.[595] At that meeting (prior to the announcement made by Kenneth Clarke) the death of a haemophiliac patient in Bristol was discussed and measures taken to follow up patients who had received the same products.[596]

4.49 The government's official message[597] was deliberately understated, in our submission, with the result that it misled the public (and the haemophiliac community) regarding the risks of blood products. In the absence of having isolated a virus responsible for the transmission of AIDS, one could hardly be expected to have conclusive proof about its aetiology and transmissibility. However, given the known severity of the disease and the strong evidence that it was being transmitted via blood products by the spring of 1983, we submit that the approach being taken by the government was insufficiently urgent and deliberately misleading from that point.

4.50 In his evidence to the Inquiry, Dr Brian McClelland made it clear that he considered the line taken by the government in this regard to have been misleading at the time.[598] This is a damning indictment of the government's deliberately adopted position. The explanation for the line relied upon was that there was a concern about alarming the public. This vague and inadequate explanation showed a disrespect for the right of the public to know the truth and a mismanagement of the response to the public health risk. Importantly, in reality, the message misled the public who heard the message, including those in at risk groups such as those receiving treatment for bleeding disorders and the recipients of blood transfusions.

---

[595] PRSE0003196
[596] PRSE0003196_0003
[597] The fact that the "no conclusive proof" line was an official message is confirmed by PRSE0001786
[598] IBI transcript for 28/01/22: 21(15) to (22) (Dr Brian McClelland)

4.51 It was noted in the agenda for a meeting of a sub-committee of the Committee for the Safety of Medicines that there were numerous bodies which were actively involved in the consideration of the AIDS problem and the development of reactive strategies. The need for cohesion in the plans adopted by these bodies and for good availability of information to them was noted. A system whereby representatives of these bodies could meet was clearly contemplated at that time.[599] It was perhaps predictable that the views reached by these different bodies would differ as, as Dr Winter pointed out in his evidence to the Penrose Inquiry, different bodies had different agendas and priorities. The UKHCDO, for example, was predominantly concerned with the management of bleeding disorders in the UK and was thus naturally inclined to be resistant to the abandonment or limitation of access to products which were used to ameliorate the lives of those suffering from those conditions. The Committee for the Safety of Medicines was primarily concerned with issues of safety but the haemophilia directors also required to consider efficacy and supply.[600] Dr McClelland observed in his evidence to the Penrose Inquiry that treatment decisions being the responsibility of clinicians was a recurrent theme in government minutes and other documents over the period where the AIDS risk was apparent.[601] This was echoed in the evidence heard by this Inquiry of the need for clinicians to have "clinical freedom", beyond the control or direction of government. What this approach failed to recognise was that government had the capacity to access the most informative and diverse information and collate and weight it most effectively and dispassionately in the interests of those at risk.

4.52 The risks of AIDS in various different areas are demonstrated clearly by the number of bodies taking an active interest in considering the problem. Professor Hann noted in his Penrose evidence that this was a period when they could have done

---

[599] Penrose Inquiry reference: **PRSE0002336**
[600] Penrose Inquiry transcript for 27/04/11 (day 16); 68 (18 to 22) (Dr Mark Winter); [PRSE0006016_0068]
[601] Penrose Inquiry transcript for 06/05/11 (day 21); 121 (3 to8) (Dr McClelland); [PRSE0006021_0121]

with a bit less democracy and a bit more guidance and that there were many views and many committees but not necessarily many decisions being taken.[602] He suggested that what was needed was an expert body to come to the best possible conclusions at the time, not many bodies just reiterating the same problems that everybody knew about.[603] In his view, this could only have been co-ordinated by government.[604] The lack of a central government advisory body in 1983 and 1984 indicated that there was a key failure over this important period to recognise the risks and the need for government, uniquely places as it was to rise above the clamour and take informed decisions in the public interest, to take a proactive lead. The evidence heard during the course of the Inquiry suggested that the key motivators for action within government were public expenditure and press attention, in particular in the evidence of Lord Clarke. It was therefore hardly surprising, against this defective structural background, where a fatal disease with a recognised latency period had not burst forth yet and become the pandemic which it would become and hence not generated the press attention that was needed to motivate the political machine into action, that those at the forefront of the risk (those exposed to blood and, in particular blood products) had become infected before that machine took very much notice.

4.53 In response to a public health crisis of this potential magnitude, of this severity and with this urgency, it was incumbent upon the government to appoint one multi-disciplinary advisory committee to formulate and oversee the implementation of a clear and co-ordinated policy for dealing with the disease. The need for such a forum was clearly recognised in 1983 but was not acted upon until 1985. The result of the lack of such a body being available to provide expert advice to the government in 1983 meant that undue reliance was placed on the advice of the UKHCDO, a body designed to consider and develop policy in relation only to the treatment of bleeding disorders and the position of which is considered below.

---

[602] Penrose Inquiry transcript for 06/05/11 (day 21); 53 to 54 (Professor Hann); [PRSE0006021_0053 to 0054]
[603] Penrose Inquiry transcript for 06/05/11 (day 21); 54 (21 to 25) (Professor Hann); [PRSE0006021_0054]
[604] Penrose Inquiry transcript for 06/05/11 (day 21); 55 (Professor Hann); [PRSE0006021_0055]

The response of the UKHCDO to the emerging threat of AIDS

4.54 The UKHCDO and its reference centre directors core group constituted a powerful force in decision making about the State response to the emerging threat of AIDS from blood and, in particular, blood products. As is discussed elsewhere in this submission, a disproportionate weight was placed on the position being taken by these clinicians (and one particular clinician, namely Professor Bloom) as to the correct approach to the risks. The rationale for the position which they took and thus the advice which they gave to governments was all based in the overwhelming priority given to continuing with the concentrates.

4.55 In the evidence heard by the Inquiry from government ministers, the "clinical freedom" was championed a means of the government evading ultimate responsibility when things went wrong in the medical sphere. In fact, given that the individual haemophilia clinicians were bound by the diktats of this group. What is more, Dr Winter described the group as being like a form of "club" where the views of the few at the top predominated. This approach to centralised decision making by a few core individuals had important ramifications for the care of haemophilia patient generally but also for the formulation of policy in the care of haemophiliacs in Scotland in particular. Decision making was not democratic and was far too bound up with the opinion of a key group of decision makers at the head. Dr Savidge had described it as a club with a few at its head.[605] It was clear that around the country, haemophilia directors followed the direction of this group without question. As was the case within government in Scotland, the policy which was formulated was based on an assumption that the reliance on commercial concentrates meant that a radical change in treatment policy was unachievable and thus decisions require to be made with those practical restrictions in mind. Of course, given its lesser reliance on commercial concentrates, its recent reliance on cryoprecipitate (in particular in Edinburgh) and

[605] IBI transcript for 01/10/20; 114 5o 115 (Dr Mark Winter)

the possibility of producing small pool concentrates, the risk assessment in relation to AIDS cried out for a different approach in Scotland than elsewhere in the UK. Temporary radical changes to treatment regimes were practically achievable and hence ought to have been seriously considered and ultimately adopted. However, the restrictions of the UKHCDO system contributed to the failure in this separate, Scottish approach to the risks taking place. Decisions were made (and advice issued to patient groups – see below) based on the restations of the supply situation in. the rest of the UK. That advice was followed in Scotland, thought its underlying rational and assumptions did not apply. The research priority of the UKHCDO is addressed elsewhere in this submission. It also played an important part in decision making in relation to the emergence of AIDS, both north and south of the border.

4.56 The minutes of the UKHCDO Hepatitis Working Party from 1 March 1983 are instructive as to the state of knowledge of the members of that group, and hence the UKHCDO, at that point in time.[606] The latest information was that there had been at least 10 haemophilia A patients reporting with the clinical symptoms of the disease (9 with no other pre-disposing factors) and three such blood or platelet transfusion patients. The disease had an incubation period of between 6 months and 2 years. Half of the haemophilia patients were already dead.[607] The total number of reported AIDS cases in the USA to 10 December 1982 was just under 800 [608] and the slow progression of the disease from the first presentation of symptoms to diagnosis was also known (meaning that it could remain hidden from detection based on clinical presentation).[609] Importantly as a result of this information and a consideration of the various theories about the aetiology of the disease the following statement was made:

---

[606] PRSE0002884
[607] PRSE0002884_0004
[608] PRSE0002884_0005
[609] PRSE0002884_0001

"All the epidemiological evidence is consistent with the existence of a transmissible agent whose mode of spread is remarkably similar to that of hepatitis B"[610]

4.57 This conclusion based on "all the epidemiological evidence" was reached by the UKHCDO, the organisation responsible for the treatment of patients with bleeding disorders in the United Kingdom. The evidence upon which it is based appears to stem at least in part from the period to December 1982. The urgency of the emerging AIDS picture in late 1982 is perhaps best summed up by the fact that the topic of AIDS was raised almost as an afterthought, possibly under "any other business" at the UKHCDO meeting in 1982.[611]

4.58 As is recorded above, Dr Mark Winter gave evidence to the Penrose Inquiry to the effect that by December 1982 any clinician looking at the available data (the MMWR articles available to that point) would have to believe that AIDS was a transmissible disorder and that it could be transmitted by blood and blood products. According to him, it was the only clinical interpretation of the data that was available.[612] Dr Winter (not a centre director by that stage and certainly not part of the UKHCDO "club") seemed to have been fully aware of this emerging picture in 1982. In light of that, it is surprising that Professor Ludlam (by then a centre director at Edinburgh for almost 3 years) saw fit to downplay his and other directors' apparent awareness of that publication in his evidence to that Inquiry and to say that "we [the haemophilia directors] weren't, apart from hepatitis, in the infectious diseases business".[613] The history of haemophilia care and the viral risk associated with it to that point, in particular the variety of pathogens which could emerge as transmissible, in particular from pooled blood products should have made it clear to clinicians like him that they were in the infectious diseases business, whether they had chosen to be or not. That did not seem to be the approach of "the club". It should have been based on brutal historic experience.

---

[610] PRSE0002884_0005
[611] Penrose Inquiry transcript for 03/05/2011 (day 18); 94 (20 to 23) (Professor Ludlam); [PRSE0006018_0094]
[612] Penrose Inquiry transcript for 27/04/11 (day 16); 8 (16 to 21) (Dr Winter); [PRSE0006016_0008]
[613] Penrose Inquiry transcript for 03/05/2011 (day 18); 95 (1 to 8) (Professor Ludlam); [PRSE0006018_0095]

What Professor Ludlam meant by that, it is submitted, was that they considered their main concern to be the control of bleeding and did not see the risk of emerging pathogens to be part of that role. It is hardly surprising, therefore, that they failed to appreciate and act upon the AIDS threat with sufficient urgency and that their advice to government and to patients via the Haemophilia Society was fatally unbalanced on that basis.

4.59 Interestingly, the Inquiry heard evidence from two haematologists who became government advisors and played prominent roles at different times in the blood contamination disaster. Dr Diana Walford was a UK government medical advisor at the time of the emergence of the AIDS crisis and at the time of rising awareness of the potential severity of NANBH, from the late 1970s until 1983. Dr Aileen Keel was an advisors in the SHHD and subsequently the Scottish government from 1992. She played a prominent role in various aspects of the disaster relating to Scotland. The role of each is discussed in some detail elsewhere in this submission. Dr Walford described that the UKHCDO was the main source of information for her about the way that haemophiliacs were treated in the period between 1979 and 1983. [614] She explained that she would not be provided with papers in reports in advance of meetings.[615] In fact, she quite often received reports quite a few months after they had been discussed at the UKHCDO meetings.[616] Minute also took a long time to arrive with her.[617] She did not routinely attend reference centre director meetings.[618] In her evidence she certainly gave the impression of being out of the loop with regard to the UKHCDO business. For example, she suggested that commercial products might start to be purchased centrally as she had no idea where it was all going. This led to no action as the haemophilia centres directors did not see it as a safety issue but an attempt to circumscribe their freedom to prescribe. This led to Dr Jones expressing some disquiet about her intervention on this important topic.[619] She described her presence as being tolerated and her

---

[614] IBI transcript for 19/07/21; 69 (Dr Walford)
[615] IBI transcript for 19/07/21; 72 (Dr Walford)
[616] IBI transcript for 19/07/21; 74 (Dr Walford)
[617] IBI transcript for 19/07/21; 76 (Dr Walford)
[618] IBI transcript for 19/07/21; 77 (Dr Walford)
[619] IBI transcript for 19/07/21; 78 to 81 (Dr Walford)

interventions as not particularly well received.[620] Dr Walford was, of course, as is examined elsewhere an advocate of the risks of NANBH and safety in treatment. This evidence shows that she was not and hence government was not invited into the inner sanctum of the UKHCDO. This is shown by the fact that she was not routinely invited to reference centre directors' meetings and that her interventions on safety were not welcomed but politely, though firmly rejected. Where the safety agenda was raised contrary to the perceived total clinical freedom of the directors, they did what they could to silence it. By way of contrast, as it explored in mor detail elsewhere in this submission, Dr Keel was someone who was welcomes into the club. As can be seen from her role in the Scottish executive investigation ordered by Susan Deacon, she proved to be a very much more accommodating external government observer, prepared to consult and defer to the *ipse dixit* of the haemophilia directors at every turn. The contrast between the way that these two government advisors, both trained in haematology were treated is illustrative of the control which the UKHCDO had over government policy. Where the government, with the ultimate statutory responsibility to maintain public health intervened, it required to play by the rules of this unelected club.

4.60 News of the infection of the San Francisco baby was described by Dr Winter in his Penrose evidence as a really critical moment.[621] According to him, there then developed a major split amongst the haemophilia clinicians as to whether it was likely that AIDS would be transmissible by UK concentrates as well, given (a) the relative safety of the voluntary blood donor system on the one hand and (b) the susceptibility of large pool concentrates to transmit viruses on the other.[622] It is interesting to note that the UKHCDO members appears to be alive by at least March 1983 of the risk to the domestic system of blood and blood product production could be at risk. As is noted elsewhere, the government thinking (informed by UKHCDO advice) and the information emanating from that body to bodies like the Haemophilia Society send to focus solely on the foreign threat. Dr

---

[620] IBI transcript for 19/07/21; 82 (Dr Walford)
[621] Penrose Inquiry transcript for 27/04/11 (day 16); 9 (3) (Dr Winter); [PRSE0006016_0009]
[622] Penrose Inquiry transcript for 27/04/11 (day 16); 9 (19) to 10 (6) (Dr Winter); [PRSE0006016_0009 to 0010]

Winter accepted that there was a body of expert opinion on that group which was concerned for the domestic supply. As ever, the lack of consensus and the lack of precautionary approach meant that action was neither advised nor taken at this crucial point in time, where the warning bell from the US had been rung, that warning had been heard by at least some on the UKHCDO, who appeared to understand the implications for the domestic supply. This was at a time when precipitate action could have prevented similar calamity in the population of those in receipt of domestically produced blood and blood products. Nothing had been done to exclude high risk donors such as homosexual men by this point. As Dr McClelland was later quoted in the Scotsman after the emergence of details of HIV infections of patients in Edinburgh through their use of SNBTS concentrates as admitting "it would not have been realistic to expect Scotland to be by-passed". Dr McClelland had liked to think that the infected blood had been given unwittingly but, as the article notes, the system had no real protection against this or deliberate donation by a member of a high risk group. [623]

4.61 The threat of AIDS to patients with bleeding disorders is mentioned in the minutes of the UKHCDO directors meeting of 13 September 1982 in the context of the July 1982 MMWR reports by Dr Evatt of the disease having occurred in three US haemophiliacs.[624] AIDS merits less than half a page in the minutes. The possibility of concentrates being involved in their infection is minuted as "remote"[625] (a word which does not appear in the Evatt article in the MMWR from July which states that the cases suggest "the possible transmission of an agent through blood products"[626]). In that article, the three patients are described as having no history of drug abuse[627], but one of the notes from the UKHCDO meeting refers to possible drug abuse in their histories, suggesting that some reference to that inaccurate state of affairs was made at the meeting.[628] In that version, the word "remote" is underlined. This comes at an early stage in the developing picture of HIV in the

---

[623] PRSE0002516 (22 December 1984)
[624] PRSE0004807 (13 September 1982)
[625] PRSE0004807_0010
[626] PRSE0000523_0002
[627] PRSE0000523
[628] PRSE0003751_0009 (Dr Boulton)

bleeding disorder community but it demonstrates that there was a lack of appreciation of the urgency and potential significance of the emerging situation for that community amongst those responsible for their treatment. In his evidence to the Penrose Inquiry, Dr Winter described the attitude of both patients and their doctors at that time as being "we really don't want to hear about any problems with them [concentrates] unless we can find a very convincing reason so to do".[629] That the patients were of this view is hardly surprising. It is of real concern that the doctors should take this view though they (unlike the patients) possessed the knowledge of the emerging serious risks and the knowledge that the patients in receipt of pooled products would be likely to be the first exposed.

4.62 As things developed, a special meeting of the UKHCDO reference centre directors was convened on 13 May 1983 to discuss the AIDS problem.[630] At the meeting, it was reported that there was one suspected case of AIDS in a haemophiliac in the UK (the Cardiff case, discussed elsewhere in this submission). It was considered important that patients with some evidence of impaired cell-mediated immunity should not be reported as AIDS cases on the basis that such patients may not develop the full-blown condition. This shows a dangerous lack of caution in light of the known consequences of the condition did turn out to be AIDS. Recent evidence existed of how the disease had started and how it had progressed in haemophiliac and non-haemophiliac patients in the US. Reference is made to the diagnostic criteria developed in the US on page 2. No restriction was proposed on the use of concentrates and the only restriction considered was on the use of imported concentrates. It was considered circumspect for clinicians who had already reserved a stock of NHS concentrate for use for mild patients and children under 4 to continue with that policy. These decisions in the form of guidance were communicated to haemophilia centre directors, including those in Scotland. No consideration was given to their different position.[631] The early reports of the emergence of the disease and its transmissibility by blood and blood products had been met in the US with a degree of incredulity in the face of evidence of

---

[629] Penrose Inquiry transcript for 26/04/2011 (day 15); 126 (5 to 8) (Dr Winter); [PRSE0006015_0126]
[630] PRSE0002212
[631] PRSE0000835 (24 June 1983)

transmission to haemophiliacs.[632] That attitude also prevailed when the infection arrived in the haemophiliac community in the UK with lessons not being learned from the US experience. Information was available from the US at the time of this guidance from the UKHCDO about the development of the disease in the gay population in the USA which suggested that the disease normally had a latency period of up to one year with no symptoms. However, it was understood to be the case that the infected person would be infective from the start of this period. Predicted mortality was 100%.[633] The material available from the US at this time is consistent with a serious disease, the prevalence of which would, by its nature, be near impossible to detect in donors. Given the knowledge of the transmissibility of the disease through blood and blood products, its severity and the experiences of similar disease such as hepatitis B, what was needed was decisive and firm guidance and immediate action. This does not appear to have been the nature of the reaction from those responsible for the treatment of patients with bleeding disorders at all.

4.63 In a publication dated August 1984, in a section about product prescription in the care of haemophiliacs written by Dr Charles Rizza, doctors within the NHS were told that the risk of AIDS from transfusion therapy was not clear, despite acknowledging that haemophiliacs had contracted the disease. The advice to the prescribing doctor was to carry on with the treatment regimes to which the patients had become accustomed.[634] In his parliamentary response on 14 November 1983, Kenneth Clarke had, in an apparent attempt at reassurance, pointed out that treatment was in the hands of local clinicians expert in the treatment of patients with bleeding disorders.[635] They were being guided (as late as 9 months after this) to carry on as if there were no risk at all.

---

[632] PRSE0000831_0004 to 0005

[633] This is amongst the information reported from the Stockholm conference attended by Dr Foster at which information about current knowledge and experiences was shared by Dr Evatt of the CDC in Atlanta - see PRSE0004071 (memo dated 15 July 1983)

[634] PRSE0003189_0010

[635] PRSE0000886

The convenience of medical uncertainty – the antigen overload theory

4.64 Much of the debate about AIDS at the time and much of the commentary by way of defence given by the UKHCDO in the aftermath of the disaster has focussed on the scientific uncertainty relating to AIDS, its transmissibility and hence the risk to those who were being treated for bleeding disorders in the UK. Throughout this submission, elements of the defence mounted by the medical community to the allegations made against it are addressed as is the evidence relating to the formulation of mantras or "party lines" trotted out by those responsible for the care of patients with bleeding disorders who became infected. These party lines emanate from the UKHCDO and have been repeated in so many places that they have developed to the status of medical truism in the collective mind of the profession. However, the legitimacy of these lines of defence must be examined. It is submitted that may will be found to be wanting in logic, evidential basis or reasonableness when viewed in their proper context. One important element of the defence relating to the infections with HTLV III is to be found in the approach taken to the scientific uncertainty surrounding the aetiology of the AIDS and hence the risk to bleeding disorder patients.

4.65 Under reference to an article by virologists Tedder and Barbara[636] and its claims about the qualities of viruses transmitted by blood, Professor Ludlam accepted in evidence to the Penrose Inquiry that it is in the nature of such viruses that they tend to have a sub-clinical initial phase.[637] This was known to the UKHCDO directors from as early as 1982, or early 1983 at the latest. It was clear from the notes of the meeting at Heathrow airport in January 1983 that this was accepted to be the nature of the condition. Their reaction to the news of transmission of a potentially lethal virus should have been informed by the knowledge that viruses transmitted by blood tend to have a lengthy sub-clinical period. A limited number of cases could, therefore, be, as some commentators did think at the time, merely

[636] PRSE0003183

[637] Penrose Inquiry transcript for 04/05/11 (day 19); 2(8) (Professor Ludlam); [PRSE0006019_0002]

the "tip of the iceberg". The incidence of the disease could not be taken to indicate the risk of future incidence.

4.66 Despite this evidence, haemophilia clinicians (such as Professor Ludlam) continued to pursue the hypothesis that symptoms of immuno-suppression in haemophiliacs might be caused by the overloading of their immune systems by their frequent concentrate infusions over a long period, known as the antigen overload theory. In our submission, this theory (a) disregarded the evidence of the San Francisco baby, deemed so influential to the opinion of Dr Winter (b) was very much outwith the generality of medical understanding and opinion at the time (Professor Lever confirmed that it was never the most prevalent theory based on the fact that there was no precedent for infection being caused by protein overload at that time[638]) (c) largely disregarded the temporal coincidence of the development of symptoms of immuno-suppression in the homosexual community in the USA and similar symptoms in haemophiliacs and (d) was based largely on research done in vitro which was not necessarily relevant to what happened in vivo.[639] Most importantly, the existence of this alternative theory did not absolve the clinicians from taking action to reduce the risk of their patients by reducing their exposure to factor concentrates. The general acceptance of the viral theory in itself was a sufficient basis upon which action should have been taken to reduce exposure of haemophilia patients to concentrates, in particular US concentrates. The fact that the antigen overload theory also deemed immuno-suppression to result from exposure to concentrates was also a reason to minimise that exposure, whatever theory one favoured as to the cause of the symptoms. As Professor Ludlam himself put it in his evidence, the genesis of the theory had been "that it was possible that AIDS was arising in haemophiliacs because during the 1970s there was increasing use, massive increasing use of factor VIII concentrates".[640] The alternative theory postulated in Professor Ludlam's 1983 paper (the HIV pre-infection cohort study) was that the immuno-suppression was caused by hepatitis which was transmitted by the concentrates. Immuno-suppression was the cause of the death of the

---

[638] Penrose Inquiry transcript for 18/05/11 (day 27); 30 (10 to 14) (Professor Lever); [PRSE0006027_0030]
[639] Penrose Inquiry transcript for 27/04/11 (day 16); 19 (4 to 15) (Dr Winter); [PRSE0006016_0019]
[640] Penrose Inquiry transcript for 03/05/2011 (day 18); 150 (2 to 5) (Professor Ludlam); [PRSE0006018_0150]

patients who had hitherto died of AIDS. Whether a subscriber to the viral transmission theory or not, that the concentrates caused immuno-suppression (and hence exposed the patients to a risk of serious disease including the opportunistic infections experienced by AIDS patients) caused either by antigen overload or hepatitis were both good reasons to limit exposure to concentrates anyway, or at least discuss these findings with the patients. The evidence heard by the Inquiry clearly shows that Professor Ludlam did neither. In his view, he did not use commercial products which was safer than some others and so he had immunity from criticism.

4.67 Professor Lever commented at length in his evidence to the Penrose Inquiry about the risks of antigenic overload and the introduction of foreign proteins into the body. He responded to the suggestion that the advantages of treatment made the downsides of such treatment a price worth paying by saying that that would be the case on the assumption that the amount of clotting factor being used was the minimum required to sustain normal clotting.[641] This was consistent with other evidence about the need that this approach be factored in to the assessment of what was safely achievable in the treatment of bleeding disorders. The evidence available to this Inquiry clearly suggests that the amounts being given to patients over this period were not controlled in accordance with that standard.

4.68 Professor Lever further expressed the view that the fact that haemophilia clinicians appeared to be less inclined to suspect a viral aetiology was due to their desire not to have to face up to the consequences of that situation.[642] Further, Dr Mark Winter informed that Inquiry that he became the local designated physicians for AIDS in his area as he "seemed to be the only doctor who knew anything of it."[643] He described the concept of "comprehensive care" for people with bleeding disorders as being based on a mistrust of their patients being allowed to go anywhere else in the hospital without them being involved.[644] Professor Lever

---

[641] Penrose Inquiry transcript for 17/05/11 (day 26); 105 (14 to 20) (Professor Lever); [PRSE0006026_0150]
[642] Penrose Inquiry transcript for 17/05/11 (day 26); 111 (9 to 25) (Professor Lever); [PRSE0006026_0111]
[643] Penrose Inquiry transcript for 26/04/11 (day 15); 44 (4 to 7) (Dr Winter); [PRSE0006015_0044]
[644] Penrose Inquiry transcript for 26/04/11 (day 15); 46 (3 to 16) (Dr Winter); [PRSE0006015_0046]

made it clear that clinical virology was emerging as a discipline at this time[645] and the material considered above makes it clear that evidence was available internationally and from other medical specialists which haemophilia clinicians may have been slow or unwilling to accept. The seeds of this approach had been sown in what Dr Winter described to the IBI as "the golden interval", the period between the presumed eradication of HBV by screening and the emergence of AIDS (see above for fuller analysis). Contrary to the view expressed by Professor Lever about the minimum intervention principle, over that period huge increases in the amounts of treatment being used had hugely and unnecessarily increased the risks. Bleeding control was unnecessarily and unsafely prioritised. Considerations of safety had been relegated to irrelevance. By the time it came to AIDS, treatment regimes could not be rolled back. The seeds had been sown for disaster.

4.69 Professor Ludlam's reluctance to face the possibility of a viral aetiology is demonstrated by the circumstances of one very interesting case of which evidence as heard by the Inquiry by a lady who gave evidence as Mrs U.[646] Her late husband was, in fact, treated by Professor Ludlam for acute myeloid leukaemia. He eventually died in GRO-B 1984. Later, it was discovered (by the HIV Lookback undertaken by Dr Gillon in 1986) that the patient had in fact been exposed to platelets from an HIV infected donor. Mrs U was not told until many years after that date, even although she herself was at risk of infection. Professor Ludlam only told her about the infection after a chance meeting in the 1990s. He had assumed that she had not had sexual contact with her husband (which was not true). She had been exposed to a risk of which she was not aware, could have been infected and could have infected others. As with his failure to discuss infections with at least some of his haemophilia patients for years (discussed below), this was, once again, an example of Professor Ludlam choosing what he considered to be best, as opposed to allowing them the right to choose for themselves. Her GP had also been aware since 1986. The evidence available to the Inquiry shows that the family

---

[645] Penrose Inquiry transcript for 18/05/11 (day 27); 19 (1 to 7) (Professor Lever); [PRSE0006027_0019]
[646] Mrs U (W0136) - Edinburgh 08/07/19

was, in fact, under the impression that the patient was being treated with blood and blood components donated by family members. Many did and were willing to do so. This, in fact transpired not to be the case. Mrs U had raised with him the issue of contaminated blood in around April 1983 when she had become aware of it as a possible explanation for her husband's distressing symptoms, which included oral thrush. She was told there were no risks from the transfusions as the blood was irradiated, which was inaccurate In his response to the Inquiry on the case Professor Ludlam pointed out that he had become aware in 1986 that the patient had been exposed to a positive platelet donation in December 1983. Further testing on stored samples showed he was HIV positive at the time of his death. The family had had concerns earlier that year that he had oral thrush, which could have been as a result of HIV infection from one of his multiple transfusions, in retrospect. Had Professor Ludlam been more open to the possibility of such signs in such patients being due to the viral agent causing AIDS (as was the case for the San Francisco baby in December 1982) which he was not due to being wedded to his antigen overload theory, he could and would have considered that possibility. A further discussion could have been had about ways to minimise the risk and more blood could have been obtained from safe family sources. As such, the risk of the infective blood being transfused in December 1983 would have been avoided. The widow also gave evidence that, tragically, she had another family member who died of the same condition as the patient, but in circumstances where the death was far less traumatic. She is now left with the very clear impression that the infection caused his traumatic demise. She has also been exposed to the trauma of knowing she had been at risk and may have infected her children. His actions have caused irreparable harm to her and her family. In addition, it is important to note that a greater openness to what might have been the cause of this man's particularly bad symptoms, including the candida known to be associated with AIDS may have led to a greater openness in Professor Ludlam's mind about the dangers to his haemophilia patients. A lesser reliance on the need for conclusive proof of the viral aetiology, against the background of the known possible risks to the Scottish (in particular the local Edinburgh) donor population may not only have prevented the infection of this patient bus also of

the Edinburgh haemophilia patients who also contracted HIV infections after 1983. Yet another opportunity for reflection and change in the interests of patient safety was missed. Oral thrush was in fact the indicative condition which was involved in the diagnosis of the Cardiff patient, which, in his oral evidence, Professor Ludlam was so keen to argue did not meet the diagnostic criteria for AIDS. The case is also clear evidence that Professor Ludlam retained blood samples of deceased patients without the knowledge of the family.

4.70 This reluctance to accept advice from elsewhere, to face up to the evidence and to accept the fact that concentrates could be the problem was a cause of ongoing endangerment of their patients and stemmed not only from a reluctance to stop using concentrates which had been so successful but also from a realisation that if the theory were true, it was possible that many of their significantly exposed patients could be infected, in particular beyond Scotland where patients had been exposed to large amounts of US derived products. The denial of those beyond Scotland was certainly unfortunate. For those in Scotland, however, this was a head in the sand approach, derived from the English fatalism that doing anything now would in any event be too late, which would prove to have fatal consequences as many of the infections had not yet occurred, they could and should have been prevented.

International evidence

4.71 Access to important international information or failure to appreciate its importance also seems to have been a factor which affected the UKHCDO's decision making. By the time of the time of the agenda for the Council of Europe blood transfusion experts meeting in May 1983 being circulated on 28 April 1983 cases of AIDS amongst the haemophiliac/blood transfusion population had been

reported in Austria (1 suspected), Belgium (1), the Federal Republic of Germany (2), Spain (3) and Finland (1 suspected)[647].

4.72 It was part of the Council of Europe's Recommendation R83(8) that efforts should be made "to expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factor products".[648] Further, it was recommended (a) to avoid **where possible** the use of coagulation factor concentrates prepared from large pools (especially **but not exclusively** in countries where self-sufficiency had not been achieved) and (b) to inform attending physicians and selected recipients, like haemophiliacs of the potential hazards of haemotherapy and the possibilities of minimising the risks (emphasis added). Part (b) of this recommendation is discussed elsewhere in this submission as are the implications for this recommendation on the responsibilities of government. However, its significance for what ought to have been expected of haemophilia clinicians based on its revelations about then current consensus thinking, reached within an internal organisation drawing on a wide range of experience and opinion is also worthy of comment. This Recommendation was made specifically "considering the growing importance of a new and severe health hazard, Acquired Immune Deficiency Syndrome (AIDS), that may be caused by an infectious agent transmissible by blood and blood products". This recommendation was therefore made at a time when this international body considered the risk to be great enough, even in countries which drew heavily or exclusively on their own products, that action required to be taken in the form of reducing exposure to concentrates made from large plasma pools. A leaflet prepared by the American Red Cross is attached as an appendix for the assistance of national blood transfusion services in the preparation of similar leaflets. No attempt was made to classify AIDS as an American problem. In his evidence to the Penrose Inquiry, Dr McClelland was of the view that the Council of Europe recommendations were mostly transfusion focussed and would not have been considered much by clinicians.[649] Given that their content shows an international

---

[647] PRSE0003366

[648] PRSE0000526 (23 June 1983)

[649] Penrose Inquiry transcript for 06/05/11 (day 21); 116 (8 to 21) (Dr McClelland); [PRSE0006021_0116]

concern which is relevant to those clinicians' patients, any limitation on the disseminated of these views amongst haemophilia clinicians was completely unreasonable.

4.73 The recommendation that factor concentrates made from large pools should be avoided "where possible" is also instructive. This phrase should be construed as having two relevant implications for Scotland. The first is that, unlike in England, the total avoidance of factor concentrates was possible in Scotland, especially in 1983 when the amount of plasma was sufficient to support a surplus of factor VIII concentrate being developed at the PFC, according to Dr Perry.[650] Self-sufficiency was achieved in Scotland in 1983. It could have been achieved with a reversion to cryoprecipitate on a temporary basis as it had even better yields than concentrate. The second is that the reasonable interpretation of this phrase is that even where complete avoidance was impossible, it was logical that reduction, if not total avoidance of concentrates would also be beneficial. This is important as even in countries where total avoidance may not have been possible, reduction would still have been a recommended step to take in the interests of safety, this reducing the total donor exposure of each patient. Reducing treatment in total and reducing the amount of that treatment given by way of concentrate is clearly what was recommended. Neither happened in Scotland. Either could have been achieved. The failure to do so represented a failure to obtemper the first branch of this Council of Europe recommendation and materially increase the risk of infection for patients.

4.74 In a characteristic attempt at self-exoneration, Professor Ludlam also claims that the recommendation has not been circulated to him. It would, of course, be damaging to his position of it could be shown or inferred that he is likely to have seen it. This is base it recommended limiting the use of concentrates, which eh die not do. It also recommended telling patients of the risk, which he did not do either. It is submitted that as a result, this is another example of Professor Ludlam seeking *ex post facto* to give a certain impression which tends to exonerate his conduct at the time. the true position is that he is unlikely to remember, however, he was

[650] IBI transcript for 31/03/22; 126 (Dr Perry); PRSE0001576 – 18 November 1983

keen to suggest that he did not think he had seen it, to create this distance and suggest that someone else was at fault for not having shown it to him. Clearly, the recommendation should have been brought to the attention of haemophilia clinicians in positions of responsibility like Professor Ludlam by the government. As is submitted elsewhere, it should also have come with advice that it should be followed (in the form of a CMO of Scottish CMO "Dear doctor" letter or something equivalent). The reasons why this did not happen and the intervention of Dr Gunson are discussed elsewhere in this submission. Contrary to his wish, this failure should not exonerate clinicians like Professor Ludlam either. Irrespective of the terms of the recommendation, sufficient compelling evidence which mandated action which was not taken was available from other sources, as is argued elsewhere in this submission.

4.75 The information communicated by Dr Bruce Evatt to the WHO/ISTH conferences in Stockholm in June 1983 is summarised in the Memo referred to above by Dr Foster (who attended) to Dr Watt.[651] That information, as detailed above, could have been and should have been considered by the UKHCDO at least by the time of its dissemination at that conference, if not sooner and appropriate urgent guidance issued. Separate bespoke consideration of its implications could and should have been undertaken in Scotland. A number of mainly European delegates were concerned that they were only seeing the tip of the iceberg, given **the latency** period of the disease and the consequent (a) difficulty with identifying infected donors and (b) delay in the emergence of symptoms amongst the recipients of blood and blood products. They were right.

4.76 **A**t the full meeting of haemophilia directors which took place on 17 October 1983 (which did not meet again until 27 September 1984[652]) Dr Chisholm raised the issue of certain of his patients having refused commercial concentrates due to the AIDS "scare" and posed the question as to whether the directors could revert to using cryoprecipitate for home therapy.[653] Professor Bloom responded to the effect that there was no need for this switch to occur on the basis that there was

---

[651] PRSE0004071
[652] PRSE0004440_0010
[653] PRSE0004440_0010

no proof that commercial concentrates were the cause of AIDS. This was simply inaccurate on the evidence and is indicative of the mindset of the leading haemophilia clinicians of the age, also a key (or perhaps the key) government advisor on these matters at that time. The absence of conclusive proof had, by this stage, been taken to mean that the issue of changing treatment to minimise the risk was simply not an option with which the directors needed to worry themselves. The presence of the risk, however mandated that they must. Professor Bloom appears to have been unable or unwilling to acknowledge any risk at all.

4.77 The meeting minute records that Dr Chisholm replied that, in addition to the safety issue, there were also problems with the supply of commercial concentrate in her region but that she could get unlimited supplies of cryoprecipitate. Other directors reported the same problems. Despite this, it was agreed at the meeting that patients should not be encouraged to switch to cryoprecipitate for home therapy but should continue to receive concentrates in their usual way.[654] No discussion took place about the possibility of reducing home therapy, either on the grounds of safety or on the grounds of supply. The inclination of Dr Chisholm to take action seems to have been corporately overruled. No consideration was given to a reduction of home therapy or a reversion to cryoprecipitate even on a temporary basis. No consideration was given to advising patients that they should use the minimum quantity of concentrates necessary on home treatment. This strategic commitment to concentrates was based on an inaccurate statement by Professor Bloom. As noted above, there was indeed strong proof by this time that AIDS was caused by a transmissible agent borne by blood and blood products. It seems likely that this poor decision at the last meeting of the directors until the autumn of 1984, by which time many of the patients with bleeding disorders who contracted HIV had become infected, formed the basis of many of those patients continuing to receive the concentrates which infected them. This decision was made against a background of two haemophilia patients having become infected in the UK and Dr Craske seeking to instigate investigations into the AIDS cases and into "suspect

[654] PRSE0004440_0010

batches of concentrate".[655] Such investigations indicated that there was clear knowledge of an emerging crisis. The approach taken was limited to this reactive line when a proactive one was merited.

4.78 It is interesting to note that the resistance to the line being proposed by Dr Chisholm emanated from Professor Bloom, the then Chairman of the UKHCDO. At the Penrose Inquiry, Dr Winter was asked about why he thought that Professor Bloom had commented that there was no proven case of AIDS in the UK haemophilia population in his comments in the Haemophilia Society letter to its members in May 1983 when other evidence suggested that he really must have known at least of a postulated case as the patient was in his centre in Cardiff (this particular matter is addressed elsewhere in this submission). His response was to propose that Professor Bloom was the head of the centre and, like many of his generation, were not clinically trained. This, he suggested, may have meant that he may not have been aware of the patient.[656] Dr Winter expanded upon this later in his evidence when he explained that there was a "sea change" in the training of haematology doctors in 1976 as from that point onwards it was no longer possible to become a consultant haematologist without having clinical training. He said that older doctors before this period "weren't used to looking after very sick people".[657] It is remarkable that individuals with this training and attitude should have been allowed to make important strategic decisions or reject clinical proposals such as that made by Dr Chisholm. Senior figures who had come from this laboratory-based background were deemed to be the representatives of the patients on important government advisory committees at the time of the AIDS crisis. The approach at that time, as at all times, should have been focussed on the safety of the patients. An individual based in a laboratory seems hardly likely to have been well equipped to adopt such an approach.

4.79 Further, it should be noted that there were other places in the world where haemophilia clinicians made radical changes to their prescribing practices in light

---

[655] PRSE0004440_0010
[656] Penrose Inquiry transcript for 27/04/11 (day 16); 41 (2 to 12) (Dr Mark Winter); [PRSE0006016_0041]
[657] Penrose Inquiry transcript for 27/04/11 (day 16); 165 (19) to 166 (23) (Dr Mark Winter); [PRSE0006016_0165 to 0166]

of the emerging AIDS threat. Dr Oscar Ratnoff stopped using concentrates completely "even though it had practical implications".[658]

4.80 It would be a reasonable inference from the contemporaneous evidence that the leaders of the UKHCDO had reached the view by 1983 that if the disease which appeared to have been transmitted to haemophiliacs in the US was transmissible and did pose a threat to their patients that there was little they could do. Their patient shad been treated with the same products as the US patients, in large quantities. Despite the clear hepatitis risks, they had no decreased exposure but increased it since these products had been licensed in 1973 and subsequently. If there was a deadly virus with a long latency period, the incidence of which they were aware in the US was (as was opined at the time) the tip of the iceberg. Their patients would have been similarly exposed and there was little they could do. This inference would explain the apparent denial in the attitude being adopted within the UKHCDO of the existence of any risk and the unwavering adherence to the continued use of US concentrates at the same level as before – the patients may as well continue to derive the perceived benefits for their bleeding disorders from their treatment regimes. It would also explain the apparent denial of Professor Bloom to recognise that the first UK haemophiliac infection was literally staring him in the face in his own centre (analysed elsewhere in this submission). This position of denial was hardly, however, a reliable basis upon which advice could be given to government. It was not a reliable basis upon which advice could be promulgated to the directors of patients who had not been exposed to commercial concentrates at all, or in the quantities of some more severe patients. The need to have a clear policy message to continue to treat the severe haemophiliacs was to the detriment of those who could still be saved from infection, including those patients in Scotland who had only been exposed to domestically products which were not yet infective.

4.81 However, for the UKHCDO leadership to advocate that the Scottish directors adopt a different approach in Scotland would be to admit that Scotland was in a position

---

[658] Penrose Inquiry transcript for 27/04/11 (day 16); 21 (17) to 22 (7) (Dr Winter); [PRSE0006016_0021 to 0022]

to make changes in the interests of patient safety where the rest of the UK could not. It would have shone a light on the fact that the failure to make the advances towards self-sufficiency which had been contemplated by the government policy dating back to the 1970s had exposed patients to a risk which could not be obviated or minimised. In Scotland, the earlier adoption of the policy and the benefit of the money made available by government to had made self-sufficient in Scotland an achievable aim (though it had not yet been achieved). This state of affairs can hardly have been an incentive for the leaders of the UKHCDO to point out to the Scottish directors that they could take a different course as by doing so they would be opening up a route to the English failures being very clearly exposed. This would have been all the more problematic as changing of treatment regimes for risk minimisation would have involved some discussion at least with patients, who would have questioned why this was happening. That would have resulted in the risks coming to light within the patient community, thus the Haemophilia Society, who would have raised more questions about the real extent of the risks. The result of this is that generic advice based on the English position was all that was issued though it was formulated on a factual basis not applicable to Scotland.

Communication of the risk and advice at the UKHCDO level to patients

4.82 As is identified in the preceding paragraphs the early spring of 1983 constituted a pivotal point in time in the fights against AIDS. The internal discussions and deliberations about the AIDS crisis are of course important but equally important was what was said by the UKHCDO to at risk bleeding disorder patients. A letter was sent out by the Haemophilia Society in May 1983 which contained advice from Professor Arthur Bloom, then Chairman of the UKHCDO, regarding the emerging AIDS risk.[659] In the letter Professor Bloom's words are quoted directly. He said, in

[659] PRSE0000330

an attempt to downplay the risk that *"AIDS...has not yet been proven to result from transmission of a specific infective agent in blood products"*.

4.83 In the first place, it is interesting to note that the advice from Professor Bloom comes against the background of the first known case of AIDS in a haemophiliac emerging. In our submission, Professor Bloom must have known about this as it was in his own centre in Cardiff. A Department of Health memo dated 6 May 1983 refers to the diagnosis of AIDS in the male haemophilia patient in Cardiff with haemophilia appears to be confirmed. It appears that the case was reported in the first week in May 1983.[660] In his letter to Dr Field, Dr Galbraith describes the haemophilia patient infected with AIDS in Cardiff as "Professor Bloom's case".[661] He had been ill for a month by that time. Further, it seems to have been assumed once details of this case emerged that the patient had been infected by commercial product but he received NHS concentrates as well as US imports.[662] There was information of 3 haemophiliacs in Spain thought to have been infected with AIDS by this time. As was the case with the government line spun to the public at this time, the focus was on the lack of conclusive proof that AIDS was be caused by a virus transmitted through blood products. The message given by Professor Bloom at this crucial time is certainly not the whole truth. This letter would not only have been read by patients but also by those treating patients with bleeding disorders. Matters in the letter were described as "highly contentious" and "misleading" by Dr Peter Foster in subsequent correspondence with his union.[663] The Inquiry should find them to have been so.

4.84 Further, his reliance on the non-emergence of AIDS cases amongst the recipients of blood products in Germany is factually inaccurate. By the time of the agenda for the Council of Europe blood transfusion experts meeting in May 1983 being circulated on 28 April 1983, two confirmed cases of AIDS amongst the haemophiliac population had been reported in the Federal Republic of

---

[660] PRSE0003286

[661] PRSE0003286_0002

[662] PRSE0004071_0002

[663] PRSE0001259_0053 to 0054

Germany.[664] In any event, it was certainly known by this time that the number of infections based on the number of reports of the disease were notoriously unreliable, given the fact that it took some time for symptoms to emerge. The conflation of incidence and risk was misleading. Professor Bloom made no mention of the unreliability of incidence figures in calculating risk which, of course, is what the audience of his letter wanted his advice about. It is interesting to note that, in terms of the subsequent Council of Europe Recommendation R83(8), it was recommended that information about the risks should be given to selected recipients of blood and blood products. Haemophiliacs are named specifically.[665]

4.85 In his evidence to the Penrose Inquiry, Professor Lever contrasted the position being taken by Professor Bloom in his advice to the Haemophilia Society and that given by Dr Galbraith only a few days later from an infectious diseases point of view (in connection with which, see submission above). He stated that Dr Galbraith had a duty to apply a precautionary principle in the public interest.[666] His position was therefore unequivocal. This was contrasted with the position of Professor Bloom who came at the problem from a haemophilia clinician's perspective.[667] A greater balance between the two extremes and proper, candid balancing exercise in the patients' best interests and involving patients was mandated. It is interesting to note that, at that time, Professor Lever confirmed that there would be consultant virologists in all large hospitals and access to virological advice in all hospitals in the UK.[668] He pointed out that links through the requirement to treat chronic infections with diseases like hepatitis B would already have been established between haemophilia clinicians and virologists.[669] Such infectious diseases experts would have been likely to have had a broader perspective and a deeper understanding of the emerging infection at that time.[670] Haematologists

---

[664] PRSE0003366_0004
[665] PRSE0000526_0002
[666] Penrose Inquiry transcript for 18/05/11 (day 27); 12 (4 to 9) (Professor Lever); [PRSE0006027_0012]
[667] Penrose Inquiry transcript for 18/05/11 (day 27); 12 (12 to 17) (Professor Lever); [PRSE0006027_0012]
[668] Penrose Inquiry transcript for 18/05/11 (day 27); 15 (22) to 16 (12) (Professor Lever); [PRSE0006027_0015 to 0016]
[669] Penrose Inquiry transcript for 18/05/11 (day 27); 17 (16) to 18 (2) (Professor Lever); [PRSE0006027_0017 to 0018]
[670] Penrose Inquiry transcript for 18/05/11 (day 27); 21 (4 to 10) (Professor Lever); [PRSE0006027_0021]

giving evidence to the Inquiry seemed to be unaware of the Galbraith recommendations at the time (as explored above). This suggests that the advice of virologists may not have been sought or, if sought, was not understood. As is discussed below, it was certainly not communicated to patients.

4.86 The overly optimistic tone of Professor Bloom's advice was, in our submission, entirely wrong for the moment. It was misleading. It is a reasonable inference in the context of the plentiful evidence heard by the Inquiry about the general lack of information about risk being shared with patients with bleeding disorders that it was the continuation of a deliberate policy of the UKHCDO not to share the whole truth about the risks with the patients, in the knowledge that precipitate action would always be required to prevent infection of patients exposed to pooled products. It must have been the case that this line was expected to be followed by the other UKHCDO directors. It would cause considerable difficulty if individual directors took a different line to that which had already been disseminated to many patients via the Society. That this line was a policy of the UKHCDO which would be followed elsewhere around the country is supported by the plentiful evidence heard from haemophilia clinicians of the day in answer to criticisms about their failures to share the risk with their patients that the patients had access to information via the Society. This was the information and advice to which they had access, supporting the line taken by so many patients in their evidence that they did not receive information about risks via their clinicians. The time had some for an urgent rethink of strategy and a minimisation of the exposure of patients to concentrates which, by this time, were known to be potentially infective. The wait and see attitude which the advice from Professor Bloom advocated was typical of a system which was ill-equipped to deal with the urgency and potential severity of the situation.

<u>The Cardiff patient</u>

4.87 There is another aspect of the evidence heard by the Inquiry in this regard which merits close attention, namely the evidence about what was known about the infection of the Cardiff patient in 1983. It is notable that, despite his position in numerous areas being that he could not remember, Professor Ludlam had a good deal to say about the Cardiff case in what appeared to be an unsolicited attempt not to dela with matters on which questions had been directed to him about his persona experience of the disaster but in an effort to exonerate his former mention, Professor Bloom. The thrust of Professor Ludlam's contrived attempt to suggest that the Cardiff patient was that the Cardiff patient did not meet the diagnostic criteria for AIDS in 1983. It seems hard to understand how Professor Ludlam thought that he would be able to prove his hypothesis when the Inquiry and not he had access to the medical record of the patient. His attempts to exonerate Professor Bloom show a disregard for the evidence and the willingness of the haemophilia clinicians of the day to seek to defend each other in an attempt to avoid criticism. This significantly undermined his credibility. The presentation made by the Inquiry on the subject shows clearly that the patient did fit the diagnostic criteria and that the patient was rightly diagnosed at the time of the May 1983 Society letter.[671] The presentation referred to a 14 March 1983 entry "unwell since after Xmas. Lost 1 stone, loss of energy, sleeps all the time. 51 or 57 kg" and a lab form dated 17 March 1983 which stated "? AIDS". It was first recorded as a potential diagnosis 3 days after the patient's presentation with symptoms including groin lymph nodes and severe oral candida.

<u>The emergence of knowledge about the risk of AIDS in the Scottish donor population</u>

Knowledge about the risks of viral transmission in Scotland

[671] IBI transcript for 2/02/21 (presentation on Cardiff AIDS case)

4.88 It was well understood throughout the relevant period that greater risks of viral transmission were associated with products which (a) were derived from larger donor pools and (b) came from the USA (partly because of pool size there being greater and partly because the plasma as collected from paid donors which increased the risk of high risk donors contaminating the products). It was due to this that the treatment regime in Edinburgh before the arrival of Dr Ludlam had been focussed on the use of locally produced cryoprecipitate. In his Penrose evidence, Dr McClelland pointed out that in Edinburgh the main treatment for haemophilia A patients had been with cryoprecipitate under the Dr Howard Davies regime prior to 1980.[672] The reasons for this, he explained, were based on elementary biology that the less donors one was exposed to, the less chance there would be of contracting something nasty from the product and the less foreign product one had, the less likely it was to that patient would contract a new virus from elsewhere.[673]

4.89 Professor Hann did not become the director at Yorkhill until 1983. However, when asked about the attitude to the risks associated with products he pointed out that it was thought that the concentrates all carried a very high risk of transmitting hepatitis[674] with the result that, if one accepted that concentrates had a part to play in therapy, the issue of viral transmission became more of a neutral consideration in product selection. In his evidence, Professor Ludlam said that haemophilia clinicians were in the bleeding business, and not the infectious diseases business.[675] By the start of the 1980s (in particular before the more convincing evidence regarding the severity of NANB hepatitis which emerged in print in around 1985) it would appear that the haemophilia clinicians had become used to not according viral transmission a very high priority in their choices of treatment. Such clinicians should have been aware of the possibility of new viral

---

[672] Penrose Inquiry transcript for 06/05/11 (day 21); 153 (11 to 14) (Dr McClelland); [PRSE0006021_0153]
[673] Penrose Inquiry transcript for 06/05/11 (day 21); 153 (19) to 154 (2) (Dr McClelland); [PRSE0006021_0153 to 154]
[674] Penrose Inquiry transcript for 06/05/11 (day 21); 22 (92 to 10) (Professor Hann); [PRSE0006021_0022]
[675] Penrose Inquiry transcript for 03/05/2011 (day 18); 95 (1 to 8) (Professor Ludlam); [PRSE0006018_0095]

threats and also weighed up carefully the advantages of treatment choices against the risk of both known and potential viral agents.

Lack of action to mitigate the risks

4.90 The evidence considered above about the emerging threat of AIDS involved predominantly the UK response to the threat, seen as a foreign threat emerging only as an issue in the UK due to its importation of US factor concentrates. The response was governed by considerations which did not apply to Scotland and were in any event inappropriate in light of the available evidence. In any event, the threat of the disease in Scotland based on that background knowledge about the foreign experience also indicates that more urgent action was merited than was taken to prevent HIV infection in Scotland.

4.91 Dr Brian McClelland was aware of evidence that had started to emerge in July 1982 which showed that AIDS was transmissible by blood. He decided that it was important to take action to reduce the risk to transfusion recipients. In his evidence to the Penrose Inquiry at Dr McClelland referred to the emerging risk and the knowledge that there was a threat, particular to his local area. In 1983, two local papers had suggested that AIDS could become a problem in Edinburgh. It was specifically suggested that Edinburgh may become the "AIDS capital of the north" based on the influx of visitors which it would expect in the summer of that year in the Edinburgh Festival.[676]

4.92 The evidence available to the Inquiry demonstrates that Dr McClelland was right to be concerned about the risk of the causative agent of AIDS entering the Scottish donor population from 1982. Infections were caused which emanated from the donor pool from at least that time, based on the information which was given to the Penrose Inquiry about the likely timing of infections. This analysis was conducted on the samples of blood which had been stored of haemophiliacs which

[676] PRSE0002627_0002

enabled historic testing to be undertaken when tests for anti-HIV became available from 1984. The tables which resulted show that one infection in Glasgow attributed to HIV infection show that at least one patient whose treatment was attributed to PFC product was infected by November 1982 (patient G7 in table 3.17). the donation or donations which rendered this product positive must have come from a donor or donors who made his/ their positive donation(s) well before November 1982 to take account of the time taken for the plasma to be processed, for the product to be administered to the patient and for the patient to exhibit a positive antibody response in the stored sample capable of triggering a positive test. The Scottish system (which was assumed by many, including Professor Ludlam whose white cell research published in 1983 was predicated upon the scientific assumption that his patients treated with could not have been exposed to the agent which caused AIDS[677]) had been breached by the killer virus by 1982 at the latest.

4.93 The emerging threat from AIDS in Scotland was not acted upon with sufficient speed or effectiveness. Dr McClelland was somewhat of an outlier in the Scottish medical community, despite evidence being available of the risks and, importantly, the opportunity existing for steps to be taken to avoid them. The issue of communication of the risks amongst relevant groups is discussed below.

4.94 Fora existed within Scotland for the consideration of what an appropriate response to the precenting the risk of AIDS transmission from blood or blood products in Scotland might be. A meeting of the Haemophilia and Blood Transfusion Working Group in Scotland took place on 22 March 1983, again at a crucial period which offered the opportunity for action to be taken which would have prevented infection.[678] It was noted that in the USA and Canada the AIDS problem had caused there to be a move away from the use of factor VIII concentrate to cryoprecipitate with resultant problems of supply. A concern about AIDS spreading to UK was also noted in the next sentence but no proposals were discussed about whether a policy change as regards product use should be

[677] PRSE0001303 (28 May 1983); and PRSE0001987_0002 (30 June 1984)
[678] PRSE0000728

considered or product availability there would me to meet it.[679] The transfusion directors were loathe to ask questions of potential donors but "it was hoped" that homosexuals and others at risk would be deterred from donating blood. In light of the recognised risk that AIDS may become a problem for the recipients of blood and blood products in the UK, it appears remarkable that the directors seemed to think that at risk donors would be discouraged from donating without any measures being out in place to ensure that happened. The risk was clearly recognised at this meeting but not acted upon. Haemophilia directors were aware of that from this meeting.

4.95 In his evidence to the Penrose Inquiry, in response to questions relating to a meeting in May 1983 and a document emanating from it, Professor Forbes indicated that, in light of the fact that there had been patients found to be HIV positive in the UK "we had no problem in saying that there was a potential for contamination of blood products even from local, home grown sources. So that was always a concern, that HIV would come into the donor population of the UK. And that has already happened". Despite this when asked about his reaction to that state of affairs, he answered by saying that "we were scratching our heads" and treatment was favoured over non-treatment.[680] He gave no indication that changing the type of treatment or reducing the amount of treatment was contemplated. Later in his evidence, under reference to a statement from Dr Sandy Macmillan who had pointed out that he had started to see patients with AIDS in the GUM department from early to mid 1983, Professor Forbes confirmed that Dr Macmillan had been part of their team and that he had been aware of these patients with AIDS in Scotland (though he could not commit to the time frame).[681] He was based in Edinburgh and Professor Ludlam also had professional contact with him.[682] One can deduce from his contact with Dr Macmillan in Edinburgh and in light of the anxiety in the haemophilia world that it seems likely

---

[679] PRSE0000728_0002
[680] Penrose Inquiry transcript for 28/04/11 (day 17); 110 (19) to 111 (11) (Professor Forbes); [PRSE0006017_0110 to 0111]
[681] Penrose Inquiry transcript for 28/04/11 (day 17); 121 (3 to 6) (Professor Forbes); [PRSE0006017_0121]
[682] Penrose Inquiry transcript for 04/05/11 (day 19); 23 (1 to 3) (Professor Ludlam); [PRSE0006019_0023]

that haemophilia clinicians would have known about the emergence of AIDS in Scotland by at least mid 1983.

4.96 Further, Dr McClelland in his Penrose evidence had a definite recollection of having had meetings with Dr Macmillan and Derek Ogg in the first half of 1983 at which he was told about his patients showing signs of a new form of immune deficiency. In the context of the information available about the nature of AIDS in patients in the US, this was a clear indication that AIDS had arrived in Scotland.[683] Dr McClelland accepted that his contact with Dr Macmillan indicated to him that the Rubicon had been crossed by this stage.[684] By the spring of 1983 the signs were such that the transfusion service needed to do something about it.[685] Dr Bouton also indicated in his Penrose evidence that by summer 1983 there was a concern in the blood transfusion service in Edinburgh not just about potentially infected homosexual donors but also about drug users giving blood in Edinburgh.[686] By that time there was a concern about the possibility that HIV had entered the donor population then or that it would do so imminently.[687] This information could and should have been clearly and swiftly relayed to Professor Ludlam, their colleague in Edinburgh and indeed to all haemophilia clinicians in Scotland. Dr McClelland indicated that he recalled having communicated this information to clinicians "quite early on" but his testimony in this regard as to when and how this was done was extremely vague.[688] He later accepted that he did not think that there was inter-disciplinary sharing of how close the risk might be.[689] At the same time, there was an ever-increasing demand for concentrates.[690]

---

[683] Penrose Inquiry transcript for 06/05/11 (day 21); 130 (14 to 27) and 135 (1 to 11) (Dr McClelland); [PRSE0006021_0130 and 0135]
[684] Penrose Inquiry transcript for 06/05/11 (day 21); 134 (22 to 25) (Dr McClelland); [PRSE0006021_0134]
[685] Penrose Inquiry transcript for 06/05/11 (day 21); 135 (22) to 136 (2) (Dr McClelland); [PRSE0006021_0135 to 0136]
[686] Penrose Inquiry transcript for 12/05/11 (day 24); 30 116 (19) to 117 (3) (Dr Boulton); [PRSE0006024_0116 to 0117]
[687] Penrose Inquiry transcript for 12/05/11 (day 24); 117 (21) to 118 (2) (Dr Boulton); [PRSE0006024_0117 to 0118]
[688] Penrose Inquiry transcript for 06/05/11 (day 21); 133 (11 to 18) (Dr McClelland); [PRSE0006021_0133]
[689] Penrose Inquiry transcript for 06/05/11 (day 21); 137 (22 to 25) (Dr McClelland); [PRSE0006021_0137]
[690] Penrose Inquiry transcript for 06/05/11 (day 21); 141 (6 to 11) (Dr McClelland); [PRSE0006021_0141]

4.97 Information consistent with AIDS having arrived in Scotland even appeared in print at that time.[691] In his evidence to the Penrose Inquiry, Professor Ludlam accepted that he was aware of the possibility that people (meaning potential donors) might become infected in Scotland and that they required to keep their antennae out.[692] He also accepted that they knew it would arrive but did not know when due to the long incubation period.[693] Indeed, it was a probability that AIDS would arrive in Scotland.[694]

4.98 This evidence is indicative of a distinct lack of urgency and decisive action by haemophilia directors and the SNBTS in light of the known and accepted risk that positive donors might have given blood in Scotland, with the consequence that SNBTS concentrates might be infected. "Keeping one's antennae out", as Professor Ludlam put it was totally insufficient in light of the fatal nature of an AIDS diagnosis, the fact that patients who were exposed to commercial or mixed treatment in England had been infected and the fact that haemophiliacs were known to be the canaries in the coalmine. AIDS was known to be a lethal disease with a lengthy sub-clinical phase. The attitude adopted was really consistent with infection having to occur within the blood product recipient community before action would be taken. This was the incidence over risk approach which was always going to be inadequate. The available evidence demanded urgent preventative action to minimise the risk of transmission.

<u>Knowledge of action being taken by the transfusionists to exclude high risk donors</u>

4.99 Professor Ludlam indicated in his Penrose evidence that he was aware of the efforts being made by Dr McClelland to institute a system of high risk donor exclusion in 1983.[695] These efforts are addressed in more detail elsewhere in the

---

[691] PRSE0003358 (Gay News of 9 July 1983)
[692] Penrose Inquiry transcript for 04/05/11 (day 19); 26 (5 to 8) (Professor Ludlam); [PRSE0006019_0029]
[693] Penrose Inquiry transcript for 04/05/11 (day 19); 27 (1 to 3) (Professor Ludlam); [PRSE0006019_0027]
[694] Penrose Inquiry transcript for 04/05/11 (day 19); 28 (13 to 14) (Professor Ludlam); [PRSE0006019_0028]
[695] Penrose Inquiry transcript for 04/05/11 (day 19); 28 (11 to 12) (Professor Ludlam); [PRSE0006019_0028]

submission but even after the donor leaflet system was introduced by Dr McClelland in the summer of 1983, it was not implemented throughout the different regions uniformly. There was little point in having a system which was not uniform in application given the pooling of plasma at the PFC. Professor Lever, in his Penrose evidence, also suggested that the system left it open to regional transfusion directors to make up their own minds, based on their own perception of the available evidence as to the risk and of the likely effectiveness of the leaflets in their region, as to whether to institute the system or not.[696] The material available to the Inquiry demonstrates that this lack of uniformity was, in fact a reality. The leaflet of the type used by Dr McClelland in the east of Scotland and dated 24 May 1983 sets out the current understanding of the disease and its possible transmission routes and refers to homosexual men, partners of bisexual men, drug users and women who have multiple sexual partners as high risks groups who should refrain from giving blood.[697] In a donor leaflet available to the Inquiry from the west of Scotland dated 16 June 1983, there is no mention of transmission routes, homosexual donors, partners of bisexual men, women who have multiple sexual partners or drug use in the text. The only reference to the disease at all is a sticker on the leaflet saying "Have you heard of AIDS?".[698]

4.100 This regional autonomy resulted in inconsistency which led to a total lack of protection. It is of interest to note that, although this system of regional autonomy existed at a practical level, the system of the provision of national health services in Scotland placed a statutory duty on Health Boards as follows:

> *"In exercising their respective functions, Health Boards, local authorities and education authorities shall co-operate with one another in order to secure and advance the health of the people of Scotland."*[699]

---

[696] Penrose Inquiry transcript for 17/05/11 (day 26); 112 (1) to 113 (6) (Professor Lever); [PRSE0006026_0112 to 0113]
[697] PRSE0000984
[698] PRSE0004816
[699] National Health Service (Scotland) Act 1072, section 20

That co-ordination was required for the sake of both best practice and consistency appears to have been routinely ignored in practice in a number of spheres in Scotland, not least the transfusion services and the provision in the transfusion of blood and the care of those with bleeding disorders in Scotland. Both in this are specifically and in this are more generally, the system appeared to have no regard to the requirement to promote co-ordination of the service. In Edinburgh, where the system was instituted to some extent, the clinicians may have taken some comfort from the fact that efforts were made to exclude high risk donors. This was a false comfort, however, on the basis that the products being used were made from plasma donated in any part of the country.

4.101 The extent end efficiency of communication and discussion between medical professionals not immediately involved in the care of patients with blood disorders to those directing their care was inadequate. Other communication issues are apparent. The extent of communication between infectious diseases experts and haemophilia clinicians on the aetiology of AIDS and the risk which it posed to patients with bleeding disorders is addressed above, as is the extent of communication between the transfusionists and the clinicians on the likely arrival of AIDS in Scotland and the extent of the protection afforded by the donation system.

4.102 From as early as 1982, there was Scottish representation at international conferences at which the emerging AIDS problem was discussed. At such a conference in Budapest in August 1982, Dr Aledort spoke about the emergence of pulmonary infection in haemophiliacs in the US (as described in the July MMWR).[700] This conference was attended by Dr McClelland and Dr Foster, not by the Scottish haemophilia clinicians. The WHO conference in Geneva in November 1983 considered the emerging threat of AIDS. Proposals relevant to various measures which might be taken to reduce the risk of the spread of AIDS were considered, including certain measures relevant to haemophilia clinicians. The

[700] Penrose Inquiry transcript for 06/05/11 (day 21); 91/92 (Dr McClelland); [PRSE0006021_0091 and 0092]

conference considered the possibility of (a) concentrate use being limited to essential situations only[701] and (b) reducing the number of donors to which a patient is exposed[702] in light of the emerging AIDS threat. The conference was attended by Dr Brian McClelland on behalf of the SNBTS. After the conference he reported back to his SNBTS colleagues, reporting on elements of the conference and its proposals which appeared relevant to the blood transfusion side. He presented this report to the SNBTS directors meeting on 8 December 1983.[703] There is no evidence of his having reported the haemophilia related proposals or information back to the haemophilia clinicians. In her evidence to the Penrose Inquiry, Dr Pettigrew discussed how she, as a junior doctor at Yorkhill, required to rely on comments from colleagues and trying to source journals from elsewhere in the hospital for up to date information.[704] Given the picture she painted of the extensive responsibilities of the consultant at Yorkhill over a number of different areas, it seems likely that he was able to achieve any greater degree of precision in keeping his knowledge up to date (as is addressed elsewhere in this submission).[705]

4.103 Dr McClelland worked in the office next to that occupied by Professor Ludlam. He indicated that the haematology department and the blood transfusion service were "extremely close together" within the RIE.[706] He was clear to point out, however, in his evidence to the Penrose Inquiry that the two were very much separate departments with one being a department of the hospital and the other being a department of the SNBTS.[707] It seems that administrative distance counted more than physical proximity. Dr McClelland stated that he had regular contact with Professor Ludlam and that he was not "immune" to considering the needs of the haemophilia treaters.[708] We would have expected that the needs and interests

---

[701] PRSE0004401_0018
[702] PRSE0004401_0017
[703] PRSE0003634
[704] Penrose Inquiry transcript for 05/05/11 (day 20); 70 (2) to 71 (16) (Dr Pettigrew); [PRSE0006020_0070 to 0071]
[705] Penrose Inquiry transcript for 05/05/11 (day 20); 8 (8 to 21) (Dr Pettigrew); [PRSE0006020_0008]
[706] Penrose Inquiry transcript for 06/05/11 (day 21); 96 (10) (Dr McClelland); [PRSE0006021_0096]
[707] Penrose Inquiry transcript for 06/05/11 (day 21); 96 (16 to 20) (Dr McClelland); [PRSE0006021_0096]
[708] Penrose Inquiry transcript for 06/05/11 (day 21); 119 (3 to 6) (Dr McClelland); [PRSE0006021_0119]

of the patients, the end users of the products he was distributing, would and should have been at the forefront of his mind in everything he did. One would have expected that Dr Boulton might form a natural bridge between the two departments as he had experience on both areas. He confirmed, however, that he would not speak to Professor Ludlam about the way patients should be treated.[709]

4.104 Dr McClelland had attended the two conferences referred to above and, indeed, (as detailed above) had been actively involved in the deferral of high risk donors in order to minimise the risk of transfusion of HIV infected blood in Scotland and the preparation of properly worded donor leaflets throughout 1983. He had been so keen that homosexual donor groups be excluded from donating blood that he had been involved in negotiations with homosexual rights groups who had concerns about this proposal. The fact that he was prepared to go through this process to ensure the introduction of a leaflet designed to achieve exclusion of homosexual donors, demonstrates that from spring 1983, Dr McClelland entertained serious concerns that HIV had entered the Scottish donor population. He had been in contact with Dr Macmillan and was aware of the possible AIDS infections in Edinburgh in the GUM clinic. There is no evidence of him having communicated these concerns to his neighbour who, at this time, continued to expose his patients to ever increasing amounts of factor concentrates, with many of them receiving home and/or prophylactic treatment. He did not communicate these concerns to any haemophilia clinicians for that matter, nor is there any evidence that he communicated the suggested risk minimisation measures proposed for haemophilia care at the Geneva conference. In his evidence to the Penrose Inquiry, Dr McClelland seemed to work on the assumption that information to which he was privy would have been available to Professor Ludlam as well. The position in Edinburgh is illustrative of the existence of sub-optimal practices as regards information communication at a time when a clear understanding of the information and a frank exchange of professional opinions between senior colleagues in different disciplines was essential to ensuring the correct response to an emerging killer disease.

---

[709] Penrose Inquiry transcript for 12/05/11 (day 24); 100 (6 to 11) (Dr Boulton); [PRSE0006024_0100]

4.105 At the Penrose Inquiry, Professor Hann was asked about a conference which he had attended in Stirling in 1982. He explained that he had attended it due to his interest in infection in immuno-suppressed patients but that (a) it was very difficult for consultant to get away to such events as they were very busy and (b) he would have expected that it was a conference of interest to leukaemia treaters and not "clotters".[710] The conference disseminated information about the emerging AIDS crisis, reporting the apparent symptoms, outbreaks of infection in the USA and Europe and the high mortality rate. It is interesting that the rigidity of medical disciplines was a reason for this information not being disseminated to those primarily concerned with bleeding disorders. Professor Hann left the conference thinking that it was most likely that this new disease was caused by a new viral agent[711] and that it might possibly be relevant to the patients whom he treated with haemophilia.[712] Professor Hann accepted that there required, over this period, to be better co-ordination amongst the various parts of the medical profession so that the best approach possible could be formulated at as early a time possible. The crisis gave rise to the need for multi-disciplinary teams to achieve this aim. The infancy of virology as a discipline was also a factor.[713]

4.106 In later evidence to the Penrose Inquiry, Professor Lowe commented as follows:

> *"So I think we have the mentality in healthcare professions that if there is a difficult topic, the best way to spread knowledge and information and good practice is to talk to each other"*[714]

One might have thought that this was self-evident. Patients had the right to expect that this should take place. However, there is little evidence of such an approach

---

[710] Penrose Inquiry transcript for 06/05/11 (day 21); 39 to 40 (Professor Hann); [PRSE0006021_0039 to 0040]
[711] Penrose Inquiry transcript for 06/05/11 (day 21); 45 (14 to 15) (Professor Hann); [PRSE0006021_0045]
[712] Penrose Inquiry transcript for 06/05/11 (day 21); 46 (3) (Professor Hann); [PRSE0006021_0046]
[713] Penrose Inquiry transcript for 06/05/11 (day 21); 57 to 58 (Professor Hann); [PRSE0006021_0057 to 0058]
[714] Penrose Inquiry transcript for 16/12/11/11 (day 80); 13 (16 to 19) (Professor Lowe); [PRSE0006080_0013]

having been adopted in connection with the emerging AIDS threat in the first half of the 1980s.

The emergence of the need for steps to be taken to mitigate the risks of AIDS

4.107 It was clear from the evidence given to the Inquiry by Professor Tedder that his ability to develop a diagnostic test for HTLV-III was based upon techniques he had developed into tests for HTLV-I and HTLV-II. These were viruses which were known to be associate with causing cancer (leukaemia) and had been available to Professor Weiss at the Chester Beatty Laboratory (where he had acquired samples of the virus to develop his tests). The former was more common in homosexual and the latter in IVDUs.[715] They were known to be transmissible by blood and sexually. Lymphotropic means infection of the T-cells which can cause leukaemia or lymphoma. These harmful viruses were already circulating in the UK population in the early 1980s. They were known to cause leukaemia. They were being passed around scientists and virologists for the development of tests. Little attention appears to be have been paid to the potentially fatal addition they had played to the dangers of blood and more particularly blood products in the UK. They created even more of a basis for changes to be made to the blood collection system to exclude these high-risk groups but also for changes to be made to treatment regimes and transfusion practices to limit exposure to these blood-borne threats until these tests could be more fully developed and rolled out. Professor Tedder revealed that there was later revealed to be something of an HTLV-II epidemic in Ireland, which could have happened in the UK and caused even more harm. The Inquiry should recommend that tests for infections with such viruses should be made available to bleeding disorder patients in the UK as well as all those with antibodies to HBV, HCV or HIV though blood or blood products.

[715] WITN3436003 @ paragraph 178

4.108 In his evidence to the Inquiry, Professor Tedder made it clear that the association with HBV and the apparent similarity in transmission routes with HBV (in particular amongst homosexual groups) emerging from the early evidence about AIDS from 1982 was apparent to him.[716] As a result he had sought government support for the isolation of the virus in the UK and the development of a test which he thought could have been done simply based on his previous experience of developing other tests such as for anti-HTLV-I.[717] His approach to Dr Walford for government support in the endeavour was rejected.[718] This was despite the fact that as far as he was concerned, from the start of 1983, he knew that they needed to move towards the development of testing quickly.[719] This approach was based on a clear assessment that the aetiology was viral and that something could be done to prevent the spread of this potential killer disease. Once again, government inaction caused a significant delay and endangered lives.

4.109 The French discovery of LAV in 1983 and the apparent lack of attention paid to it appears to have been a significant omission in the government response. The Inquiry has evidence available to it from Dr Abraham Karpas about the reasons for that. The Danish Melbye group which collaborated with the Glasgow haemophilia centre in AIDS related research in haemophiliacs had access to the LAV derived tests in 1984. These were made available to the Glasgow centre, as is discussed below. An earlier adoption of technology derived from that discovery could have permitted earlier testing and prevented infections. At least more investment in the science could have allowed cleared decision making about the viral aetiology of AIDS from 1983, which could have allowed other measures to be taken to prevent infection.

4.110 Systems in place to ensure that the most up to date information was shared and disseminated to all of the people who needed were inadequate. Apparent reliance

---

[716] WITN3436003 @ paragraph 37

[717] WITN3436003 @ paragraph 44

[718] DHSC0003824_164; WITN3436003 @ paragraphs 58 to 59

[719] WITN3436003 @ paragraph 69

on press information. No central system for any effort to be made to ensure that the dissemination of information worked as it should, against a background of consultants within relevant departments being under huge time and resource pressure to deliver some kind of service to their patients. This results in information being disseminated in a haphazard way.

4.111 The evidence available to the Inquiry clearly demonstrates that even by 1985, the minister of state, Kenneth Clarke MP continued to misunderstand and underestimate the nature of the threat. The fact that he appeared to argue after the discovery of the virus and the emergence of the possibility of screening for the disease that such a measure was perhaps not merited based on the fact that heat treatment would soon be introduced to eradicate the threat of HIV from factor concentrates demonstrated a complete failure to appreciate the dangers. He was unaware, it seemed, of the infections of the haemophilia patients in Edinburgh (known about in October 1984 as a result of the testing undertaken by Dr Tedder) and elsewhere in the UK as a result of domestically produced blood products. This was despite the fact that the fact of these infections had been published in the press in December 1984. This approach demonstrates that even by that time, when there was incidence and not just risk of infection as a result of domestically collected blood

5. Conclusion

5.1 There was a lack of attention to the cumulative risks of AIDS, in particular given how serious it clearly was. Unlike NANBH there was no room for dubiety that this was a killer disease. The confused response showed that the system was not ready. It should have been.

F. THE COLLECTION OF BLOOD

1. General ambit of this section in relation to Scotland

1.1 The impact of failings in this area in Scotland extend beyond the dangers of blood transfusions to those infected by blood products as most treatment used for haemophilia in Scotland was produced at the PFC.

1.2 Issues arise with regard to the lack of clear lines of responsibility and accountability in the interest of public health. The regional directors' autonomy, the lack of central SNBTS control, the lack of definition in the role of the national medical director, issues with the interaction between the haemophilia directors and the transfusion directors at regular meetings and the dysfunctional relationship between government and the medical community all played a part. The need for plasma drove the collection practices, as opposed to considerations of securing safe supply which caused danger to all. There was a lack of proper oversight by government (SHHD), who took no time to invest either intellectually opr financially in the system.

1.3 The fallacy of voluntary donation and the sanctity of domestic products based on the principle that blood and blood component donations in Scotland emanated only from volunteers underpinned the systemic failings. Collections took place in prisons and military institutions were the domestic equivalent of skid row, where donations were not voluntary but paid for. Donations given by prisoners or in military institutions were not voluntary either. Whereas there were good reasons in theory to think that blood which emanated from a voluntary donation system would be safer than blood which emanated from a non-voluntary system, the actual way that the SNBTS in practice operated the system of blood donation in Scotland for the material period over which infections were occurring was not voluntary and it was not safe. From the time of "The Gift Relationship" prison donations had been known to be dangerous on the basis that they could be considered to be voluntary. Titmuss did not think that individuals in prisons or the military (whom he described as "the captive voluntary donor") could be described

as "free agents".[720] Thus, the reliance in the US system on plasma which emanated from the prisons system was one of the principal reasons which the system could not be trusted.[721] Indeed, the inquiry has access to evidence which suggests that in the west of Scotland at least prisoners were incentivised to give blood by not only time away from the cells but also the possibility of rewards like sugar or cigarettes.[722] Even by the time he was a minister in the Scottish Office, by which time the full horror of AIDS had become apparent, an emotional Lord Forsyth told the Inquiry that he was less than impressed with the way that HIV infection was controlled in Scottish prisons.[723] There were no such controls in the first half of the 1980s.

2. Regular donor sessions

General – regular donor sessions

2.1 The inquiry heard evidence donor sessions worked in general. In theory there was a doctor at the session being in charge of donor deferral, the only means other than limited HBV screening of promoting safety. There was regular monitoring of the way that the session worked or the consistency effectiveness of the measures being taken. The system was essentially old fashioned and passive, despite the looming threat of potentially fatal disease. The need for blood to fuel the need for plasma meant that the system was totally deferential to the donor.

2.2 The evidence heard by the Inquiry was to the effect that those running donor sessions and those who were organising them, in light of the need to try to encourage the altruistic act of blood donation and hence maintain the blood supply, exhibited a significant degree of deference to the donor. The principles of

---

[720] See HSOC0019917 – "The Gift Relationship" at page 84
[721] See HSOC0019917 – "The Gift Relationship" at page 87
[722] PRSE0001019_0004 (statement of Rosalind Prior)
[723] IBI transcript for 20/07/22; 125 to 126 (Lord Forsyth)

voluntary donation/ altruism clouding the limitations of such an approach which were largely ignored. The system was drawn to heavily in favour of the retention of donors and not heavily enough in favour of the safety of the donation and the ultimate wellbeing of the recipient of the transfusion. What use was trying to encourage risky donors to become repeat donors? One such example of an attitude prevalent at the time was that it was "**probably** wise not to accept a volunteer who has been a drug addict" (emphasis added).[724] This resulted in a system which was not proactive but reactive to transmission which had already been allowed to occur. The general attitude conveyed by the Wallace text from 1977 was that it would suffice to ask indirect questions which would not offend the donor but which would allow guesses to be made about the actual state of the potential donor's health. He acknowledges the limitation that such an approach involves by talking about the apparent priority of donors being "human and volunteers" and the possibility of transmissible disease requiring to be investigated with the caveat "as far as can be ascertained".[725] This lack of direct questioning was clearly inadequate, on any view. The approach to donor deferral was near complete donor deference. The need to avoid interrogation was emphasised by Dr Wallace in 1977 as well as the limitations of testing in preventing viral transmission, the importance for clinical reasons for not subjecting the donation to a barrage of tests and delaying the use of the donation and overall the apparent total faith that donors will be truthful and those with what he describes as "significant bacteraemia" would not donate.[726] His text does identify the donor with a clinically silent viraemia as being a potential source of issues but does little to suggest that the system would do much to weed him or her out.

2.3 In the background to the approach which was being adopted was the attitude of the WHO which had consistently urged blood transfusion services to promote the use of voluntary as opposed to paid donation, in accordance with the principles espoused by Titmuss and examined elsewhere in this submission. WHO Guide to

---

[724] The view expressed by Dr John Wallace - PRSE0002052_0028 (1977)
[725] PRSE0002052_0039 (1977)
[726] PRSE0002052_0039 (1977)

the Formation and Operation of a Transfusion Service (1972) stated that "The blood must be available in the quantity needed, at the place and time required. All other considerations are subservient to this."[727] Supply was therefore the ultimate goal. Though this was of course an important consideration, there questions for resolution is whether the relative safety of the voluntary donor system provided a false comfort about the safety of the supply. Relative safety was one thing. Safety was another.

2.4 The Medicines Inspectorate conducted investigations into the Scottish transfusion centres in the early 1980s as part of the limited commitment of the SNBTS to regulation of its activities, despite reliance on Crown Immunity (addressed elsewhere in this submission). Against the background set out above of the dangers of infectious disease being transmitted by blood, there was a need for the highest of safety standards to be maintained. The analysis in the reports about the safety of the centres is indicative of inadequate regard being had to safety overall. They revealed such failings as these:

(a) The MI report dated 24 March 1982 (Aberdeen transfusion Service) found there to have been chronic lack of space which resulted in hepatitis positive blood being transfused on one occasion and there to have been an existing danger of hepatitis B positive blood being transfused[728];

(b) The MI report dated 25 March 1982 (Dundee transfusion Service) found that the centre's licence expired (as per the 1979 Crown immunity advice discussed above), The view was expressed that the inspectors could not endorse the continued collection of blood from prisons and borstals. Dangerous storage facilities were identified[729];

(c) The MI inspection of Glasgow centre in March 1982 was spoken to by Dr Gabra in his oral evidence.[730] The centre had been inspected in 1980 and it was said

---

[727] PRSE0002035_0014
[728] PRSE0003178
[729] PRSE0000132
[730] SBTS0000407_006; IBI transcript for 03/02/21; 15 et seq (Gamal Garbra)

that the area for bottle preparation was substantially worse than it had been previously. It was (worryingly) said that this was beyond the control of the centre staff and was bound up with the uncertain future of the freeze drying facility. It appears that this facility had been allowed to go to ruin, which meant that this production option was effectively ruled out though it offered considerable viral safety advantages (see below). Storage was inadequate. There was dripping pipework and dirty conditions. Preparation area for containers was deemed appalling. The aseptic areas were not up to an adequate standard, creating health risks. Dr Gabra summed the centre up as "certainly not up to standards".[731] He stated that he was pleased to see that the inspection had led to improvements even though a new facility as not opened in Glasgow until 1992.[732]; and

(d) The MI reports dated March and May 1982 (Edinburgh transfusion Service) – found that the licence there had also expired. The report questioned appropriateness and necessity of the continued collection of blood from prisons and borstals. It rated the facilities as inadequate and ranked them amongst the worst seen anywhere.[733]

2.5 As is noted below, responses to the reports both took up time from the development of safety protocols in the early 1980s (a time of significant viral threat), were dilatory and were inadequate based on the lack of resources and the fact that no sanction could be imposed due to Crown Immunity.

The identification of the risk of HBV in donors

[731] IBI transcript for 03/02/21; 16 (Gamal Garbra)
[732] IBI transcript for 03/02/21; 26 to 27 (Gamal Garbra)
[733] PRSE0000132

2.4 The evidence heard by the Inquiry indicates that historically, the risk of a donor carrying and hence potentially transmitting viral hepatitis was associated with the donor identifying a history of jaundice. This approach was limited in a number of ways, not least that (a) the approach assumed (incorrectly) that icteric hepatitis was the only form of transmissible viral hepatitis of concern and (b) that a patient's memory of the episode of jaundice. This was a scientifically limited and inherently unreliable means of achieving safety in the blood supply.

2.5 By the time of the 1971 WHO Guide to the Formation and Operation of a Transfusion Service it was stated that:

> "Patients with clinical jaundice are not the main source of the disease; far more significant sources are the mild anicteric case, the convalescent carrier, those incubating the disease, and the healthy contact carrier, all of whom at one time or another may be viraemic."[734]

By this time, the threats posed by the clinically silent form of viral hepatitis were well understood.

2.6 This line of scientific thinking was developed in a 1973 WHO report entitled "Viral Hepatitis: Report of a WHO Scientific Group'.[735] That report highlighted that "limited surveys have also shown that the prevalence of hepatitis B antigen is no higher amongst donors with a past history of jaundice than in those without such a history."[736] The paper indicated that studied of hepatitis B infection amongst volunteers suggested that "a greater proportion of individuals who have had a mild or inapparent infection become chronic carriers of the antigen than of those who have had a more severe illness" with the result that it was acknowledged that

---

[734] PRSE0002035_0020 - "Blood Transfusion – A Guide to the Formation and Operation of a Transfusion Service"
[735] PRSE0001968 - World Health Organization Technical Report Series, 1973, No. 512
[736] PRSE0001968_0016

excluding those with a history of infection may not materially reduce the frequency of transmission.[737]

2.7 The WHO paper also made it clear in 1973 that despite screening cases of post transfusion hepatitis continued to occur. Screening was thought only to prevent around 30% of cases of post transfusion hepatitis.[738] The prospects of better eradication rates resulting from more sensitive techniques were not thought to be great. These cases were thought to result from CMV or other unidentified agents – the message at that time appeared to be that the risks of serious disease from viral hepatitis continued to be a serious problem of transfusion.

2.8 In a paper published in The Lancet entitled "Long-incubation post-transfusion hepatitis without serological evidence of exposure to hepatitis-B virus" by Prince et al the subject of viral hepatitis was considered further. The study found that an agent other than HBV was the cause of 71% of cases of PT hepatitis.[739] This was a significant paper which demonstrated that hepatitis B was not the cause of the vast majority of cases of PT hepatitis. Significant research and resources had been invested in trying to eradicate the global problem of PT hepatitis, in recognition that it was a phenomenon which required to be addressed in order to avoid the emergence of a controllable, man-made public health problem. This paper was a key element of the international understanding that something else was causing that condition over which the screening procedures which had been put in place had no control. The study involved a group of cardiovascular surgery patients who had had blood transfusions as part of their operative procedures. Pre-operative blood samples were available and tested to rule out pre-operative causes for liver damage. The blood which was transfused was tested and antigen positive blood discarded. The patients were followed up for evidence of past transfusion hepatitis and in those who showed liver markers indicative of infection (51), 36 tested negative both for antigen and antibody to HBV, indicating that their liver

---

[737] Ibid.

[738] PRSE0001968_0017; see also PRSE0003817_0005 - Minutes of UK RTD meeting on 11 March 1970 – even before the test was to be introduced it was thought that it might eradicate only 40% of the cases of pest transfusion hepatitis

[739] PRSE0001431 (Prince et al, The Lancet, 3 August 1974)

derangements was caused by another agent which was labelled hepatitis C. Given that certain patients were given blood which had tested positive for HB antigen and their results almost all tested positive, the authors were confident that the tests they were using for the detection of HB antigen were sensitive, meaning that the hepatitis cases which did not positive were unlikely to be due to insensitive testing but due to another agent.[740] In addition, only 21 of the 51 patients who were defined as having hepatitis showed a history of jaundice, indicating that jaundice was an unreliable marker for viral hepatitis infection.[741] The paper also sounded a warning about the possible progression of the NANB disease. Though the NANBH cases had had a mild clinical course generally, the fact that in the long term s HBV infection had been associated with chronic liver disease, cirrhosis and hepatoma more frequently in cases where the acute phase had been mild and anicteric meant that it would be unwise to discount the possibility that the long terms consequences of the NANBH infection may lead to chronic disease. It could simply not be known with any degree of certainty what the course of the NANBH disease would be but this evidence about the progression of HBV in the milder, anicteric form in the acute phase was a wise one.[742]

2.9 Thus, at this time, it was known both that the assays available for the detection of HBV were not able to detect all cases due to a significant problem of false negatives and that not all cases of post-transfusion hepatitis were caused by HBV infection.[743] The likely eradication rate of only around 25% of viral hepatitis had led to significant discussion about the cost effectiveness of the measure, the scientific reasons for which were discussed by Dr Wallace in his 1977 book about transfusion.[744] This actual position was in contrast with what has been described as the prevailing mood of the time. In a written statement to the Penrose Inquiry, Dr Brian McClelland described the prevailing mood in 1977 as being an assumption that the screening measures being taken were or would be wholly effective and

---

[740] PRSE0001431_0004
[741] PRSE0001431_0002
[742] PRSE0001431_0006
[743] PRSE0001968_0013 and _0017
[744] PRSE0002052_0044 (1977)

that they would in effect eradicate the problem of post transfusion hepatitis. The apparent inconsistency in this attitude towards the effectiveness of the screening measures from hepatitis B in eradicating post transfusion hepatitis and (in particular in the context donations from high risk sources, such as prisons) and the actual evidence appears to have been appreciated by Dr McClelland in hindsight.[745]

2.10 This continued to be the case as the decade progressed. The International Society of Blood Transfusion (ISBT) Guide Criteria for the Selection of Blood Donors (1976) stated that:

> *"In spite of recently developed tests for the detection of HBsAg, only a relatively small proportion of carriers can presently be detected. No routine screening test is presently available for the detection of hepatitis A virus, or of other viral agents that cause transfusion-associated hepatitis."*[746]

2.11 By this time the more reliable third generation tests had become available and yet the detection rate still remained at 50%. There was no scientific reason to conclude at this stage that the disease which would be transmitted in this way would be any less serious than the disease which was known to be potentially fatal – see the commentary, for example, on the Edinburgh hepatitis outbreak above.

2.12 By 1978, there was continued evidence of the lack of sensitivity in HBV testing in eradicating even infections by that virus, far less all cases of post transfusion hepatitis. It was reported by Dr Craske at a meeting of the Hepatitis Working Party of the UKHCDO on 20 August 1978 that it was evident that screening tests for HBsAg were not sensitive enough to detect all donor plasma infected with hepatitis B virus, even when the concentrate was prepared from donations of plasma from volunteer donors. It was stated that efforts were being made to increase the sensitivity of screening tests, but it seemed unlikely that this would

---

[745] PRSE0002653_0008
[746] PRSE0000885_0012

significantly reduce the incidence of hepatitis B from the then present level. [747] It was also pointed out during the course of this discussion that efforts to minimise transmission of HBV by way of screening for the virus in effect had no effect on the treatment of severe haemophiliacs who continued to be exposed via concentrates to large amounts of the virus.[748]

2.13 The fact that screening of blood for indications of HBV did not eradicate transmission of viral hepatitis illustrated an unusual attitude towards proof adopted by the medical community in relation to the risks of disease. In relation to the possibility that serious disease could be and would be transmitted by blood and blood products, the medical community at times appeared to require conclusive proof before feeling that action to prevent transmission was mandated (this is discussed elsewhere in this submission. As regards the level of evidence required to be satisfied that safety measures had in fact been effective a much lower bar appears to have been applied. The evidence from the early 1970s was that the efforts made to eradicate viral hepatitis from blood products demonstrated not only that there was far from conclusive proof about their success, but there was clear evidence that the risks continued despite them. In the face of this evidence, products not only continued to be used but high-risk pooled products continued to be used in ever increasing quantities.[749] One standard was applied to the assessment of safety measures, another to the evidence that there was a risk to be concerned about.

2.14 Further evidence was needed to try to understand the extent of the HBV problem and the threat which had emerged late in the decade from NANBH. Certain research in Scotland (some of which is referred to above) had provided a preliminary though limited picture of the position. More would be needed to be able to come up with real, long lasting solutions to the position in the late 1970s and early 1980s. There was a failure to invest time and resources in finding these answers.

---

[747] PRSE0000780_0006 - _0007

[748] PRSE0000780_0006

[749] That pooled products carried high risk is acknowledged in the 1973 WHO report – see PRSE0001968_0016

2.15 Research work on identifying the extent of NANB Hepatitis in the west of Scotland, begun in the late 1970s, was continued by Dr Follet and the team on the west of Scotland with grant support from the Scottish Hospital Endowments Research Trust.[750] A full, wide-ranging prospective study was clearly needed. It was not undertaken.[751] It was not possible in light of the absence of this research to understand the evidence-based epidemiological basis upon which measures donor exclusion methods in regular donor sessions might be thought proportionately to reduce the risk of transmission whilst also maintaining the blood and plasma supply. Dr Dow continued his research into the risk posed by prison sessions as prisoners had already been shown to have a high incidence of Hepatitis B and NANB Hepatitis was also thought to be blood-borne. This is discussed in more detail below. People with haemophilia (who were excluded from donating blood, largely due to the risk to themselves as opposed to the risk to the recipients, which they also posed), intravenous drug users and renal dialysis patients were also obvious populations which merited study.[752]

Donor selection policies in the late 1970s and into the 1980s in normal donor sessions

2.16 In light of this context (the failure to eradicate HBV and the clear threat of a new form of viral hepatitis), the measures used to exclude donors at risk of viral hepatitis transmission need to be considered. The issue which presented with the detection of those at risk of hepatitis in "normal" donor sessions was the fact that viral hepatitis tended not to present with overt signs of clinical illness – a reliance on the reporting of jaundice, even in cases where the donor had a clear recollection and understanding of his or her full medical history was an unreliable means of trying to ascertain the actual risk. As a result, further protection measures, such as the use of surrogate testing or systems mentioned above such

[750] PRSE0001312_0005 (Dr Dow Penrose statement)
[751] PRSE0001312_0006 (Dr Dow Penrose statement)
[752] Penrose Inquiry transcript for 18/03/11 (day 8) (Dr Dow); 149 - 150; [PRSE0006008_0149 to _0150]

as excluding donations from groups known to pose a risk such as those who had received transfusions were the only reliable means of reducing the number of positive donations beyond this very unreliable system. At the very least, there needed to be clarity with patients in receipt of blood or blood products that the system could in all honesty afford little protection against the transmission of these diseases. It was only if that message as communicated that the system could be deemed to act in the best interests of patients.

2.17 In Scotland the structure of the blood collection system allowed significant autonomy to the regions. Records and publicity materials were produced locally in the 1970s and subsequently.[753] This gave rise to the possibility and indeed a reality or significant variation and of postcode lottery about the system, both in principle and in practice. Local directors at the top of the collection system were left able to determine collection practices in accordance with their own knowledge and preferences. The practical effectiveness and safety of donor sessions depended on the effectiveness of the dissemination of information and systemic guidance in a region, with little national oversight. It seems hard to understand why such a system was maintained throughout the period over which infections occurred, especially in light of the fact that other aspects of the system operated on a national basis. The system of the production of blood products operated nationally. Guidance was issued in that area trying to set out good manufacturing practice from 1979.[754] Though the uniformity of their implementation may have given some cause for concern, there were national "Notes on Transfusion" which were issued by government to try to guide transfusion practice.[755] The "Standards" issued as guidance in 1979 stated that certain illnesses and conditions disqualified a person from being a donor, including illicit drug taking, current jaundice or hepatitis or the presence in the blood of HBsAg. Discretionary disqualification ("deferment") applied where the person reported jaundice or hepatitis in the preceding year or contact with 'a case' within six months. Temporary deferment

---

[753] PRSE0002164_0005
[754] PRSE0003128 (1979)
[755] PRSE0001980 (from 1973 – this was revised guidance, the fifth edition issued *inter alios* on behalf of the SHHD)

applied to an individual who had had contact with an infectious disease but had not been infected with it, tattooing, acupuncture or ear-piercing within six months or who had a transfusion within that period.[756] This left significant room for local interpretation.

2.18 The Advisory Group on Testing for the Presence of Australia (Hepatitis Associated) Antigen and its Antibody (the Maycock Group), originally set up in September 1970, was re-convened on 6 December 1973. In its second report, published in September 1975, it recommended that the practice of excluding donors with a history of jaundice should be discontinued, provided that HBsAg was not detected using a sensitive test and the donor had not suffered from hepatitis or jaundice during the previous 12 months.[757] But there was still no means of limiting the risk of transmission of other viruses causing post-transfusion hepatitis. The existence of long-incubation post-transfusion hepatitis unrelated to Hepatitis B, postulated by Dr Alfred Prince and colleagues in The Lancet published on 3 August 1974, was not noted in the Maycock Group's discussion of the topic of exclusion on grounds of jaundice or hepatitis history.

2.19 The Memorandum on the Selection, Medical Examination and Care of Blood Donors was produced by the NBTS in 1977 and had an influence on practice in the Scottish transfusion service.[758] Though recommending a basic medical examination, they proceeded on the basis that "a donor is the best judge of whether he is in normal health and truthful answers to simple questions concerning his medical history and general health form the main part of the examination".[759] They seemed to proceed on the basis of deference to the donor and almost an assumption that the voluntary principle meant that the donor could not carry a risk. The donor's blood would not be used if there was a 12 month history of hepatitis or jaundice, a positive HBV test admitted or suspected illicit drug taking.

---

[756] PRSE0003128_0005
[757] PRSE0004371 (1975)
[758] PRSE0003820
[759] PRSE0003820_0004

2.20 The donor selection criteria in the period focused on lifestyle and the presence of history of jaundice as a means of preventing the transmission of known hepatitis viruses by blood and blood products. In the period after 1972, when HBsAg testing was introduced in Scotland, there was a reliance on screening for HBV which (as is discussed elsewhere in this submission) was misplaced, both on the basis of the reliability of that testing for the detection of positive HBV cases but also insofar as it failed to provide a system for the detection of cases of so called non-A non-B hepatitis (NANBH) – a form of hepatitis which became known from the time of the Prince paper in 1974 as being of increasing concern.[760] The importance of that paper is discussed above, in the context of the emerging knowledge about the risks of viral hepatitis from blood and blood products. Jaundice was not a reliable marker of the new form of infection and in any event evidence of the progression of HBV had shown that it tended to become more serious in cases which had presented in a milder, anicteric form in the acute phase. It was thus necessary, in these circumstances, to do all that could be done to make efforts to exclude donors who may be at any risk of hepatitis infection, in particular the form which was not detectable on HBV screening, labelled hepatitis C by the Prince group. Other measures needed to be relied for detection of Hepatitis B infection but also for other risks of transmission of viral infection due the limitations in testing of detecting either or any of these agents.

2.21 As far as the Scottish donor population was concerned, on 21 July 1979, The Lancet published a letter from Dr Robert Crawford et al at the Glasgow and West of Scotland BTS reporting on their study into blood donors with a history of jaundice. They found that a history of jaundice was not materially higher in donors who tested positive for HBsAg than in those who did not.[761] They concluded that history of jaundice does not materially increase the prevalence of HBsAg among blood-donors and is likely to imply previous infection with HAV rather than with HBV.

---

[760] PRSE0001431 (Prince et al, 3 August 1974)
[761] PRSE0004660

2.22 On 23 October 1982, the British Medical Journal published a letter by Mr Archie Barr et al at the Glasgow BTS.[762] Only 12 cases of overt post-transfusion hepatitis possibly attributable to non-A, non-B agents have been notified, none of the donors involved in the eight cases associated with red-cell transfusion had given a history of jaundice. Despite the limitations of the notification process, this did not support the disease that jaundice was associated in Scotland with NANBH transmission. Interestingly, this result was used as a justification for the current British donor selection criteria whereby most patient with a history of non-recent jaundice could donate. Jaundice was not associated with risk for those conditions, it appears. However, it seems hard to understand why exclusion of donors with a history of jaundice was thought to provide any meaningful protection. This actually revealed that the system had little meaningful protection from infecting end users at all – the jaundice test did not protect from NANBH or HBV, the HBV test protected from only a proportion of HBV.

2.23 It appears hard to understand why this period was selected or the epidemiological reasoning behind acceptance of donors with this history or the 12 months period. The connection between infectivity and any acute history of jaundice does not appear clearly evidence based, far less why the 12 month cut off was selected. In effect, little was really done in terms of minimising risk. Given that guidelines and practices before the emergence of HIV were based very much on standard practice, there seemed to be little flexibility in the way in which selection criteria continued to have scientific validity. Much was said to the Inquiry at various times about the risk by excluding donors of the loss to the system of blood. However, there appeared to be little evidence of there being systemic assessment and review of the following factors:

(a) The scientific risks in terms of possible disease transmission posed by certain types of donors, such as those with a history of jaundice or other factors;

---

[762] PRSE0002306

(b) The reliability of certain factual material emanating from a donor, such as the accuracy relating to medical history;

(c) The consistency with which donor selection criteria were applied locally, wither on the basis of the comprehensibility or subjectivity of the criteria applied;

(d) The likely impact on the blood (and plasma) supply of the exclusion of certain possibly at risk patients and the consequent effects on disease transmission to and morbidity/ mortality in the recipient population;

(e) The possibility that a diminution on the blood or plasma collected could be accounted for by analysing and improving transfusion practice amongst clinicians, including the use of blood components and blood products to try to enable the system to work more within its safely achievable means; and

(f) The possibility of deploying other donor recruitment measures to make up for any loss of blood or plasma which would be the consequence of excluding certain types of donors.

2.24 The national guidance was in fact at odds with some international guidance from 1976. The International Society of Blood Transfusion's guide, Criteria for the Selection of Blood Donors noted that, despite the introduction of HBsAg tests, "only a relatively small proportion of carriers can presently be detected". It noted that there were no tests for HAV, nor other viral agents that could cause transfusion-associated hepatitis. The ISBT therefore recommended general precautions that ought to be taken to reduce the risk of transfusion-transmitted infections, including where the donor gave a history of viral hepatitis at any time during their lives save for the first five months of life.[763] Professor Dame Marcela Contreras, in her evidence to this Inquiry, suggested that the purpose of such guidance was "mostly directed to those countries that do not have guidelines"[764]. In our submission, if this was the reasoning behind the Notes on Transfusion guidelines providing deferral of 1 year for those with any history of viral hepatitis,

[763] DHSC0002179_067

[764] IBI transcript for 02/12/21: 86 to 88 (Dame Professor Marcela Contreras)

as against permanent exclusion for any such history, this was entirely the wrong approach to take. The UK were in a better position than those where guidance did not exist. Professor Contreras also suggested that there was no evidence that donors with a history of jaundice were transmitting more hepatitis by transfusion. We say that, by 1979, when the UK guidelines were published, it was beyond doubt that hepatitis was transmitted by transfusion. The exclusion of those who gave a history of viral hepatitis at any point throughout their life would have been a reasonable and appropriate step to have taken; the absence of evidence that such individuals would be *more* likely to transmit the infection than those without such a history should have been given very limited weight, particularly in circumstances where the international guidance was so clear. In any event, the ISBT's guide does not suggest that it was targeted in the way Professor Contreras suggested.

2.25 Generally, the lack of analysis of these factors in light of ongoing developments in medical knowledge and hence the risk/ benefit balance between excluding certain donors and the apparent stagnancy of the donor selection criteria led to a system where almost any donor selection practice appeared to be justified in the minds of the transfusion community. The lack of proper analysis makes such assertions devoid of any scientific basis. There seems to have been little actual consideration given and in any event little proper scientific basis for not introducing measures which would have had the ability to reduce the infection rate. The risk posed by donors was that they were infectious with diseases which could be passed to the recipients of their blood, in particular by transfusion. Thus, the exclusion of individuals who had a history of transfusion would have been a logical means by which a risk could have been excluded. Though this would have meant the loss of much uninfected blood, in the absence of any clear assessment of whether this would have been tolerable for the benefit (as later happened in relation to the exclusion of the much more remote vCJD risk) makes an argument on this basis hard to sustain. A proper epidemiological risk/ benefit analysis may have led to consideration of excluding donors who had had significant transfusions, measured by the point at which infection became an intolerable risk, on balance. In any event, evidence heard at the Penrose Inquiry was to the effect that the transfusion services a result initially excluded about 3.5% of donors on this basis and that they

exclude only about 1% of donors on the grounds of past transfusion on an ongoing basis. As some people do not know whether they have been transfused, if it is inferred from other history that they probably have been transfused they will then be excluded on a precautionary basis.[765] Even in 1991/ 1992, 158 anti-HCV positive donors (0.088% - annualised 316 donors) were found of which 62 had a history of IVDU 39%). 15.2% (24) were found to have been infected by a previous history of blood transfusion which suggests that those who had had previous transfusions ought to have been deferred as donors. Alternatively, other less exclusionary criteria might have been considered and applied. They appear not to have been.

2.26 In late December 1984, Dr McClelland and Dr Ludlam discussed excluding close family members of haemophiliacs as potential donors. The decision to exclude such donors in Scotland was communicated by circular addressed to the moderate and severe haemophilia A and B patients being treated in Edinburgh and Glasgow, with the circular being sent to the three other Haemophilia Centres in Scotland for distribution. A decision was taken at that time not to add "these potentially high risk donors" to the published list of those to be excluded under SNBTS criteria[766]. It is notable that this circular was sent to the patients, rather than those who might actually be giving blood in these circumstances, and it is not clear what instructions were given to donor session clinicians and nurses in this regard.

2.27 Equally, little consideration appears to have been given to the inherent unreliability for relying on the testimony of the donor. Whereas it seems to have been legitimate to have placed some reliance on donors who were making donations altruistically and voluntarily. However, this seems in the evidence heard by the Inquiry to have been considered as offering a total protection from infection risk. There seems to have been little consideration of measures such as the following:

(a) The possibility that donors may be truthful but not reliable. A patient may have been embarrassed to mention risk factors or have forgotten about past incidents

[765] Penrose Inquiry transcript for 22/03/11 (day 7); 17 to 20 (Professor Turner) [PRSE0006007_0017 to _0020]
[766] PRSE0001009

such as episodes of jaundice. The system seemed to pay little heed to the possibility that donor may not understand the questions, couched often in medical language about their history. A system which relied on and appears to have no means to access medical records to check, at least in case of doubt or uncertainty, bred the possibility for honest infection;

(b) The fact that certain donors may be so motivated to donate that they would not wish to disclose any factor which might prevent that laudable aim. This might apply to those with a history of transfusion or be close to someone who had relied on blood or blood products. Their altruism would have been perfectly reasonable or understandable based on the fact that they were motivated by a desire to give back to a system which had helped them or a loved one. However, the fact that they were so motivated may have been the very reason that they were at risk of having contracted transmissible disease which derived from transfusion, either directly or indirectly; or

(c) The need for there to be consideration given to different but clear rules relating to workplaces or other public places such as shopping centres, both in relation to HIV and vital hepatitis. Donations from workplaces were common and there were also similar "public" donation sessions which were operated, in order (one assumes) to try to derive a greater degree of altruism from the corporate nature of the experience. To an extent these were not completely voluntary donations, as per the classification of different donor types set out by Titmuss in "The Gift Relationship". Though also not quite the same as the captive donor, the possibility of exclusion in the workplace and the stigma attached to homosexuality, risky sexual practices or IVDU may have out pressure on donors there to be less than fully truthful about their history.

Exclusion of donors by these more stringent donor selection mechanisms would have led to infections by transfusion being avoided completely and the viral load on those receiving pooled products reduced.

2.28 As is discussed below, the inherent unreliability of donor screening led to the introduction of surrogate testing as a means of adding to the inherently unreliable

information provided by donors about their own medical history/ risk factors by availing the system with some scientific evidence to be included in an assessment of a donor's suitability. In reality there was no apparent scientific analysis of the reliability of answers given by voluntary donors to questions about the health/ medical history/ lifestyle. There was, in fact, blind reliance on that system based on an unscientific faith in the reliability of the volunteer donor.

2.29 In any event, the evidence shows that even within a system whereby consensus was need to alter donor selection practice and directors were accorded significant autonomy, there appeared to be little evidence of any assessment being done of the extent to which any rules were actually followed at donor sessions. They were often run by volunteers. For example, Professor Urbaniak relied on the honorary donor consultants in Aberdeen and "casual medical staff" to perform the medical functions at donor sessions.[767] He accepted that his donor population included a significant population of sailors, peripatetic merchant navy seamen and fishermen".[768] In Edinburgh Dr Boulton identified that sessions could be run by voluntary leaders and spoke of them judging 'lifestyle preferences' of donors inappropriately.[769] Dr McClelland confirmed that the donor attendants were not medically trained. And so did not recognise all of the problems in the guide which he issued.[770] Against this background it is hardly surprising that in their PFC report, the Medicines inspectorate described "the selection of donors [in Scotland as] largely a matter of chance".[771]

2.30 The deficiencies in the system were set out BMA committee (including Drs Perry and Gillon) looking at transfusion medicine in relation of the risk of HIV (1989).[772] It recommended (in light of problems with blood supply/ getting and retaining donors) (a) survey of donor attitudes (b) a publicity campaign to encourage more donors (c) the need for greater collaboration between the BTS and epidemiology to be able to assess risks prospectively (as with HTLV I in Japan) (d) as there has

---

[767] Paras 34(b) and 48 of Professor Urbaniak statement at WITN6960001
[768] Para 43 of Professor Urbaniak statement at WITN6960001
[769] para 299 of Dr Boulton witness statement @ WITN3456002)
[770] IBI transcript for 27/01/22; 39 to 40 (Dr McClelland)
[771] PRSE0003112 - 5 July 1982
[772] NHBT0010270_003

been little effort to adopt rational prescribing policies to reduce blood exposure to a minimum, the need for hospital blood transfusion committees) (e) due to the advent of CPA 1987, national product specifications. These measures could and should have been in place long before this. The risks were apparent or ought to have been and there was no need for the tragedy of HIV to have precipitated these steps being taken.

Development in the early 1980s

2.31 This background led to the system being inherently dangerous by the time of the HIV crisis, which required radical changes in the way that donor selection criteria needed to be approached. A safer, more scientifically based approach to donor selection would already have had some confidence that certain at risk groups which posed a risk of HIV transmission would already have been excluded, due to the common infection routes between HBV (sexual and blood) and NANBH (blood) and AIDS. By this time (as is discussed elsewhere in this submission) the need to increase the blood supply and hence push the balance in favour of the non-exclusion of donors had been tipped by the ever increasing demands for plasma for fractionation into factor concentrate products. In the report by the Medicines Inspectorate following their visit to the Edinburgh and SE Scotland BTS in May 1982, the MI asked whether donors in that area really read the questionnaire and "Just how comprehensive is the questionnaire?".[773] This led to the practice which had been based largely on the approach from the 1977 Memorandum being changed and a new leaflet being introduced in that region but not until the time of the response in the following year.[774] Crown Immunity meant that further regular inspections did not take place and that the effectiveness of those measures was not followed up. The criticisms shows that these unsafe practices had been going on for some time. Further, there is no evidence of any significant change

[773] PRSE0000132_0002, para 11(a) (10–11 March and 10–12 May 1982)
[774] PRSE0002562 _0004 (January 1983)

occurring in other regions, when matters became more focussed on the donor leaflet and the needed to take steps to exclude new types of high risk donors for HTLV III.

2.32 The new systems in place in Edinburgh were set out in different documents which were issued to staff and set out in the MI response in 1983.[775] These included an alphabetical list of conditions which should prompt exclusion and clearer directions as to when the medical consultant needed to be involved in decision making. In relation to hepatitis, the new guide to donor exclusion provided that detection of HBsAg at any time excluded all donations except with the approval of the Transfusion Director. It remained hard to understand why such donations should be accepted at any time. There were general directions related to medical conditions which might exclude donation, permanently or temporarily. It remains hard to understand how these guidelines were scientifically based so as to minimise the risk of transmission of HBV in undetected cases or NANBH. There was a health check questionnaire which included question on whether the donor had ever had a serious illness or operation, and questions related to piercing, acupuncture and tattoos. These still relied on accurate reporting by donors and were subject to the limitations set out above. There was still not a specific question relating to history of transfusion.[776] However, these efforts were merely scratching at the surface of the problem. In his evidence, Dr McClelland gave an indication as to why the response to the MI report was inadequate. He referred to a heated meeting at which he represented the CMO (ie on behalf of the whole service). There was a considerable reluctance on the part of the DoH to spend any money.[777] This was completely inadequate. The State had identified serious failings in an area of its operation dealing with a hazardous material, in a number of respects (blood). The consequence was that the safety of donors sessions was

---

[775] PRSE0002562

[776] See PRSE0000885 - Item 2 in the section of the 1976 ISBT Criteria for the Selection of Blood Donors had provided for exclusion where the transfusion had been received within the previous six months, therefore indicting some basis for excluding those with a history of transfusion from donation. The rational for the 6 month period again appeared to confuse acute reaction with the fact that NANBH existed on the basis of the Prince study and was "long incubation"

[777] IBI transcript for 27/01/22; 24 to 25 (Dr McClelland)

compromised, in particular as there could be no confidential interviews.[778] It had been hoped, also, that a comprehensive questionnaire might be introduced. These practical restrictions that impossible until later.[779]

2.33 It should be noted that a standard guide on donor selection within SNBTS was not agreed until 1986[780] (based in large part on the east of Scotland practice) and it was not adopted until 1988.[781] This was against the background (which continued) that there was a large amount of variation in the way in which various staff (some volunteers) assessed potential donors, leading to inevitable inconsistent in practice and implementation which Dr McClelland admitted was hard to control.[782] Dr Gillon gave evidence of his His report on the donor selection practices around the country.[783] He said that he could offer no explanation as to how (even by 1986) there could be such variation in practice and that each variation had been defended locally.[784] This was a broken system.

2.34 Further, it was not until 1995 that donation session began to incorporate the ides of personal donor interviews.[785] Given that matters relating to the safety of a donor often involved intimate details the lack of such personal interviews was a fatal flaw in the system. It was only by direct questioning in a private space that the truth about the risk would be likely to come to light. Otherwise, donors would be likely ignore the rule, misunderstand them or simply keep quiet about such personal matters in particular in spaces like workplaces or small communities. Dr McClelland accepted that careful questioning to detect clinical abnormalities was precisely what they were not able to do.[786] In particular there was a queasiness in

---

[778] IBI transcript for 27/01/22; 37 to 38 (Dr McClelland)

[779] IBI transcript for 27/01/22; 38 (Dr McClelland)

[780] PRSE0001653 at para 2 - Minutes of SNBTS Co-ordinating Group meeting on 30 April 1986

[781] PRSE0001327 - Guidance for the Selection of Blood Donors, November 1988

[782] Penrose Inquiry transcript for 22/03/11 (day 9); 20 to 21 (Dr Brian McClelland) [PRSE0006009_0020 to _00421]

[783] PRSE0000997

[784] IBI transcript for 19/01/22; 57 (Dr Gillon)

[785] Para 214 of statement of Dr George Gabra; SBTS0000463_005, para 7 (17 May 1995); and WITN6931003 – study demonstrates the importance of personal donor interviews rather than questionnaires in identifying high risk donors

[786] IBI transcript for 28/01/22; 27 (Dr McClelland)

his view about doing anything about sexual behaviour which resulted in a "light touch" in this regard.[787]

2.35 The need for these things was not innovative. It was fundamental to the system to "know your donor". The lack of privacy and direct questioning meant that that would never be achieved in an emergency situation like his. in his evidence to the Inquiry, Professor Tedder was clear that it was fundamental for him from the time of his training in the early 1970s that it was imperative to know your donor which, in practical terms meant that an environment required to be created whereby the donor could be truthful with the transfusion services. He specifically mentioned the need for privacy in door sessions as an important element of that approach.[788] There was no evidence provided to the Inquiry that this was an element of donor sessions in their efforts to protect against NANBH transmission. By the time it got to around 1983, privacy and the lack of direct questioning were major flaws in the donor selection systems or at least there was no evidence of these being monitored or enforced.

2.36 An employee of the west of Scotland BTS reflected in her evidence to the Penrose Inquiry the unreliability of these systems when she said that "We were never told to ask any donors if they had ever used intravenous drugs or had tattoos or piercings. At that time HIV was not known and we were not instructed to ask any questions about hepatitis".[789] The chaotic system in the west of Scotland BTS undermined patient safety. It was the service which continued prison collections until 1984, despite the fact that a consultant there, Dr Gabra expressed the view in his statement that blood collection from "captive donors" was unacceptable.[790]

Plasmapheresis

[787] IBI transcript for 28/01/22; 38 (Dr McClelland)
[788] WITN3436003 @ paragraph 108

[789] PRSE0001019_0004 (statement of Rosalind Prior)
[790] Para 64 of Dr Gabra statement at WITN5495001

2.37 The Inquiry heard evidence about the technique of using plasmapheresis for the collection of plasma. This is the process by which plasma was collected by the US pharmaceutical companies for the collection of large amounts of plasma for use in the creation of their factor concentrate products. It could be contrasted with the more traditional methods of plasma collection – the collection of the whole blood and the "recovery" of plasma from it, ie the separation of the plasma from the whole blood. It had the advantage over the traditional methods of collection that donors were restricted in giving whole blood to doing so only on a relatively infrequent number of times a year. Plasmapheresis donors could donate more frequently, thus resulting in a larger net yield of plasma from each donor and providing a significantly greater amount of plasma for fractionation. As the shortage of plasma for fractionation was the main impediment to the achievement of self-sufficiency, this was a technique which merits further consideration. The fractionation expert group explained that donation by apheresis would take 90 – 120 minutes.[791] This is of some significance in the analysis of the Scottish system. It would have been difficult to maintain volunteer donors if the UK system had depended to a large extent on such apheresis sessions due to the length of time that they took. In the US (where plasmapheresis was far more common) donors were paid. They were thus prepared to devote this time to a session. Thus, the amount of plasma which could reasonably be expected to be collected by a volunteer system was less than was able to be collected in a paid system.[792] The advantage of the UK system was the perception of relative safety. However, a system which had these practical limitations could not be expected to collect anywhere near the same levels of plasma as a paid system. Thus, clinicians using the products of such a system required to prescribe with restraint so as not to stretch the system to the point where the safety of the volunteer donor was lost. That clinicians, exercising an unfettered clinical freedom, did not respect this fundamental limitation of the volunteer system caused the system to break.

---

[791] EXPG0000044_0019
[792] Ibid

2.38 Plasmapheresis was a technique which appears to have been in use over the material period, though the evidence suggests that its use was mainly limited to the collection of "high titre" plasma, ie plasma which was being collected not in regular donor sessions but in specially designed sessions where selected donors whose blood was likely to be rich in desired antibodies.[793] These were in effect high risk donors whose blood or plasma would normally be avoided for precisely the reason that it was being collected using these methods, namely the fact that the donors was at high risk of having previously been exposed to viral antigens. Such plasma could be used in the development predominantly of immunoglobulins but also other developments for which access to the antigen or antibody was necessary, such as tests or vaccines.

2.39 A study in this area led to a report to the transfusion directors in April 1984.[794] Prior to this plasmapheresis limited to a manual system at Law Hospital. After this study automated aphereis came on stream in the centre in St Vincent Street branch of the WSBTS but this was too late for many of the infections which could have been prevented by a more efficient system.

2.40 In some areas, such as North London, there was a broader plasmapheresis programme which was able to significantly increase the plasma collection within the region. The programme stretched back to 1967, when the manual technique was used. By the 1980s, the region had 3 plasmapheresis clinics; Professor Contreras told this Inquiry that the programme was "the best way" of increasing plasma yields[795]

2.41 At the second meeting of the Advisory Committee of the NBTS in 1981, Dr Gunson was tasked to establish a Working Party to explore plasma collection.[796] Dr Gunson's reported to the third meeting of the Committee on 1st June 1981 with an outline of the merits of machine or manual plasmapheresis and detailed costings of the relative costs of plasma from whole blood and manual or machine

---

[793] Para 22 of statement of Dr Gabra at WITN5495001 – plasmapheresis sessions were undertaken for high titre plasma donations in Glasgow city centre from 1974 – 1989
[794] SBTS0000238_104
[795] IBI transcript for 02/12/21: 143 to 145 (Dame Professor Contreras)
[796] CBLA0001287 at para 17

apheresis, concluding that sourcing additional plasma from plasmapheresis would be feasible.[797] These practices (used widely in the commercial sector in the US) should have been looked at earlier as a means of collecting more plasma and collecting it more safely. Given the fact that these practices for plasma collection were being looked into in 1981, they should have been introduced more widely earlier by the early part of the 1980s.

2.42 Greater use of the technique of plasmapheresis in regular donor sessions in Scotland would have been likely to have assisted in the achievement of self-sufficiency in Scotland. Dr Foster spoke in his evidence to the Penrose Inquiry to the fact that plasmapheresis would have produced more plasma which would have been better for self-sufficiency on the basis that it was the lack of plasma which created there being a target which was always moving away.[798] In his evidence to the Penrose Inquiry, Mr David Watters gave evidence to the effect that he recalled there having been efforts on the part of the Haemophilia Society to raise the advantages of plasmapheresis with the Department of Health. He recalled that these requests fell on deaf ears.[799] Given the fact that the drive for plasma was the reason why self-sufficiency was never achieved, we would submit that greater efforts should have been made to maximising plasma yield by the use of plasmapheresis in Scotland, as was the case in certain other countries. Professor Contreras, in her statement to this Inquiry, noted that self-sufficiency in plasma was not achievable when using recovered plasma techniques without wastage of red cells. Plasmapheresis both increased plasma yields and avoided the "immoral and unacceptable" wastage of red cells[800].

2.43 In Edinburgh, Dr Gillon spoke of the substantial increase in plasma which they were able to collect (after his arrival in 1985) they opened the plasmapheresis programme up until 8pm.[801] This could and should have been done earlier. The lack of earlier attention paid to the possibility of scaling up plasmapheresis

---

[797] CBLA0001377_0002
[798] Penrose Inquiry transcript for 10/05/11 (day 22); 71 (14) (Dr Foster)
[799] Penrose Inquiry transcript for 19/01/12 (day 87); 116 (4 to 9) (Mr David Watters); [PRSE0006087_0116]
[800] WITN5711001, para 472
[801] SBTS0000255_023; IBI transcript for 19/01/22; 27 to 28 (Dr Gillon)

programmes was in many ways indicative of the failure of the system in Scotland. It was largely recognised that the techniques used in the US to collect plasma by plasmapheresis from paid donors were not safe. That system had the advantage that it was not limited by the generosity of the paid donor. It generated enough plasma not only to meet US domestic demands but also to supply a huge international demand for concentrates to fill the gap generated by the systems of other countries, to varying degrees. That gap existed because of a fundamental flaw in the approach of the system. The treatment regimes and their haematological advantages which emerged in the 1970s and 1980s required more and more concentrates. That demand for more and more concentrates was met by the US plasma collection practices. Those haematological techniques (including home and prophylactic treatment) required a system of collection which was not limited by the generosity of the donor, which the UK system was. There was a mismatch between the ambitions of the haemophilia clinicians and the system upon which they relied. As a result, that system became unsafe. Plasmapheresis is an example of a technique which could have bridged that gap and maintained the principle of the sanctity of the voluntary donor, matched with a technological means of collecting more plasma. Whilst the need for greater investment in fractionation facilities was recognised in the UK (though not met) the need for greater plasma to plug this gap appears not to have been. This was a fundamental flaw in the system, which is why Dr McClelland identified practical and ethical problems as having been associated with taking increasing amount of plasma from volunteer donors by apheresis.[802] Greater use of plasmapheresis programmes coupled with a more incremental approach to the expansion of treatment programmes which was more based on safety could have allowed not only the gap to be bridged but for it to be bridged safely by allowing the SNBTS to be more selective about its donors. Similarly, more use of DDAVP administration to plasma donors to increase factor VIII yield could and should have been implemented.[803]

---

[802] Para 103 of Brian McClelland statement at WITN6666001

[803] Para 234 of Dr Boulton witness statement @ WITN3456002

Further issues with the blood collection system in the early 1980s

2.44 The system was based on complete autonomy of the regions which did not permit any checking of compliance with any policy which might have been devised in the best interests of patients. As is submitted elsewhere in this submission, the WSBTS generally did to adopt policies which were in the best interests of patients in the way in which it sent about collecting blood. There was little that anyone within the system could do about that. In any event, the systems which existed in the west of Scotland for blood collection and the treatment of patients with bleeding disorders were chaotic. These comprised:

a) The laboratory of the west of Scotland BTS at Law Hospital;[804]
b) The freeze drying plant at Law Hospital;[805]
c) The laboratory and the blood bank in the GRI under the control of consultant haematologist Dr Davidson. Professor Lowe described its role in is evidence to the inquiry, including the ordering and storage of blood products from Law Hospital, some of which came from the PFC (concentrates) and some of which came from Law Hospital itself; [806]
d) The virology team under Dr John Wallace;[807] and
e) The work of the Microbiology Reference Unit (MRU) at Ruchill Hospital, Glasgow (Dr Eddie Follet and Dr Brian Dow).

2.45 The history is again instructive. Many of the ways that things were done were simply done because they had become ingrained within the system. They were not challenged or checked regularly (as they should have been) in order to ensure that

[804] IBI transcript, 9 December 2020, page 40, line 18 to page 41, line 6) (Professor Gordon Lowe)
[805] IBI transcript, 9 December 2020, page 64, line 1 to page 66, line 18) (Professor Gordon Lowe)
[806] IBI transcript, 9 December 2020, page 40, line 10 to page 42, line 20) (Professor Gordon Lowe)
[807] Para 185 of statement of Dr Gabra at WITN5495001

they complied with maximising the safety of the recipients. The Medicines Inspectorate reports about the transfusion practices in the regions of Scotland which were inspected represent the culmination of a failure to have anything like sufficient regard to considerations on the safety of the end users of blood and blood products in Scotland. The failure to respond to the criticism meaningfully and timeously (until 1983) is illustrative of a broken system, incapable of recognising its own shortcomings are adapting to informed criticism, comforted by a misguided sense of the relative superiority of its "volunteer" donor system.

2.46 Evidence was given to the Penrose Inquiry to the effect that decisions with regard to donor selection (both before and after the emergence of the AIDS crisis) were taken without active involvement from SHHD, in line with the practice/ policy which had emerged over previous decades that regional transfusion directors would be entitled to make autonomous decisions about the way in which transfusion operated within their regions. Despite the responsibility for the safe operation of the NHS in Scotland, there was therefore no involvement at governmental level in policy decisions about the way in which that safety should be achieved.

2.47 There was little control on the part of the directors about how the policies of the regions were implemented or enforced by the doctors who were responsible for the donor sessions (who were possibly part time doctors, simply earning extra money by "supervising" at the sessions). Little monitoring of adherence to any standard rules theoretically in place in any given region.

2.48 The increased demand for plasma was the driving force in the policies and practices of the Scottish regional transfusion centres. Bleeding more and more individuals to meet ever increasing targets for plasma was the principal concern. In his statement, Professor Urbaniak of the Aberdeen BTS talked about the importance of meeting targets in the collection of blood and plasma but did not mention that safety targets played any part in that exercise.[808] The lack of involvement of government in decision making left little room for considerations of public health or the safety of the blood/ plasma which was being collected.

---

[808] Para 67 of Professor Urbaniak witness statement at WITN6960001

2.49 There is a question mark over whether the transfusion doctors had access to all of the best information about emerging risks or paid sufficient attention to them. The context again is important – the driving force behind the practice was the need for blood and plasma, in particular. That overriding objective cannot have left sufficient room for a proper balancing exercise to have been conducted between the need for volume and the need to maintain maximum safety, against the background that in the world of pooled plasma products even the smallest breach of the system by a harmful virus would have created a risk of infection via pooled products.

2.50 The issue of communication between the transfusion directors and the clinicians responsible for the care of the "end users" of the products, those responsible for advising on/ administering blood transfusions or blood products in multiple fields and those responsible for the treatment of those with bleeding disorders is addressed elsewhere in this submission.

Reaction to the emerging threat of AIDS

2.51 The factual context to measures taken to try to deal with the risks of AIDS is set out above. Dr McClelland was the main driver of these initiatives, in the SEBTS area. he was aware of evidence that had started to emerge in July 1982 which showed that AIDS was transmissible by blood. Two local papers had suggested that AIDS could become a problem in Edinburgh. He decided that it was important to take action to reduce the risk to transfusion recipients.[809]

2.52 In Edinburgh, that was not entirely straightforward. Dr Gillon stated in his evidence that Dr Anne Smith-Dewar (his predecessor) left her post around 18 months before he took up his role on 1 April 1985 and that Dr McClelland required to undertake the responsibility for the donor consultant role over that period. Does this mean that the SEBTS had no dedicated donor consultant over the key period

[809] See statement of Dr McClelland to the Penrose Inquiry at PRSE0002627

for AIDS risk in the region from around 1 September 1983 to 1 April 1985.[810] This meant that the collection system lacked direction at this crucial time. In addition, the whole system was still dealing with the inadequacies of accommodation and facilities which had been identified in the MI reports. These were not responded to immediately as crown Immunity meant that there was no sanction for the shortcomings.[811] The SEBTS centre had not held a manufacturing licence since June 1991.[812] The system as also underfunded meaning that Dr McClelland had to 'seek...forgiveness, not permission' for overspending his budget.[813]

2.53 The system imposed significant limitations the ability to minimise known risks, despite the fact that pooling meant that or fractionated products at least the system. Was only as safe as its weakest link. There was a regional variation in donor sessions, impact on blood products. In the Aberdeen service, they did not use the leaflet as Dr Urbaniak though that as soon as the donor had walked through the door it was too late to do anything about it. Where the leaflet was used, there was no record kept of many donors were excluded by these methods. No monitoring appears to have been done to enable any assessment of the effectiveness of what was the only line of defence (where used) against disease.

The donor leaflet

2.54 The various iterations of the donor leaflet serve in themselves to demonstrate that there was lack of cohesion and clarity in the way that the threat of AIDS was to be handled within the BTS.[814] Given that the leaflet was really the only means that

---

[810] IBI transcript for 19 January 2022 at page 132, line 17 to page 133, line 6

[811] MACK0001898_001 – report titled "response to the medicines inspectors report south east Scotland BTC 12/01/1983". The response was not compiled until January 1983

[812] SBTS0000407_007 - the existing facilities ranked as among the worst seen anywhere

[813] para 550 of Brian McClelland statement at WITN6666001

[814] See eg Leaflet, 'AIDS and how it concerns blood donors' by the National Blood Transfusion Service, September 1983 [BPLL0007247]; Leaflet, 'Important Message to Blood Donors' by the Scottish National Blood Transfusion Service, mid-1984 [PRSE0000286]; Leaflet, 'AIDS, Important new advice for blood donors' by the National Blood Transfusion Service, January 1985 [NHBT0096480_022] ; Leaflet, 'AIDS: Important information

the service had to prevent infection, a decisive, hard-hitting approach was merited from the start. This simply did not happen.

2.55 As the evidence of the risk to those who receive blood or blood products began to emerge by early 1983 at the latest, the system required to consider what it could do to prevent transmission. The careful protection of the end users of blood or blood products mandated close and careful control of blood being collected from known high risk groups, including IV drug users and homosexuals, in whom there was a known risk of AIDS by that time. The need to protect end users led to the development of a leaflet to be given to donors in response to AIDS risk. In the absence of any testing being used, this was the only protection against high-risk donors being allowed to donate blood at standard donor sessions. It was therefore imperative that all was done within the power of the system to prevent these donors from donating – the consequences were potentially fatal for the recipients of blood or blood products.

2.56 Donor selection was within the province of the SHHD only to the extent that the relevant minister was ultimately responsible for the health service. [815] In practice, donor selection was handled by the SNBTS directors.[816] the Inquiry heard evidence to the effect that this was done without detailed involvement of the SHHD.[817] The government thus relied exclusively on the RTDs to implement policies to protect public health in this important area.

2.57 As had been the case in connection with the continued practice of holding non-standard donor sessions in prisons and military institutions, the system permitted to each director a high degree of autonomy in this area, in effect an unchecked freedom to develop and implement policies and practices as he saw fit.[818] Although there was discussion between regional transfusion centres at a national level, consensus was not always reached. In addition, every donor session was

---

for blood donors' by the National Blood Transfusion Service, September 1985 [CBLA0002255]; Leaflet, 'AIDS: Think before you give blood' by the National Blood Transfusion Service, July 1987 [NHBT0007310]

[815] Penrose Inquiry transcript 24/03/11 (Day 11): 138(5-10) (Dr Scott); [PRSE0006011_0138]

[816] Penrose Inquiry transcript 24/03/11 (Day 11): 138(5-10) (Dr Scott); [PRSE0006011_0138]

[817] Penrose Inquiry transcript 25/03/11 (Day 12): 45(19) to 46(5); 64(17) to 65(9); 103(3) to 104(3) (Dr McClelland); [PRSE0006012_0045 to 0046; 0064 to 0065; 0103 to 0104]

[818] Penrose Inquiry transcript 25/12/11 (Day 12): 33(17) to 34(17) (Dr McClelland); [PRSE0006012_0033 to 0034]

overseen by a doctor who had the final say on all matters of donor selection.[819] Thus, the system lent itself to a degree of variability between the regions and also within each region.

2.58 The leaflet in itself should not be considered to be a magic bullet. Leaflets presented a useful source of trying to provide clarity as to the extent of the medical knowledge available and had the potential to provide consistency. Undoubtedly, the dialogue which could have gone into the production of a uniform leaflet amongst those who had relevant knowledge and experience would have added to the debate. This might have involved all of the regional directors, the national medical director and those with expertise of the disease from the GUM, infectious diseases and virology spheres. No such forum existed in Scotland, where the principle of autonomy ruled. Nationally, there was no EAGA until 1985 and thus no national forum for such a discussion to take place. Even had such a co-ordinated approach been taken to the production of a leaflet, the limitations of a leaflet in practice required to be borne in mind. Leaflets have the potential to diminish, not promote careful analysis of the risks associated with a donor. Their wording, distribution and a means of verification that they had been read and understood needed to be considered. The fragmented system did not lend itself at all to a clear, consistent effective yet workable solution to be found.

Developments in the SEBTS

2.59 In early 1983 Dr Brian McClelland, the regional director of the Edinburgh and South East Scotland Blood Transfusion Service, took steps towards discouraging high risk donors in his region from donating blood by preparing a leaflet containing information about the groups known to be at high risk of AIDS. He was aware of evidence that had started to emerge in July 1982 which showed that AIDS was transmissible by blood, which he thought was the most likely of the theories as to

[819] PRSE0000954_0006

how it was transmitted. Two local papers had suggested that AIDS could become a problem in Edinburgh, claiming in 1983 that Edinburgh could become the "AIDS capital of the North" due to the immigration during the International Festival in the summer of that year and the likelihood that it would attract men at risk of AIDS from abroad. From May 1983 or possibly a bit earlier, he was aware from GUM colleagues that they thought that patients of theirs in Edinburgh had started to shows signs of AIDS.[820] He decided that it was important to take action to reduce the risk to transfusion recipients.[821] Dr McClelland decided that the obvious approach for reducing the risk of transmission of AIDS to recipients was to follow the principles of the US Public Health Services Interagency Guidelines, with slightly amended recommendations for Edinburgh. As a result, he prepared a draft leaflet which was tabled at a meeting of the SNBTS co-ordinating group on 24 May 1983. It is interesting to note that the US guidelines which had influenced his approach had advocated a precautionary approach to donor selection, indicating that all donors from high-risk groups should be rejected, even though many will not be infected/ at little risk. It was made clear in those guidelines that these were reasonable measures which would in any event only be temporary, until laboratory tests were developed.[822] It appears that Dr McClelland has seen enough to make him of the view that the approach taken in the US should be followed in south-east Scotland. No distinction was made in his mind between the risk in the US and in his region. Further, he was working on the basis of the precautionary approach which acknowledged that this was likely to be a temporary measure. It is interesting to contrast this plan with the "business as usual" approach of those treating patients.

2.60 The leaflet was put together by Dr McClelland and his staff. Its title "Some background to the recent publicity" gave it the tone of information as opposed to a means of mandating a clear donor exclusion policy.[823] It talked about who could

---

[820] PRSE0002627_0004

[821] Penrose Inquiry transcript 25/03/11 (day 12): 2(3) to 10(16); 28(25) to 29(4) (Dr McClelland) [PRSE0006012_0002 to 0010; 0028 to 0029]; Statement of Dr McClelland to the Penrose Inquiry @ PRSE0002627_0002

[822] PRSE0002627_0001 to _0002

[823] PRSE0002627_0002

get the disease by referring to "homosexual men, particularly those with multiple partners", whereas bisexual and other men who had sexual intercourse with men ("MSMs") were in fact the clear at risk group. The US literature had realised this and used a wider definition.[824] It involved no plan as to how it would be ensured that donors had read the leaflet and declared all relevant information by signature or some other means. There was no plan to have discussions or direct questioning of the potential donors. This was all inadequate, given the risks of transmission of a fatal disease. In his evidence to the Inquiry, Professor Tedder made it clear (based on his considerable virological experience of the spread of HBV throughout the homosexual community and the early indications that AIDS was spread the same way that the exclusion of MSMs should have been the goal from the outset.[825] This was clearly an appropriate part of the response which did not happen, based it appears on the sensitivities around the discussion of homosexual activity.[826] This is the kind of advice which would have been able to have been incorporated in the response, had more attention been paid to the virological opinion of experienced professionals like Professor Tedder. That men who had sex with men at all were at risk was described as a "common sense approach" by Professor Tedder. This appears not to have been realised or at least acted upon until the national leaflet was re-published in 1985.[827] By then it was too late.

Wider publication/ use of the leaflet in Scotland

2.61 Dr McClelland's leaflet was tabled at a meeting of the SNBTS co-ordinating group on 24 May 1983. The system of regional autonomy at the time meant that different approaches were being taken by directors in other regions. In this regard Dr Mitchell (SNBTS Glasgow) had introduced into the health questionnaire a question inviting those who were worried about AIDS to consult the doctor at the

[824] PRSE0002627_0002
[825] WITN3436003 @ paragraph 109
[826] WITN3436003 @ paragraph 114
[827] WITN3436003 @ paragraph 116

session. Again, this lacked adequate measures to ensure donor exclusion as opposed to mere information. It was far from clear what being "worried about AIDS" would mean. A far more proactive approach was required in light of the severity of the risks. Dr Mitchell left the onus on the donor to take action. The minutes suggests that no high risk groups were identified in the material provided in the WSBTS at that time and that the McClelland leaflet was not being used in the WSBTS.

2.62 This was a good example of the issues which were experienced with the way that the WSBTS want about taking steps to secure patient safety. In this case as in the continued collection of blood from prisons until 1984, patient safety was not adequately respected in the west. In his evidence to the Inquiry, Dr Gillon described the WSBTS as being culturally different from the SEBTS.[828] He was of the view that there was a resistance to adopt new approaches to blood collection in the west in the interests of improvement/ safety, which of course was at the forefront of the mind of Dr Gillon when he arrived in the SEBTS in 1985.[829] He expressed the view that that cultural resistance to change emanated "from the top", ie from Dr Mitchell.[830] In this assessment, Dr Gillon was right when his opinion is measured against the contemporary documentation. This cultural difference was seen in the fact that those in the west remained resistant to donor questioning even after the AIDS crisis. In 1987, Dr Gabra wrote about proposed alterations to the donor leaflet and said no questioning was necessary. He expressed the view that even then they should simply just release the criteria and trust the donors. He desribed this as the great advantage and drawback at the same time of the voluntary, altruistic donor system, as if nothing could be done to limit the risks. He expressed a concern about "embarrassing" direct questions of the donors.[831] Dr Gabra was keen on making the donors the owners of the service.[832] This WSBTS culture was an abdication of the BTS's responsibility to

---

[828] IBI transcript for 19 January 2022, page 67; line 1 to page 68; line 20 (Dr Gillon)
[829] Ibid
[830] IBI transcript for 19 January 2022, page 68; lines 2 to 3
[831] SBTS0000680_171
[832] Para 297 of Dr Gabra statement at WITN5495001

apply its scientific knowledge to ensuring the safety of the system, which the donors could not be expected to possess. Without taking the responsibility to engage in direct questioning of donors, they could not be sure that they understood the potential relevance and severity of not declaring certain medical history

2.63 Further, Dr Urbaniak (SNBTS Aberdeen) had decided to do nothing locally as he was of the view that once a donor entered the session it was too late to do anything.[833] This was clearly a completely inadequate response to this potentially fatal problem.

The development of the leaflet

2.64 Dr McClelland's leaflet was subsequently amended to accommodate concerns raised by the Scottish Homosexual Rights Group (SHGR). The amended leaflet was distributed in the South East of Scotland in June 1983. Although this leaflet was made available to other regional transfusion centres, it is not clear whether or not they actually distributed it. It seems likely that they did not as their directors appear to have adopted quite different approaches to the problem. There was a concern that embarrassing intrusions into the donors' private lives to identify in individuals who might have an increased risk of carrying a transfusion transmitted disease, might deter people from donating.[834] The option of questioning donors was suggested but rejected.[835]

2.65 At a national level the DHHS, with input from Dr McClelland, published a leaflet which was available for distribution throughout the UK by 1 September 1983. No action appears to address the clear issues that simply having a leaflet available would entail. It seemed that it was considered that the leaflet would be adequate, irrespective of how it was distributed and the fact that mere distribution would

---

[833] PRSE0003620_0005
[834] Penrose Inquiry transcript 25/03/11 (Day 12) 23(7) to 25(17) (Dr McClelland); [PRSE0006012_0023 to 0025]; and PRSE0000954_0007
[835] PRSE0000954_0007

not guarantee that donors would read it or understand it or that it would influence their actions.

2.66 The regional transfusion directors were allowed to introduce and implement the use of the UK leaflet autonomously which led to an inconsistency of approach. In a system where one positive donation would be known to contaminate the whole plasma pool, this inconstancy was intolerable. There seemed little point in there being central control over the wording of leaflet and the general approach to be taken (including ministerial involvement) where the implementation of the centrally decreed message/ approach was implemented inconsistently.

2.67 It took until August 1984 for further alterations to be implemented due to having to wait overly long for ministerial approval. The leaflet was further altered in November 1984. In Scotland, once the use of the leaflet had been centrally mandated within the DHSS and by extension within the SHHD, there was an inconsistency in the way that the leaflet was used in the management of donors. In the North they were put on display with other publicity leaflets at the donor session and in the plasmapheresis room. In the North-East they were available at all mobile and fixed site sessions. In the East they were put on display and anyone requesting information was referred to the Medical Officer on duty. In the West Dr Mitchell had incorporated into his health notice the question "Have you ever heard about AIDS? If you wish to know more you may ask the Medical Officer at the session in confidence or your General Practitioner or write to the Transfusion Director" and the leaflets were available on request at sessions.[836] This was an inadequate system which failed to make clear to donors what the potential effects were of donating if they posed a risk of this fatal disease.

2.68 At a meeting on 8 December 1983, the SNBTS directors agreed that every donor should receive the leaflet and that the health questionnaire should include the question "Have you read and understood the leaflet on AIDS?, but a decision was not taken on the best method of distribution. At a further meeting of the SNBTS directors on 2 February 1984 the effectiveness of the leaflet was discussed. It was

---

[836] Minutes of Directors Meeting Held in the BTS Headquarters Unit on Tuesday 13 September 1983 - PRSE0002617 from _0002 to _0003

stressed that the leaflet must be given to all prospective donors, implying that it had not been to that point. At a meeting on 13 March 1984 it was agreed by the SNBTS directors that the leaflet should be sent once to each donor as an enclosure to the call up letter.

2.69 This leaflet was subsequently withdrawn following the introduction of the UK leaflet in September 1983.[837] By November 1983 it was recognised that the leaflet that had been prepared by the SNBTS had not been particularly useful and that there was still a problem about how to screen out those in high risk groups who might present as donors despite the leaflet.[838] By December 1983 Dr McClelland recognised that there was a problem with the wording of the UK leaflet in that it was too reassuring, and in early 1984 the DHSS also recognised this problem. Dr McClelland redrafted the leaflet and the revised version was available for distribution in August 1984

2.70 In November 1984, following the infection of the Edinburgh Cohort, a decision was taken by the SNBTS directors about distribution of the donor leaflet, which was to be enclosed in every donor call-up letter, sent to the address of known donors who were not normally called to sessions, given to every donor at the session, distributed in advance of a sessions to which donors do not receive a personal call-up letter and enclosed in the registration book sent to new donors. . In December 1984 Dr McClelland suggested a further revision including that the words "sexually active homosexual men" should be changed to "homosexual or bisexual men". Dr McClelland explained that the reason for this proposed change was probably because the phrasing relating to gay men had become a bit diluted and they were trying to tighten it up.[839]

2.71 The effectiveness of the leaflet as a mechanism for deterring high risk donors from giving blood was undermined by the continued inconsistent approach taken to the distribution of the leaflet in Scotland, even after a national leaflet as agreed in September 1983. In this regard, given the nature of the fractionation process at

---

[837] Penrose Inquiry transcript 25/03/12 (Day 12): 114(3-10) (Dr McClelland); [PRSE0006012_0114]
[838] Penrose Inquiry reference SNB.001.51988; Penrose Inquiry transcript 25/03/11 (Day 12): 54(12) to 55(14); [PRSE0006012_0054 to 0055]
[839] Penrose Inquiry transcript 25/03/12 (Day 12): 55(17) to 68(10)(Dr McClelland); [PRSE0006012_0055 to 0068]

the PFC, blood from different centres would have been pooled to produce factor concentrates. In our submission a robust uniform approach should have been taken earlier to enhance the effectiveness of the donor leaflet as a mechanism for discouraging higher risk donors from giving blood. Moreover, given natural concerns about donors not internalising the information contained in the donor leaflets, the more direct methods that were introduced subsequently, ought to have been introduced at a far earlier stage.

Conclusions in relation to the donor leaflet

2.72 As a result of opposition from the Scottish Homosexual Rights Group (SHRG) to any suggestion that homosexual men should not be able to give blood, the leaflet was amended in consultation with the SHRG to include wording that they were able to endorse,[840] and was available for distribution in June 1983.[841] The removal of the word "homosexual" from the original draft of the donor leaflet used in Edinburgh to appease the concerns of the SHRG demonstrated an inappropriate priority given to the rights of donors over the rights of end users of blood and blood products. The system meant that the RTDs deemed themselves unable to defer healthy donors and meant that they needed to secure the agreement of homosexual donors to deferring themselves. The system, gave away control of its deferral policy unnecssarily and unsafely.

2.73 The lack of direct questioning of donors in relation to AIDS was disproportionate to the threat which the disease posed. It was known that the disease could be rapidly fatal. It was known from the outset that it could be transmitted via the homosexual community. It was considered inappropriate to questions donors – they were responsible adults who knew what they were consenting to. Given that blood donation had always involved testing for syphilis and hence the risk that risky sexual practice would be revealed by the process anyway, it is hard to

[840] Penrose Inquiry transcript 25/03/12 (Day 12) 18(19) to 23(23) (Dr McClelland); [PRSE0006012_0018 to 0023]
[841] Penrose Inquiry transcript 25/03/12 (Day 12): 69(20-25) (Dr McClelland); [PRSE0006012_0069]

understand why there a reluctance to quiz donors about their sexual practices. There was a need for a proper assessment of their answers by a medical professional to ensure accuracy in light of the extreme risks. Indeed, the donor had a right to properly presented information about what his donation would mean and the potential consequences of any untruthfulness in his responses or dubiety about them, in particular in the absence of testing. The use of ambiguous terms such as "homosexual" as opposed to men who have sex with men and the lack of mention of bisexuality was confusing, in the same way as other materials mentioned the need for "drug abusers" to exclude themselves.

2.74 In Scotland, homosexuality had still been illegal only a few years before the period in question.[842] There was still a strong stigma associated with it and the public declaration of the orientation. It was inherently unlikely that reliance on a donor leaflet would be the most reasonable way of excluding at risk donors especially as:

(a) The collection of blood from group settings such as in the workplace or prisons may mean that the declaration of homosexuality may have been practically impossible and resulted in an at risk donor giving blood.

(b) The use of the term "homosexual" was stigmatised and inaccurate as a means of identifying the at risk group. Men who had had sexual intercourse with other men in the last few years may not have considered themselves to have been homosexual or at least have declared it.

---

[842] Homosexuality had only been decriminalised in Scotland on 1 February 1981 As a result of the coming into force of section 80(1) the Criminal Justice (Scotland) Act 1980 which provided that "Subject to the provisions of this section, a homosexual act in private shall not be an offence provided that the parties consent thereto and have attained the age of twenty-one years"; and

"When the applicant lodged his complaint in 1976, the relevant law applicable was substantially similar to that currently in force in Northern Ireland. Section 7 of the Sexual Offences (Scotland) Act 1976, a consolidating provision re-enacting section 11 of the 1885 Act, provided for the offence of gross indecency; the offence of sodomy existed at common law. However, successive Lord Advocates had stated in Parliament that their policy was not to prosecute in respect of acts which would not have been punishable if the 1967 Act had applied in Scotland. The Criminal Justice (Scotland) Act 1980 ("the 1980 Act") formally brought Scottish law into line with that of England and Wales. As in the case of the 1967 Act, the change in the law originated in amendments introduced in Parliament by a Private Member." (*Dudgeon v UK, ECHR, 7525/76, paragraph 18 relating to the law of Scotland)*

In addition, homosexuality in the military was illegal until 2000 - see https://www.bbc.co.uk/news/uk-scotland-60053929 - story about a man being dismissed from the navy for being gay in 1982

(c) Donors would have been tested for syphilis anyway and so their involvement in the process of blood donation would inevitably involve the possibility of risky sexual practices or their infection with venereal disease coming to light.[843] Thus donors who attend to donate blood would be aware of that possibility and would already have been put off attendance if they were embarrassed or reluctant to have the experience leading to the exposure of these elements of their history. Asking direct questions about sexual history was not only absolutely necessary in light of the potentially fatal threat but also not something which would in all likelihood have taken the donor by surprise or have deterred him or her from attending. Professor Contreras in North London felt that it was the reticence of her older colleagues that drove the concerns regarding discussions with donors relating to their sexual history, rather than concern that the donors themselves would be offended[844]. The leaflet actually afforded no protection at all against the threat of this fatal disease. Far more could and should have been done to try to prevent it.

2.45 By way of contrast with the cumbersome, inconsistent system of the SNBTS, the Penrose Inquiry heard evidence of the system that was in place in Finland at this time in which the Finnish Red Cross Blood Transfusion Service had an organisational structure that was a combination of centralisation and decentralisation. In this regard the FRC BTS had its headquarters, laboratory and plasma fractionation centre in Helsinki. The blood collection centres had no medical director but were managed by a local head nurse, with the guidance of a part-time consultant doctor, under the supervision of the medical staff in Helsinki. This organisational system meant that it was relatively easy to implement a national policy once a decision had been made centrally.[845]

---

[843] See for example PRSE0002052_0038 (1977) which refers to the practice of donations being tested for syphilis
[844] IBI transcript for 02/12/21: 175 to 176 (Dame Professor Contreras)
[845] PRSE0000179_0002 – Statement of Professor Leikola to the Penrose Inquiry

Steps taken after emergence of HIV infection/ AIDS in the blood and blood product community in Scotland in late 1984

2.75 Measures taken after the emergence of infections in Scotland from domestic blood or plasma included the introduction of a health questionnaire that donors were required to sign, confirming that they were not in a high risk group.[846] Furthermore, a flash card system was introduced in August 1986 in an attempt to address the concern that donors might pick up the leaflet but not read it carefully or at all. This was administered when the donor was face-to-face with the member of the donor selection staff. A donor would be asked questions about whether he had read the leaflet and whether he belonged to any of the high risk groups.[847] Subsequently personal interviews were introduced for new donors and donors who had not attended for more than two years, and from January 1992 this included direct oral questioning about risk activity rather than simply asking if they had read and understood the information provided.[848] Furthermore, in 1989 a pilot study had been carried out on the use of an impersonal interview using computer software, which was a more effective method than direct oral questioning, but the project was abandoned after an unsuccessful funding application.[849] Even by 1985, donor sessions in Edinburgh were not very private at all.[850] These steps were taken too late in the day, in particular for those "canaries" who would be exposed to the risks of any emerging threat.

2.76 In any event, from 1982, there was a lack of control over donor sessions beyond Scotland which took place in Northern Ireland which meant that Scottish patients were subject to the donor collection practices there (and vice versa). Though Dr Foster indicated that "standard validation studies" which were undertaken on Northern Irish plasma before it was fractionated along with the Scottish plasma,

---

[846] Penrose Inquiry transcript 25/03/11 (Day 12): 70(18) to 71(3) (Dr McClelland); [PRSE0006012_0070 to 0071]
[847] [PRSE0002627_0009]; and Penrose Inquiry transcript 25/03/11 (Day 12): 74(10-21) (Dr McClelland);; [PRSE0006012_0074]
[848] PRSE0000954_0012
[849] PRSE0000954_0012
[850] IBI transcript for 19/01/22; 42 (Dr Gillon)

this could not make up for lax donor selection measures.[851] Such measures could not have been about safety from viral infection.

3 The collection of blood from high risk donor sessions outwith the regular sessions

The significance of such donations to the ethos of blood donation in the UK

3.1 The significance of the principle of voluntary blood donation and its centrality to the "gift relationship" at the heart of the system of blood donation in the UK is discussed elsewhere in this submission. The progress towards self-sufficiency in Scotland was based on the importance accorded to these principles. Part of the philosophy was that local donation was likely to limit the exposure of the recipients of blood, blood components or blood products in Scotland to foreign pathogens. Another part was that the use of blood and plasma only from voluntary donors would be likely to minimise the likelihood of infective donations as voluntary donors, giving of their own time and effort to come to donate blood or plasma would be less likely to have been exposed to the risky behaviours associated with a higher risk of viral infectivity.

3.2 Therefore, donations of blood or plasma which were collected within that system other than in accordance with those principles would constitute major breaches of the principles by which the Scottish system of blood collection held itself out as safe, or at least safer than other similar contemporary systems.

3.3 As will be explored in this section of the submission, when measured against the philosophy underpinning the gift relationship and when against contemporary practice elsewhere, the collection of blood and plasma in Scotland otherwise than in normal voluntary donor sessions materially increased the risks of viral transmission to the recipients of blood and blood products produced domestically.

---

[851] page 33 of Peter Foster witness statement at WITN6914001, para (iii)

Given that these are the principles by which the domestic system claimed superior safety when compared to non-voluntary systems (such as the system of blood and plasma collection undertaken using paid donors in the US), the result of these practices was, in essence, to reduce the safety of the Scottish blood donation system to the level of those foreign systems. This is particularly the case for the recipients of pooled plasma products, for whom a single infected donation would contaminate an entire batch of concentrate made from a pool of many plasma donations.

3.4 This approach to the continued reliance on these "higher risk" donations was based in part on the mistaken attitude within the UK in the late 1970s and early 1980s that NANB hepatitis was not a serious problem. In his evidence to the Penrose Inquiry on the subject of prison donations in Scotland, Dr Brian McClelland expressed the view that the only large prospective study which had been done on the significance of the UK was the MRC study from 1974. He clearly stated, on reviewing the data, that the position adopted in favour of prison donations in the book from 1977 by Dr John Wallace ("Blood transfusion for Clinicians") conflicted with the results of that study which he claimed had been misinterpreted and actually showed that NANBH in the UK was a significant problem.[852] The continuation of prison sessions approach unreasonable when considered in light of the contemporaneous data. Dr McClelland highlighted that this attitude was all the more surprising in continuing to accept donations from higher risk donors in light of data which showed that NANBH was a significant problem and testing for HBsAg only excluded 25% of positive donations.[853]

<u>The known risks of prison donations</u>

---

[852] Penrose Inquiry transcript for 22/03/11 (day 9); 44 (6) to 45 (5) (Dr Brian McClelland) [PRSE0006009_0044 to _0045]

[853] Penrose Inquiry transcript for 22/03/11 (day 9); 50 (15) to 51 (6) (Dr Brian McClelland) [PRSE0006009_0050 to_0051]

3.5 Evidence provided to the Penrose Inquiry by Professor Leikola of Finland was to the effect that a study had been undertaken in Finland in the early 1970s which had revealed a considerably higher prevalence of HBV in the prisons compared to the rest of the population. A study by Helske demonstrated that prisoners there were associated with a high risk of hepatitis which was significantly above the mean.[854] As a result prison donations were stopped in 1974, not only as a result of the risk which they posed of HBV transmission (as testing in Finland had been instituted for HBV in 1970) but also of other unknown viruses which it was assumed would be transmitted by that population.[855] No false reassurance was taken from HBV testing (which appears also to have had similar limitations in its detection rates of PT hepatitis) and the probability of the prison population being at a similarly increased risk of other viruses played an important part on the decision making about risk. It might reasonably be surmised that as the severe haemophilia A population in Finland was treated with volunteer derived cryoprecipitate only (Finland being self-sufficient in that product) the pressure to keep up with these risky donations was less than in Scotland where, as discussed elsewhere, the increasing demand for plasma concentrates drove the collection system. Their system before the advent of heat treatment thus had a double safety benefit – low exposure to donors in the products and the ability to be more discriminating about donor source. Finland had a notoriously low HIV infection rate as a result. It is notable that Professor Leikola was selected as an expert witness by the Penrose Inquiry on the basis that its population was roughly comparable to that of Scotland and so expert evidence from that country was thought possibly to have some relevance to the determination of important questions being considered about Scotland by that Inquiry. That country had (a) no early commitment to factor concentrates and (b) the ability to operate autonomously as a relatively small country, a power which Scotland also nominally had but also was seldom able to exercise, given its position within the wider UK system.[856]

---

[854] PRSE0002287_0057 (1974)
[855] PRSE0000179_0001, in particular para 6
[856] See for example, submissions relating to the introduction of testing regimes below

3.6 By the mid 1970's it was appreciated that post transfusion hepatitis was being caused by blood-borne virus or viruses other than hepatitis A and hepatitis B. It was appreciated that the risk from hepatitis B was greater among certain groups, including prisoners. It was also understood that NANB hepatitis was blood borne.[857] Despite the lack of reliability (at least initially) of hepatitis B testing no significant alteration to donor selection policy or procedure appears to have occurred in Scotland. Recipients of blood and blood products were placed at unnecessary risk from the mid 1970's onwards in Scotland because of the failure to take into account the potential danger posed by NANB hepatitis and indeed HBV from high-risk donors such as prisoners and to introduce more selective donor policies. Had this been done at this stage and a more proactive and precautionary approach been adopted in light of the known risks of transmission, donations would simply not have been available from these higher risk sources and the risk to the recipients of blood and blood products from HBV, HCV and indeed HIV would have been materially reduced.

3.7 In the UK, advice from the CMO (England and Wales) contained in a letter of 1 May 1975 had intimated that there was a known higher risk of viral hepatitis transmission from prisoners at that time and that prisoners were an easily identifiable category of high-risk donor.[858] Although this risk was predominantly for HBV, the common transmission routes with HCV meant that the increased threat from prisoners never disappeared from that time onwards, in light of the limited ability of HBV screening to eliminate transmission of that virus and the emergence of the similarly transmitted HCV. This evidence appears not to have influenced the SNBTS's commitment to prison collections.

3.8 In 1976, the International Society of Blood Transfusion "Criteria for the selection of blood donors" provided that:

"In spite of recently developed tests for the detection of HBsAg, only a relatively small proportion of carriers can presently be detected. No routine screening test

---

[857] PRSE0002637 (4 February 1972 speech by Professor Cash to the Royal Society of Edinburgh); PRSE0001431 (3 August 1974 paper by Prince et al); PRSE0002114 (1 July 1977 paper by Hoofnagle et al); and PRSE0001250 (1 July 1979 paper by Berman et al) in connection with which see analysis above

[858] PRSE0000009

is presently available for the detection of hepatitis A virus, or other viral agents that cause transfusion-associated hepatitis. It follows, therefore, that some general precautions should be taken in an attempt to reduce the risk of such viral agents being transmitted from donor to recipient. Prospective donors should be excluded if it is known that they: 1. Give a history of viral hepatitis at any time, except during the first months of life. (This rule may not be acceptable in all countries and may have to be modified where viral hepatitis is endemic) ... 5. Are suspected to be parenteral drug addicts ... 7. Are inmates of a correctional institution."[859]

3.9 The basis for the exclusion of such potential donors was their risk of viral hepatitis. The clear international guidance in this paper appears not to have had any effect on the practice of taking blood from prisoners in Scotland. The executive Council of this international body included the consultant advisors to the DoH (Dr Tovey), who was a past president.[860]

3.10 It was clear from the evidence of Professor Tedder, whose background had included being a research assistant to Professor David Dane who had been a pioneer of the development of knowledge about HBV that the fact that blood was collected from prisons was one of the key reasons why he had gained knowledge of that disease. He was aware of the fact that HBV had been prevalent in the homosexual community and that it had been sexually transmitted between men who had sex with men for some time.[861] In prisons, he pointed out that the danger arose from the fact that (a) the only sexual activity available was homosexual (b) there was always an incentive to donate based on the possibility that doing so would provide some better conditions or treatment (c) donation was done in circumstances where there was an incentive to keep dangerous homosexual or IVDU behaviours silent.[862] It seems that these factors had been drummed into Professor Tedder by his mentor Professor Dane with whom he had worked from

---

[859] PRSE0000885_0012 to _0013
[860] PRSE0000885_0002
[861] WITN3436003 @ paragraph 22
[862] WITN3436003 @ paragraph 107

around 1973. These truths about the dangers of prison donations were therefore known and accepted wisdom in virological circles throughout the period when infections were occurring as a result of blood and domestic blood products from at least the early 1970s. He made it clear that the protections which were reasonable including the avoidance of prison donations should apply to the voluntary donor system as much as the commercial one.[863]

3.11 The continued practice of the collection of blood from penal institutions in Scotland was specifically criticised on inspection of the Scottish facilities, as reflected in a letter from D Haythornwaite of Medicines Inspectorate to Dr Cash dated 4 June 1982.[864] The letter identified wider donor selection issues, including exclusion of donors by "chance". There was an opportunity to do a lot more within SNBTS as a result before the advent of AIDS but the system was slow to react, if they reacted at all. The primary consideration of the SNBTS ought to have been reducing the risk to the recipients of blood to a minimum. This advice would have been followed from around 1975, if not from 1982. The SNBTS directors ought collectively to have discussed and discontinued the practice prison collection long before to the matter being raised by the Medicines Inspectorate in 1982. If they had done so, they would have prevented one of the at risk transmission routes for AIDS when it emerged from 1982 onwards.

3.12 It should also be borne in mind that the evidence available to the Inquiry suggests that those prescribing domestically manufactured blood products were unaware on the fact that the products had plasma from these sources. On arrival at Yorkhill in January 1983, Professor Hann discontinued the prophylactic regimes which had been instituted by his predecessor and moved them into treatment with mostly domestic factor VIII concentrate. He was an advocate of the local philosophy of others like Dr Ludlam. He told the Inquiry that he was, however, unaware of this practice and only learned of it some years later, to his dismay, equating the practice with what he knew of the risks from US products, which he knew ought

[863] WITN3436003 @ paragraph 108
[864] PRSE0000401_0002

generally to be avoided. [865] If he (and other directors) did not know this practice and the risks created by it, they could hardly have appraised patients or their parents of it.

Prison collections – SNBTS practice and risk assessment

3.13 The SNBTS had a long history of collecting blood from prisons and other penal institutions in Scotland. The Medicines Inspectorate undertook an inspection of the Scottish regional transfusion centres and the PFC which reports in 1982, which reported in 1982 (examined in detail elsewhere in this submission). At that time the Medicines Inspectorate identified the practice of donor collections in prisons and other penal institutions as being one which did not conform with good manufacturing practice and should be discontinued. The lack of proper licensing controls over the transfusion centres and the PFC had meant that they were not subject to regular inspection by the Medicines Inspectors. As a result, the practice had not ever been questioned in Scotland and indeed there appears to have been no consideration undertaken by SNBTS of the risk posed to recipients of blood or blood products from continuing to accept donations of blood from prisoners or other "higher risk" donors. There are no documents from the late 1970s and early 1980s showing concern or discussion of the topic.

3.14 Indeed, at a national Scottish level detailed consideration was given to the higher risk posed by the collection of blood in prisons only because of the advent of the crisis posed by AIDS rather than the concerns expressed by the Medicines Inspectors and the literature and data concerning the risk from hepatitis. This reflects the notional authority which the Inspectors had in a system where domestically collected blood and domestically produced blood products were not subject to real licensing control.

[865] IBI transcript for 08/12/20; 24 (Professor Hann)

3.15 Indeed, the actual policy adopted following the meeting of the SNBTS directors on 29 March 1983 appears to have been that the directors were free to continue to collect blood from prisons. Despite the MI report, the autonomy of the directors meant that the SNBTS or its director (Professor Cash) appear to have had no desire or perhaps power to contravene the autonomy of the directors, even though by this time the evidence analysed elsewhere in this submissions shows that the risk of AIDS had made the need to stop high risk donations all the more urgent. There is no evidence that any of the RTCs recorded a policy decision to stop collecting blood in penal institutions. Even in the SEBTS, where prison sessions had not found favour in comparison with the other regions, no policy decision was taken at that time to stop them formally and though they never happened there again, the door remained open to the possibility.[866] It seems that those responsible for decision making wanted to keep their options open rather than closing off the possibility of collecting blood from prisons in the future. As late as 12 January 1983 Edinburgh maintained in its response to the Medicines Inspectorate that prison donors would only be used in an emergency but it is noteworthy that the minutes for the meeting of the SNBTS directors for 29 March 1983 record that all directors present said that sessions were held in all regions.[867] It is notable that there was no discussion at the March 1983 meeting of either the time which had elapsed since the MI commentary on the practice of prison or borstal donations or the increased risk posed by the emerging AIDS threat, either specifically in respect of prisons or indeed more generally. The ultimate determination was that the Inspectorate would simply be informed that no decision had been taken as no agreed position had been reached. All of these factors demonstrated a disregard for the significant conclusions reached about safety by the MI report.

3.16 The tables in the final Penrose report made it clear that blood was still collected in prisons in Scotland until 1984 in the west of Scotland and in two of the other centres (east and north east) until 1983.[868] Collections in the north (around

---

[866] See Penrose Inquiry transcript 22/03/11 (day 9); 35(7) to 35(23) in relation to Edinburgh (Dr Brian McClelland); [PRSE0006009_0035]
[867] PRSE0000193_0005 (29 March 1983)
[868] See Penrose final report, table 26.3

Inverness) occurred until 1983 also in at least one prison, though precise figures were unavailable. The Penrose table lists the final collection in the south-east centre (Edinburgh) as having taken place in 1981. The evidence available to the inquiry suggests that is, in fact, likely not to be accurate. In fact, the evidence suggests that collections continued to take place there until 1983 also. As late as 12 January 1983 Edinburgh maintained in its response to the Medicines Inspectorate that prison donors would only be used in an emergency, meaning that they would still be collected and used.[869] The minutes for the meeting of the SNBTS directors for 29 March 1983 record that all Directors present (including the south-east) said that sessions were held in all regions.[870] In his statement, Dr McClelland talked about having checked the donors cards from prison sessions at some point in the past and stated that he had examined donor cards from Saughton Prison in Edinburgh for "1980, 1981 and subsequent years".[871] The fact that these collections continued to take place at a time when collections were known to be dangerous is significant in the analysis of the relative safety of the system of blood collection in Scotland. As the plasma from these donations was being pooled for concentrates meant that the risk was spread to all recipients. Dr McClelland ultimately accepted that not only should prison donations not have happened after 1975 but they should probably have never happened at all.[872]

3.17 According to Professor Cash there was no SNBTS management decision because such decisions required consensus within the directors' group or an instruction from SHHD. Neither was forthcoming despite the MI report and the developing risk of AIDS. Professor Cash stated in his evidence to the Penrose Inquiry that guidance was sought from the DoH but none came.[873] There is no basis in any documents or from any other witness that any decision required unanimity or that it was necessary to refer the matter to SHHD. The precise structural position is unclear. It may be that this was the problem – nobody knew who required to take

---

[869] PRSE0000193
[870] PRSE0000193 at para 7
[871] Para 252 of Brian McClelland statement at WITN6666001
[872] IBI transcript for 27/01/22; 118 (Dr McClelland)
[873] Professor Cash Penrose Inquiry statement @ PRSE0004484_0002

the initiative to make this important and clearly necessary decision regarding prison collections. SHHD representatives were in attendance at the meeting on 29 March 1983. It can hardly be said that in the absence of an SNBTS policy to prevent prison donations that those in attendance from the government can be taken to have required to give instruction on any change of position. Professor Cash's assertion that he was not "the boss" is indicative of a clear leadership structure to enable them to do what was in the best interests of the recipients of blood and blood products.[874] The evidence presented on these matters is redolent of a system which was not fit for purpose. If the evidence of Professor Cash is correct, it seems unworkable that the directors could have thought that they should rely on the control of the SHHD or the DoH on these matters. The directors were the experts on these matters in Scotland and the SHHD would have relied on them to highlight the issue and provide advice in any event. The lack of SHHD directive was hardly surprising in light of the failure of the directors to act themselves by adopting a policy in light of the MI report and the increasing risks from AIDS. In addition, the evidence heard by this Inquiry suggests that the DoH at this time was unaware that Scotland continued to collect blood from prisons, a practice which had been abandoned in England in most places long before March 1983. In North London, for example, a decision was made to cease all collections from prisons in 1973 in recognition of the higher rates of HBsAg detections in prison donations[875]. The fact that advice was sought (according to Professor Cash) and not received from the department which would have expressed surprise at and opposition to the practice suggests that the advice was not sought effectively or indeed at all.

3.18 The precise reasoning for why prison and borstal donations was discontinued in Scotland (ultimately in 1984) remains elusive. In a report which was conducted in the west of Scotland between September 1980 and August 1983, it was found that prison donations had ten times as many grossly elevated ALT levels than normal blood donations. It was commented in 1985 when the study reported that "These facts have also helped dissuade SNBTS from visiting prisons to obtain blood for

[874] Penrose Inquiry transcript for 23/03/11 (day 10) (Professor Cash); 42 (11); [PRSE0006010_0042]
[875] JPAC0000002_039

transfusion purposes".[876] There appears to have been little sense of urgency about excluding the obviously hugely elevated risks.

3.19 Despite this, and even at the height of the emergence of the AIDS crisis, at a meeting of the SNBTS directors on 13 September 1983, there remained resistance in the west from there being any form of control over Dr Mitchell's autonomy to continue to collect blood from prisons. Despite other directors taking a different view he intimated that it would be "unfortunate" if stopping prison sessions might at some point feature in the "Red Book".[877]

3.20 Throughout the relevant period it was known and appreciated that donations from prisons posed a higher risk. [878] The large-scale production of pooled plasma products made from thousands of donations led to a drive for self-sufficiency because of the dangers of accepting blood from "paid donors". The very same characteristics that made "paid donors" objectionable such as unreliable histories, dissolute lifestyles, increased risk of parenteral transmission and questionable motivation all existed in the prison population long before the Medical Inspectorate reports[879] and even longer before the last donation was accepted at Glasgow on 25 March 1984. No attempt could made to justify the donations obtained from prisons in the early 1980s as being necessary because of any specific emergency given the limited amount of blood which was collected – it provided a limited contribution to the blood supply but also increase the risk to the recipients of blood and blood products considerably and unnecessarily. In the event, the evidence available to this Inquiry discloses that ceasing to collect blood from prisons did not affect the blood supply, even in the west of Scotland where the practice was insisted in the longest.[880] The evidence does not support the contention that the continued use of prison and borstal donations was necessary or proportionate in the interests of the blood supply. Indeed, Dr Mitchell's

---

[876] PRSE0002577_0006 - Follett/Dow reported in July 1984
[877] PRSE0002617_0006
[878] Penrose Inquiry transcript 23/03/11 (day 10); 59 (Professor Cash); [PRSE0006010_0059]
[879] PRSE0003608 and PRSE0000132
[880] Penrose Inquiry transcript 22/03/11 (day 9) (Dr Ruthven Mitchell); 163 (7) to 164(13) [PRSE0006009_0163 to _0164]

evidence to the Penrose Inquiry shows that any issues with shortages could be addressed by other means, in reality.[881]

3.21 A letter dated 12 April 1983 from Professor Cash to Mr Haythornthwaite states that that the practice of donor sessions at prisons and borstals had been discussed at length by the SNBTS Directors at the meeting and that "opinion was strongly divided and it was not possible, at this time, to obtain a consensus view'; that, nevertheless, the Directors recognised that the problem would require further discussions; and, to that end, that Dr Brookes had agreed to raise the matter at the next meeting of the UK Working Party.[882] In a letter dated 23 August 1983, Dr Brookes advised Professor Cash that the Working Party had met for the first time on 30 June 1983 and that "no discussion was necessary since as far as England and Wales are concerned these sessions have already been stopped. It is now left to the Scottish regions to decide whether they will do the same".[883]

3.22 When confronted with the advice given by the English CMO from 1975 accepted in his evidence to the Penrose Inquiry Dr McClelland accepted that they should have stopped sooner, despite his centre in the SEBTS having been the earliest to stop prison collections in Scotland.[884] This position was accepted with the benefit of hindsight relating to the period from 1975. He also accepted that he had not really addressed his mind to this issue (despite evidence such as that informing the 1975 CMO letter in England) until around 1980. Like so much in the SNBTS, it appears that a practice had developed which was not reviewed on the grounds of safety. The practice had become automatic and was not subjected to any reasonable system of review. Though in his Penrose evidence Dr McClelland found it impossible to answer as to whether the practice was unreasonable on the basis of evidence available at the time, the evidence presented from contemporaneous sources indicated that it was. The simple fact is that a contemporary analysis of

---

[881] Ibid.
[882] PRSE0003038
[883] PRSE0002981
[884] Penrose Inquiry transcript 22/03/11 (day 9); 77 (14) -79 (8) (Dr Brian McClelland); [PRSE0006009_0077 to _0079]

the safety of the practice appear not to have been undertaken, despite this evidence.

3.23 A different attitude was maintained by Dr Mitchell in his oral evidence to Penrose.[885] He maintained the position that there was not any good reason to discontinue the practice focussing on the civil right and indeed civic duty of prisoner to donate. This attitude represented a dangerous approach to the collection of blood and a disregard for the safety of the recipients of blood and blood products. In common with the approach to the defence of transfusion practice seen elsewhere, Dr Mitchell relied on the fact that the epidemiology of NANB hepatitis transmission was not well understood, an illegitimate assumption that all case of NANBH would be reported (and hence the prevalence well understood) and an apparent assumption that drug addict prisoners would self-report and self-exclude. These are all illegitimate and unreasonable bases for his continued collection from prisons.

3.24 There was considerable evidence that this practice was dangerous and ought to have been discontinued. One Glasgow witness who was born in the 1970s told the Inquiry that his mother had worked for the transfusion service. He recalled the service taking blood at prisons when the Glasgow fair was on – the 2 week traditional holiday period in the west of Scotland when the factories were shut. [886] This shows not only reliance on prisons at such times but also the reliance on factories for the rest of the year. There was no evidence available to the inquiry, on any view that he recipients of blood pr blood products were ever told that blood or plasm used to make products came from prisons, military institutions or even how the blood or plasma was collected.

3.25 The system also created a problem that there was a lack of clarity about knowing who had responsibility for making decisions in this area. There was an influence of the influence of the Home Office which appears to have served as a deterrent to action being taken, in particular where the blood collected was adding to the blood available, even in small amounts. This was apparent from SHHD note dated 11

---

[885] Penrose Inquiry transcript 22/03/11 (day 9); 164 (19) -165 (8) (Dr Ruthven Mitchell); [PRSE0006009_0164 to _0165]

[886] IBI transcript for 08/06/2019; 135 to 136 (WITN2245, aka Mr V)

August 1983[887] and also appears to have been an issue in England the decade before. At a meeting of the English transfusion directors on 26 September 1973, it was noted that the Home Office should be informed before any change in the policy there.[888] A DHSS memo dated 23 August 1983 from Mr Winstanley to Mr Brown refers to the need for close liaison with the Home Office, 'since they have in the past been very much in favour of blood donation by prisoners.'[889] Dr Brookes, in her statement to the Penrose Inquiry stated that when she arrived in Scotland in 1981 as Director of the Dundee RTC, she understood, based on her experience working in England, that it was long-standing government policy that the BTS should visit prisons to 'permit prisoners to make some restitution to society' and to 'do something which many of the community did, to help their return to normal life after release'.[890] The fact that is that while that went on in Scotland, nobody spoke up and confronted the practice despite clear evidence that it was not necessary for the blood supply and dangerous, until it was too late Transfusion directors under pressure to make quotas for plasma and given freedom to do it in a dangerous way, in effect turning a blind eye to the reckless practice as it had been done for years. This was an area where government needed to take a lead. Diana Walford had a clear view in her oral evidence that collecting blood from prisons was a "terrible idea" at any time. She had no idea that this had been going on and expressed the view that it should not have been. [891]

3.26 It would be difficult in any discussion the risks associated with prison donors not to consider the known association between prisons and IV drug use. It had been known since the 1970s in Scotland as a result of work done at Ruchill Hospital that cases of HBV which were reported to them had a significant percentage of cases (just under 30%) associated with IV drug use, not just in Glasgow but in the whole of Scotland. This was considered to be an underestimate due to the perceived likelihood that association with drug use would be under-reported.[892] By 1983,

---

[887] PRSE0003281
[888] PRSE0003952 at page 8
[889] PRSE0004729
[890] PRSE0001873
[891] IBI transcript for 21/07/21; 181 to 183 (Diana Walford)
[892] PRSE0004802 (1976)

HMI of prisons in Scotland had pointed out the IVDU in Scottish prisons as having involved 490 prisoners who were recorded as being dependent on or having recently used drugs, nearly all of whom had been using heroin and indeed other drugs of addiction.[893] As had been the case in 1976, one would expect a considerable degree of under reporting in the latter category at least due to the criminal nature of the activity and the likelihood that prisoners would want to keep their drug use a secret as a result for fear of further punishment. The rise of the misuse of these drugs in society is noted in the report as is the link between such misuse and the numbers of inmates rising. In 1983, Scottish prisons were increasingly becoming populated with IV drug users. Their blood continued to be collected and used in Scotland. The Scottish policy of criminalising drugs in the early 1980s, in particular was well known.[894] IV drug users were likely to be found in Scottish prisons.

3.27 In conclusion:

(a) Known high risk donations were collected from prisons and borstals in Scotland until 1984 which were not needed for the blood supply but which endangered the into the HIV period but also before that long after the risks of HBV and NANB known;
(b) By the time of HIV and the criminalisation of IVDU in Scotland, prisons were a hotbed of transmissible disease;
(c) Prison donations were not voluntary;
(d) There was systemic confusion about this area and who could take responsibility for it. Thus, it was just left alone to the transfusion directors who were motivated by getting as much blood and plasma as possible, despite the known risks;
(e) This practice materially increased the risk of infection, in particular amongst the haemophiliac community who received pooled products but also for the

[893] PRSE0002615_0004 (1983)
[894] https://www.thenational.scot/news/16301049.drug-policy-scotland-trapped-1980s/

recipients of transfusions who may have had the misfortune to receive red cells from a prison donor;

(f) In effect meant that we had an incentivised, non-voluntary donor system in Scotland, with many of the hallmarks of the system of paid donation which the entire system was in theory committed to avoiding.

Military donations

3.28 The material provided by the SNBTS to the Penrose Inquiry also reveals that there were continued collections from the military institutions in Scotland, including the US military in Scotland from at least RAF Edzell (Dundee centre) and Holy Loch (Glasgow centre) for the entire period with which infections were occurring from blood and blood products. The collections from Holy Loch by the west of Scotland centre took place from an unknown date (data is available from 1982) until 1990.[895] Holy Loch was, of course, not only a military base but a US military base, staffed by US military and other staff. The US navy base was there from 1961 until 1992. The collections at RAF Ezell took place between 1963 and 1996.[896] It was operated by the US navy from 1960 to 1997. The collections in these bases are likely to explain one of the apparent anomalies about the evidence heard by the Inquiry. One witness (Mr X) gave evidence about having received a blood transfusion in Dumfries in the late 1970s and having been told by the nursing staff that it was from the US and that he would speak with an American accent after having received. This unusual story had the ring of truth about it as it was the kind of unusual thing which might stick in one's mind. The apparent anomaly was that the UK did not import blood. However, this evidence shows that in Scotland blood was collected and used from foreign military personnel. Thus, "foreign" blood was used in the Scottish system. Dumfries is around 100 miles from Holy Loch. Like in the UK military, homosexuality was illegal in the US military until the "Don't Ask

[895] Penrose Inquiry final report para 26.206 and table 26.6
[896] Penrose Inquiry final report para 26.206 and table 26.5

Don't Tell" legislation passed by the Clinton administration in 1993. Thus, the likelihood of anyone self-excluding on those grounds was virtually zero. Similarly, self-exclusion on the grounds of other risky behaviours was also unlikely in case they came to the attention of the military bosses. Indeed, when anti-HIV screening was introduced, US military authorities required their service personnel to sign a form that mandated the blood service to report testing results to the US military[897]. Of course, this was not the only "foreign" blood used within the Scottish system. From around 1982, plasma started to be fractionated at the PFC in pooled along with Northern Irish plasma. The consequence of this was that the recipients of Scottish products made there became subject to the donor selection policies and practices there, beyond the control of the SNBTS. In September 1982, the "concern" about the use of blood in Scotland that had been imported from Southern Ireland came to the attention of the DoH.[898] This is another blood collection system beyond the direct control of the SNBTS which exposed recipients to unmanaged risks. It seems that stopping US military base donations was considered in 1985 and it was thought that there was no reason to stop them.[899]

3.29 As with prison blood, the relatively small amounts collected there suggest that the system could have survived without these donations. They continued to be collected over a period when there was a known risk of AIDS from the US. The collection of blood from these US military bases (and indeed the evidence of Dr Brian McClelland to the effect that he was aware in 1983 of tourists to the Edinburgh festival donating blood in the south-east region) put pay to any suggestion that the Scottish donor system was local. One of the perceived advantages of the Scottish system (including Scottish concentrates made at the PFC) was that it used from local blood donations. This was thought to minimise the risk of foreign pathogens entering the system. The fact that blood was positively sought from these US military bases and from known foreign donors (in particular in the emerging AIDS crisis from 1983, when US donations were known to be of a higher risk) demonstrate that both for pooled products and for the unfortunate

---

[897] NHBT0004776
[898] para 8.8 of Lord Clarke statement @ WITN0758001 and DHSC0004047_434
[899] PRSE0002258

individuals who received the red cells from these donations, blood and blood products were not local. Indeed, they came from known high risk populations.

3.30 The evidence available to the Inquiry suggests that blood was also collected at other military bases in Scotland. Dr Galea spoke of the likelihood that collections were undertaken at RAF Kinloss near Inverness as his predecessor Bill Whitrow was a military man and had connections in the military. There appears to have been no consideration of the possible increased risk posed by such sessions.[900] He continued the practice despite his mantra to medical students that "the safest blood is the blood which is not given", which suggested (as with Professor Contreras) that a precautionary approach to collection was always best.[901] The evidence available to the Inquiry is that the practice of collecting blood even from UK military bases was unsafe. Military personnel had been known to be high risk for hepatitis for decades, possibly due to their service abroad, possible risky behaviours and also exposure to industrially produced vaccinations made from pools which may have been made in part from human derived components (see the commentary on the yellow fever vaccine above). Research into hepatitis rates amongst UK and US military personnel had indicated that they were probably high risk donors had been available for years. One study from 1964 by Professor Zuckermann looked at the ongoing problem of hepatitis in the military in the UK (RAF), as HBV was deemed to be significant public health condition of significant concern. He discovered 895 cases of which 100 thought to emanate from syringe transmission. Though looking at transmission routes, this appears to have been a significant enough issue to be studied and concluded that it was bad idea to continue taking blood from military donors who had high rates of hepatitis.[902]

3.31 The precise nature and extent of military donation in Scotland is not known. However, the evidence does tell us that military collections were going on at the relatively safe south-east centre up to 1985. It is therefore likely that such donor sessions were going on elsewhere. It is submitted that military donations came

---

[900] IBI transcript for 07/12/21; 33 to 34 (Dr Galea)

[901] IBI transcript for 07/12/21; 25 (Dr Galea)

[902] RLIT0001239 – RAF paper re hepatitis (1964); See also WITN2235007 – risks from US military personnel in UK of lots of transmissible diseases

from a known high-risk source and also were not voluntary. The very attraction to such donor sessions was that there was a captive population which could not question whether to donate or not. The likelihood that military personnel would declare issues which made them unsuitable to donate was low. They had been ordered to do so. In particular, as homosexuality was in effect illegal in the military until 12 January 2000, the possibility that such behaviour would be declared would be very low indeed.

3.32 It was a combination of these factors which led Dr Gillon to conclude that the military sessions which were going in at a base south of Edinburgh (in Penicuik) on his arrival at the centre in 1985 were not truly voluntary and therefore not safe. He discontinued them. He also mentioned other sessions at 2 other bases in Edinburgh.[903] It seems that the sessions did not run as normal sessions did and that there was, at one base at least, an enthusiasm for making them work, ie for making sure as much blood was collected as possible. They had, of course, been going on for many years before that, without question. Thus, there were further donations into the Scottish donor pool which were not voluntary, contrary to the assumed principle applied to all donors. As the military was a "captive" population, its donations could not have been deemed to be voluntary in accordance with the Titmuss principles from "The Gift Relationship".

3.33 In any event, no steps were taken to minimise the risk from former prisoners or former members of the military being able to donate. They had the same risks of long terms chronic infection as the current military or indeed the partners of such individuals. This was another clear hole in the system.

Investigations into the collection of prison blood in Scotland – general

3.34 Of course, given the fact that much of the blood collected was used for its recovered plasma which was then pooled and used in the production of

[903] IBI transcript for 19/01/22; 18 to 21 (Jack Gillon)

fractionated concentrates made from large donor pools, those in receipt of those products were subject to the lowest standards of safety, the lowest common denominator in the service. Certain efforts were made to try to co-ordinate the blood collection practices in the whole of Scotland via the national medical director, Professor Cash but his power to impose his view of safety or any other aspect of the BTS was ultimately non-existent, as discussed elsewhere in this submission.

3.35 The reasons why the Glasgow centre, in particular, continued to collect blood from prisons until 1984 is an important issue for the Inquiry to consider. It is particularly important when one bears in mind that, though it had been known for some time that it was a high risk source for blood which may be contaminated with viral infection, the continuation of the practice until 1984 not only maintained a link with a clearly identified source of increased risk for viral hepatitis infection but also unnecessarily opened up a risk of HTLV III infection as well which probably would not have existed had the practice been stopped only a few years earlier, due to the likely timing of the introduction of HIV into the Scottish blood donor pool (1982). This practice created such a risk for the recipients of blood and blood components in the WSBTS region but also increased that risk for the recipients of all blood products, including factor concentrates made at the PFC, by that time not only in Scotland but also in Northern Ireland due to the pooling of the plasma to make those products. Some light is cast on the practice in a book written by Dr John Wallace and published in 1977.[904] Reliance was placed by Dr Wallace placed on certain factors in favour of the continued use of blood from prisons, which continued in the west of Scotland until 1984:

- That few areas have so much blood that they can continue to reject donations in the way that the rejection of prison donations in an "ultra cautious" fashion involves. This was contrary to the standard practice in many areas of the UK, as is highlighted above. It would, therefore, be difficult to justify the description of the approach as "ultra cautions" based on standard practice elsewhere. The fact

[904] The practice is discussed from PRSE0002052_0049 (1977)

that this statement is made in the context of a discussion about the risks of transmission of a potentially fatal condition (HBV) seems also to suggest that this description is less than apt.

- A suggestion is made that there is a need for the service to rely on collections from prisons or else the blood supply will run short. This does not stand up to logical scrutiny. In the first place the amounts of blood being collected from prisons were not great (see the figures supplied to the Penrose Inquiry) suggesting that, although dangerous they were unlikely to have been indispensable. Further, the suggestion is made that reliance was placed on these in times of national holiday, presumably as other blood donors were otherwise occupied. It sems unlikely in light of the amounts collected that these could not have been offset by advance planning for these known periods of time. In any event, the predominance of the evidence from Scottish witnesses to the Inquiry was that the main pressure on blood collection in Scotland in the late 1970s and 1980s was not red cells but the need for plasma for fractionation, meaning that red cells were in surplus in many areas. The need to rely on the relatively small amount of blood collected from prison donations could this have been avoided by (a) more assiduous use of plasma products in the treatment pf patients with bleeding disorders, in particular factor VIII (b) better sharing of red cells amongst the regions if some were in surplus if the west of Scotland was ever short (c) better use of red cells as opposed to whole blood for transfusion to free up more plasma for fractionation.
- That the total incidence of HBsAg antigenaemia in the prison population in accordance with a study was only 1% and so that did not justify the loss of blood which stopping prison donations would involve. In addition to the argument above, this argument also seems hard to understand in the context on which it was made. In the earlier text in the book, Dr Wallace had expressed concerns about the accuracy of testing for HBsAg in light of the fact that at best it was thought only to detect 25% of post transfusion hepatitis. His faith in this figure in light of evidence to the contrary from other parts of the UK seems misguided. What did he think was special about prisoners in the west of Scotland such that their risk was lower? Surely the more obvious conclusion in light of this evidence

was that the Glasgow study may have been unreliable, or at least that the risk of that justified caution. The viral risks associated with social deprivation was spoken to evidence to the Inquiry by Dr Huw Lloyd – the same social issues were prevalent in Glasgow over this period, in particular amongst those who ended up in prison.

- That excluding prisoners was socially and psychologically undesirable, because permitting them to donate aided rehabilitation and would lead to prisoners donating after release from prison. This appears to be based on no real evidence. Again, it seems odd that rehabilitation was not used as an excuse in other areas where prison donations had been abandoned many years before. It sems odd also that transfusion doctors like Dr Wallace seemed to see their role as promoting social rehabilitation over blood safety and promoting making a known risk group into repeat donors, thus encouraging prison donors to become a continuing threat to the donor pool (as the evidence was that repeat donors would not be subjected to the same rigid selection criteria as new donors, meaning that former prison donors would by this logic be encouraged to continue to donate with little by way of restriction in future). It sems very difficult to understand how this apparent lack of concern about the safety of donations from male prisoners fits with the more traditional analysis delivered later in the text about the higher risks of viral hepatitis in paid donors who may be IV drug users, alcoholics or sexually promiscuous.[905]
- It is worthy of note that in this same passage Dr Wallace promoted the use of donors from tropical areas, who were excluded in other parts of the UK on the basis of similar principles of promoting social integration.[906] One assumes that this was the policy in the west of Scotland as well. This approach would seem to offend the most basic of epidemiological and transfusion principles about trying to rely on local donors in order to limit the possibility of foreign pathogens being introduced into the UK donor pool. In the very same passage where this is justifies Dr Wallace supports it by the end to collect red cells for transfusion from

[905] PRSE0002052_0059 (1977)
[906] PRSE0002052_0049 (1977)

rare blood types which may be needed by foreign nationals requiring transfusion in the UK, without any apparent consideration being given to the unnecessary risk created by sourcing these cells from foreign donors. He seems to be advocating a form of social autologous blood transfusion, whilst not suggesting that the cells or the plasma would be restricted from transfusion to the indigenous community. This is said despite the fact that in the same text high rates of positive HBsAg were known in donations from tropical areas, and are equated with paid donors.[907] The overall analysis of this text by a senior member of the transfusion community in the west of Scotland is that the service there adopted a scientifically fluid attitude towards the safety of the collection of blood. Paid donors were anathema but donations from populations known to be dangerous – those from male prisoners and tropical areas, akin to non-voluntary donations in safety terms – were justified on the grounds of blood supply issues which were either fanciful or could have been avoided by simple measures to negate them.

3.36 The delay in Glasgow of donations from prison donation sessions being discontinued became all the more inexplicable in light of evidence which arose in the area thereafter. The emergence of information about the prevalence of NANB hepatitis in the west of Scotland was supplemented by the PHD which was undertaken by Dr Brian Dow in Glasgow from around 1979 when the diagnosis of NANBH by exclusion became possible due to the availability to Dr Follet at Ruchill Hospital of reagents for HCV to accompany tests for HBV.[908] Dr Dow presented in evidence in 1981 of the significantly higher rate of ALT in prisoners, who had specifically studied due to the known higher prevalence of HBV in that community and the premise that NANBH (which was the object of the study) was also blood-borne.[909] No action appears to have been taken despite the PHD having been commissioned specifically at the instigation of the RTD, Dr Ruthven Mitchell to

[907] PRSE0002052_0053 (1977)
[908] PRSE0001312_0004 and _0005 (statement by Dr Brian Dow)
[909] PRSE0001312_0005

examine the extent of NANBH in the west of Scotland. Importantly, in addition, Dr Dow confirmed in his statement to the Penrose Inquiry that no steps were taken to prevent former prisoners from donating blood even after the regular prison donor sessions stopped in 1984, meaning that the threat from these high-risk donors was not even brought to an end in 1984. Dr Dow confirmed that it was only due to press reporting of the high levels if IV drug use in prisons that the sessions were stopped in 1984.[910]

4 Analysis of the breaches of the SNBTS system for the collection of blood

General

4.1 In this section we present an analysis of the available statistical material which casts some light on the question of the circumstances in which infections were caused by blood or blood products which were collected or made in Scotland. The purpose of this analysis is to assist the Inquiry in coming to a view as to how robust the SNBTS system of blood collection was in the period over which infections were allowed to occur.

4.2 The SNBTS has taken the opportunity over the years to paint a self-portrait which has emphasised certain of the positive qualities of the work which was able to do in the collection and processing of blood. Though there are many things about the work of that organisation which stand to be admired, the way in which that analysis has been compile and presented is an incomplete narrative which needs to be viewed in the full context. This part of the submission attempts to do that.

4.3 The circumstances of the infections which occurred as a result of the administration of blood, blood components or blood products are analysed in detail elsewhere at various points in this submission. This section attempts to bring

[910] PRSE0001312_0006

the details of the other parts of the submission together in order to provide a comprehensive analysis of how and when the security systems of the SNBTS were breaches which might otherwise be lost in the more piecemeal analysis.

Infection with viral hepatitis

4.4 The analysis of infections with viral hepatitis does not need to be further analysed in detail. The evidence above of the nearly 3,000 HCV infections caused by blood transfusion and the Fletcher et al paper, which indicated that by the early 1980s domestic concentrations could be assumed to transmit NANBH on first infusion indicate that the system was breached many times. There was no effective protection in place prior to April 1987 and September 1991 respectively.

Infection with HIV

The implicated batch

4.5 The circumstances in which the initial infections of haemophilia patients in Edinburgh came to light and how they were communicated to the patients involved are analysed elsewhere in this submission. As is stated there, the initial analysis of the possible sources of infection of the 16 patients who had initially tested anti-HTLV-III positive showed that 15 had been exposed to a single batch of SNBTS factor VIII concentrate. It was assumed from that point forward that that batch had been the batch which had been the source of the infection. Against this background, batch 023110090 was identified in the aftermath of the infections of the cohort as the batch which was implicated in the infections of 15 of the 16 who had tested positive. There were other interpretations of the treatment histories of those who had tested positive. Logically, there must have been at least 2

infected batches. The individual who had tested positive who had not been treated with the implicated batch meant that there were at least 2 infected batches. Many more could have been positive. The explanation of the implicated batch being the source of the infections of 15 out of 16 of the positive patients was a convenient one. It minimised the number of breaches of the system which could be deemed to have occurred. It was the basis of the subsequent cohort research – the studied cohort thereafter being able to be restricted to those infected and non-infected who had received that batch, a common source of treatment which lent notional scientific legitimacy to the study. That other batches appear not to have been located and tested indicated an unsafe approach to the potential infectivity of other batches. The convenience of the narrative being attached to the events seemed to trump the immediate need to protect others from infection.

4.6 A meeting on 15 November 1984 led to an analysis being presented of the role of the implicated batch in the infections of the positive patients.[911] Two batches were looked at and could not be excluded from possibly being infected. A further 4 batches were listed from treatment records and being possible sources of infection but there was no time for these to be investigated more fully. At least 7 batches had been used in treatment and could have been responsible for infections. It seems unusual that the batches were not subjected to testing, as they could have been. It was suggested that on conformation of the positivity of the patient who did not receive the implicated batch, a further re-assessment of the data would be necessary. In his evidence to the Penrose Inquiry, Professor Ludlam described this exercise which was undertaken (as far as he was concerned) as trying "to see if we could pin it down to a single batch".[912] The approach was therefore predicated upon an erroneous and dangerous assumption that only one batch could have been implicated in the infection of those who had tested positive. That was quicky proven to be wrong as at least one patient did not receive it. There appeared to be little appetite for the working hypothesis to be disproved.

---

[911] PRSE0001828 - letter from Dr McClelland to Dr Cash outlining the exercise undertaken on 15 November 1984
[912] Penrose Inquiry transcript for 21/06/11 (day 36); 23 (21 - 22) (Professor Ludlam); [PRSE0006036_0023]

4.7 Some analysis of the position of the individual who had not received the implicated batch was described in the article written by Dr Ludlam et al in the aftermath of the infection of the members of the cohort.[913] In the article another batch is identified which was received by that patient and 8 of the other 15 who had been found to have seroconverted. It is likely that the sixteenth patient was also infected by an SNBTS factor VIII concentrate as he had not received commercial product.[914] No factor VIII batches other than the implicated batch were ever recalled. Three other patients had been identified as also having seroconverted and having received the "implicated batch" by the time of a further article written by Professor Ludlam & Ors, published in the Lancet in May 1988.[915]

4.8 There is evidence available to the Inquiry that some further investigation was at least done into how the implicated batch had come to be infected. It was thought at a subsequent meeting of the SNBTS directors that the batch may have been infected by a single positive donor who was "presumed to be a homosexual", had tested weakly positive for VD and lived in the west of Scotland.[916] After further investigation into his HTLV III status, this theory was found to be wrong. Dr McClelland had investigated the possibility with Dr Tedder of having the blood components donated by the donors to the implicated batch tested.[917] That did not happen. Therefore though the importance of identifying the positive donor was recognised in understanding how the infections had come to occur and learning lessons for the future, this appears not to have taken place. Further, it had been decided initially that the red cells and other blood components from donors to the implicated batch should be destroyed. By the time of the RTDs meeting on 11 December 1984, that decision had been changed due to reasons of supply, leaving the decision instead with the directors individually.[918] That decision was a dangerous one when it was known that the batch had caused infections.

---

[913] PRSE0000903_0002 (3 August 1985)
[914] PRSE0000903_0002
[915] PRSE0004673
[916] Meeting of the SNBTS directors on 11 December 1984 - PRSE0001767_0004
[917] PRSE0000224 (28 November 1984)
[918] PRSE0001767_0004

4.9 Evidence is available to the Inquiry which has given rise to much reasonable speculation about the circumstances in which patients came to be infected with HIV in the Edinburgh haemophiliac population. No explanation was or has ever been given to the infected patients or their families about how the infections occurred. Other staff within the Edinburgh centre have spoken to the Dr Ludlam having presided over a culture of secrecy about AIDS, a subject which he wished to retain under his control.[919] This has given rise to a natural and understandable curiosity on the part of the infected and affected as to how the infections came about, in particular as they had consistently been told that they were safe from that risk. It is important in understanding the effects of the HIV infections in this community that the Inquiry understand and acknowledge that members of this community has been driven to the conclusion that they were deliberately infected. It is submitted that this was a reasonable conclusion for them to have reached, in light of what they had been told of the risks, the lack of explanation from those responsible and what they discovered when they started to investigate the matter for themselves. Whether the Inquiry shares the view of these individuals about this claim, it is important to understand the basis upon which the claim has been made and the fact that having reached this position was entirely reasonable based on what evidence there is and also the circumstances in which those so tragically afflicted have had to reach it. At the very least, a clear understanding of the sequence of events shows the effects of failing to keep patients informed and involved in their treatment. For these patients and their families, the culture of secrecy had exponentially and irreparably compounded the harm of their infections.

4.10 First, as is narrated clearly elsewhere in this submission, there was a scientific motive for the deliberate infection of the group. The value of the infected and indeed the uninfected group exposed to this batch of factor VIII concentrate within the cohort was considerable. The wider cohort group continued to be studied for many years outwith their knowledge. The value on their infection was the

---

[919] PRSE0001844 @ para 11 - statement of Billie Reynolds – she was told by Dr Ludlam not to instigate discussions with the patients about AIDS or HIV

information which the group was able to provide about the disease and its progression to the State generally. Part of the value of the group lay in the fact that around half was infected and around half were not – comparison between the two groups, similarly treated and exposed to the batch was a valuable part of the exercise. As the contemporary materials show, in particular the Gordon response (analysed below), the scientific value of part of the cohort becoming infected was clear in advance – the ability to compare the consequences of infection on the immune system with the pre-infectious position in a community which had unwittingly provided a consistently stocked batch of serum samples was clear. On the other hand, the value of an uninfected group of patients was far more limited. It would only tell a tale which could be told by any similarly treated group of haemophilia patients, namely the immune effects of consistent antigenic assault from factor concentrates in the absence of infection. Second, there was the fact that secrecy and ignorance were integral to the plan, not only before the infections but for many years after them. If patients had been told of the risks, they might not have continued their treatment. If their infections had clearly been explained to them or the fact that they had been tested and studied, at least some might have refused to continue to comply. Given the apparent commitment to a long-term plan of which the ignorance of the patients played an integral part, the motives of those involves in the study were already seriously questionable. Thirdly, as is narrated elsewhere, the explanation provided by Professor Ludlam as to why he selected certain patients for testing by Dr Tedder is unconvincing. Contrary to his stated position, it submitted elsewhere in this submission that he had good reason to suspect that certain of his patients were infected based on recent immune function tests carried out in the autumn 1984 (which could have been compared with other tests which had been carried out since the spring of 1983), the glandular fever-type illness of one of the infected patients after infection. It could equally reasonably be deduced from this unconvincing explanation that Dr Ludlam knew whose samples to send for testing as he already knew which patients were infected. Fourthly, there was the focus on the implicated batch. The wider cohort which went on to be studied had all been exposed to this single batch. Part of the value of the study was that they all that

this common exposure from which some had been infected and some had not. A closer examination of some of the medical records of the patients made one batch (the implicated batch) appear to stand out in the way in which records of its administration had been recorded by medical staff (0090). This appeared consistent with some special significance being attached to this batch before the infections or the significance of this batch were known about, something which has not been explained subsequently. Fifthly, there was the question of opportunity. In order for patients to become infected in a deliberate and controlled way, it would be necessary for those involved to know in advance to know that patients already involved in the immune study (or at least some of them) would become infected. There required to be access to the cause of infection. There is evidence which could be construed as providing such an opportunity. Viral material was made available to the UK health services, including individuals with whom Dr Ludlam had contact, including Dr Craske and Dr Tedder for the development of testing. The paper referred to below published in The Lancet on 1 September 1984 makes clear that such material included both HTLV-III material from the US and also LAV from the French group led by Montagnier, which had been discovered in 1983. By September 1984 the publication made it clear that that group considered the two viruses to be the same.[920] In addition, the Glasgow group had been collaborating with the Melbye group in Denmark in connection with their immune function study. They had access to viral material to make an anti-LAV test early in 1984.[921] The infected cohort was infected between March and May 1984. Access to viral material (in the form of HBV) from the US had already happened in Scotland. Professor Cash told the Penrose Inquiry that 'I saw Alfred Prince in my 1969 visit to the States, he gave me a small vial of Australia antigen in New York and I brought it back, and that was the first beginnings of testing for Australia antigen, certainly in Scotland. This was an outstanding

---

[920] PRSE0000197 (The Lancet, 1 September 1984)

[921] This is apparent from the face of the Glasgow research published in 1984 conducted in collaboration with the Melbye group, discussed below. It was Possible to spike product with plasma known to contain hepatitis virus, as had been done to prove the effective pasteurisation of albumin – see EXPG0000044_0032 (fractionation expert group)

group'.[922] It was, of course, possible to spike a product with HIV and Dr Ludlam appears subsequently to have taken an interest in that.[923] Sixthly, there is the issue of timing. This is the very essence of what happens when clinicians keep patients in the dark. No written evidence has ever been forthcoming about the timing of the testing undertaken on the infected Edinburgh cohort patients. Such written material underpinning the testing and subsequent study must have existed at some point in time. The lack of clear proof (other than the oral testimony to subsequent Inquiries about the precise timing and circumstances of the emergence of evidence of infection) have simply added to the justifiable suspicion and righteous anger. Seventhly, there is the fact that they were all infected by the same implicated batch or at least assumed to be and the apparent prominence given of the number of this batch in their medical records, as if that batch had some special significance. The full number of this batch was written out in records, unlike others. Logically, this must have been recorded at the time of administration and not when the infections were discovered. The significance must have been known about prospectively.[924] Eighthly, there are the completely unacceptable circumstances in which patients came to learn of the risk that some patients had been infected. The combination of the shortcomings of the December 1984 meeting (discussed elsewhere in this submission) and the focus at that time on the assurance being given to patients that demonstrates that there was a temporal coincidence between the infection of the cohort patients (between March and May 1984), testing for infection (at some point from the summer of 1984) and the emergence of a heat treated factor VIII concentrate (October to December 1984). Though the reassurance given to patients at that time is criticised elsewhere in this submission as misleading, the fact that the reassurance was given in such confident terms has led patients reasonably to understand that the new products must have been tested in live patients. It was reasonably

---

[922] Penrose Inquiry transcript for 23/03/11 (day 10); 10 (Professor Cash); [PRSE0006010 _0010]

[923] See PRSE0003497 – December 1989 response to inquiry from Ludlam by Perry looking to have access to materials "spiked" with HIV

[924] WITN2232001, first witness statement of WITN2232 @ para 38; WITN2232035, second witness statement of WITN2232 @ para 4 and WITN2232038; WITN2190001 @ para 12 (first written statement of Robert Mackie)

assumed that this was also part of the real cohort infection story – the infections of some of the group having emerged as a result of some being given infected and some being given heat treated material.

Other infective batches

4.11 The statistical analysis presented above indicates by a process of logical examination that there must have been multiple HIV infected batches which breached the SNBTS's ineffective system to protect recipients of blood products. An "HIV look back" study regarding infective concentrates was undertaken in 1988, presumably on unheated samples from the batches retained for testing.[925] At least 4 infected batches appear to have been discovered.[926]

4.12 Despite this it remains far from clear precisely how many batches there were in Scotland. Even after this Lookback, Dr Ludlam wrote to Dr Perry in 1990 looking for access to samples of factor VIII concentrate back to 1980 in connection with ongoing studies of immune function as a result of HIV and factor VIII, including the implicated batch or batches.[927] Further, in 1991, Dr Ludlam wrote to Dr Foster seeking details of batches known to have HIV as there were several patients for whom they did not know how they came by HIV, referring to major and minor cohort).[928] Even at that time, it seems that the accurate number of infective bathes was not known. Other evidence suggests that there must be at least 18 infected batches, dating back to 1979.[929]

4.13 The evidence suggests that the SNBTS has (like the haemophilia directors) been keen to make sure their position on matters relating to the disaster was fixed around the time of the HIV litigation, shortly after these requests. Correspondence letter from Dr Foster to Professor Cash dated 5 November 1991 refers to the

---

[925] PRSE0000131 (PRSE0001079) and PRSE0001484 (1988)
[926] LOTH0000045_005
[927] PRSE0004543 (30 April 1990)
[928] PRSE0004244
[929] LOTH0000045_009

existence of an Edinburgh HIV discussion group.[930] The letter refers to claims which had been made about the unique and constructive relationship between the PFC and its customers. The letter goes on to refer some negative commentary about the PFC from Dr Ludlam and suggests that the possibility of public scrutiny of the circumstances of the patients' infections with HIV (ie in the litigation) had made this a particularly problematic time for Dr Ludlam to have said what he had said, namely to criticise the quality of the PFC products. It was suggested at that time that the SNBTS should decouple itself from these arguments that certain measures like early heat treatment and batch dedication could have prevented infections. This was a process by which, as a result of the ongoing litigation, positions were adopted which remained fixed for many years, whether the whole truth or not.

Conclusions

4.14 It would be wrong, in our submission, to focus on the arbitrary and incomplete statements issued by the SNBTS which seek to focus only on its apparent achievements in isolation. This analysis reveals that there were numerous breaches of the systems which it had in place (even after screening was introduced in the hope of eradicating the viral threats from transfusion of the blood or blood products collected or made in Scotland) and numerous infective batches of blood products.

4.15 Though there are elements of the system of which the SNBTS should rightly be proud and indeed individuals within the system, the SNBTS and the NHS in Scotland culpably allowed multiple breaches of its defences systems against viral infection to occur. This is the appropriate context on which their other achievements must righty be seen.

---

[930] LOTH0000045_002, which refers to PRSE0001953

4.16 The practices used in the collection of blood in Scotland were unsafe in light of the known risks and were certainly not focussed or in in the best interests of end users of blood and blood products produced in Scotland.

G. SCREENING OF BLOOD FOR VIRAL INFECTION

1. Lines of responsibility/ considerations

1.1 Whereas matters relating to the care of patients the collection of blood fell into the operation sphere of haemophilia doctors and the transfusion directors, the possibility of a seeing regime necessarily involved government. Realistically, the SNBTS could not roll out screening without government involvement, consent and ultimately funding. In theory, they were dealing with the Scottish Office (SHHD) who had constitutional autonomy to act in these matters alone. In fact, they were often fighting with a hidden combatant, namely the DoH, whose views on these matters, based on non-Scottish considerations virtually always prevailed. This was despite the fact that scientific expertise meant that technologies to achieve these aims were developed independently within Scotland at times.

1.2 The possibility of testing for viral infection in the 1980s arose against a background of Scotland having developed its own HBV testing regime, the details and limitations of which are discussed above. Scotland thus had ongoing experience of a large-scale screening regime and he technology and facilities to deliver it.

2. Anti-HIV screening

Surrogate testing for HTLV-III

2.1 There are numerous confirmed HIV infections from transfusions in Scotland which occurred before 1985, on the data available.[931] These might have been prevented by better donor selection measures or the introduction of surrogate testing for HIV amongst donors, either of immune function or anti-HBc, neither of which were routinely used in Scotland as detection methods.

2.2 Extra protection could have been afforded by the routine use of anti-HBc testing in addition to the routine HBsAg testing which had been undertaken since around 1972. As is detailed above, that testing regime still resulted in HBV positive donors not being detected by the screening programme due to its insensitivity. Given the known severity of the disease and its characteristic similarity with HBV from the outset, it was or should have been realised that there was a need to do whatever was necessary to prevent the spread of the disease by blood and blood products and that, given that groups who were high risk donors for both HBV and HIV were similar due their shared parenteral and sexual transmission routes, bolstering the system to prevent HBV antibody or antigen positive donors to include HBV core as well as HBV surface antigen testing was a reasonable step to take explored and taken. Professor John Barbara, North London RTC's microbiologist, advocated that testing for anti-HBc should be considered as a surrogate marker for HIV in May 1983. He told this Inquiry that "viruses [run] in packs" given the common source of some infections, such as IVDU, and believed that anti-HBc should be considered an indication of past or present infection that could co-infect with HIV[932].

2.3 In his evidence to the Penrose inquiry, Dr McClelland was of the view that there was some possibility of immune function testing being used as a surrogate laboratory test for AIDS/ infectivity with the agent that caused AIDS. He pointed out that this was never routinely introduced in the UK.[933] This would have involved using one or more laboratory tests of immune function to identify individuals who might have sub-clinical evidence of impaired immune function. The intention

---

[931] See Penrose final report, table 3.20 – of the 18 confirmed infections (likely to be an underestimate of the total number of HIV infections from transfusions in Scotland, as discussed in more detail above) 15 occurred before the start of 1985, on the analysis presented by Dr Gillon to the Penrose Inquiry

[932] IBI transcript for 26/01/22: 38 to 41 (Professor John Barbara)

[933] PRSE0002627_0003

would have been to detect the consequences rather than the cause of AIDS.[934] What was also considered was the use of a screening test for antibody to the hepatitis B virus core antigen (anti HBc), which was thought might act as a marker that an individual had been exposed to an infection other than HIV, known to be transmitted by blood or other body fluids with a known similar transmission route to AIDS. The SNBTS investigated the use of such tests and made proposals to the Central Blood Laboratories Authority Research Committee (England and Wales) for studies in the UK but the proposals to evaluate surrogate tests were not taken up[935] and surrogate testing for AIDS risk was not pursued into the routine practice of blood donor assessment in the UK.[936] Once again, this approach in the absence of a more specific test demonstrated a lack of appreciation of the severity of the situation and a lack of ambition in pouring effort into finding a precautionary solution.

Anti-HIV testing – general

2.4 Donor screening for HIV (anti-HIV) was introduced in Scotland, at the same time as in the test of the UK in October 1985 despite confirmation of AIDS cases in the recipients of domestically produced blood products from at least the autumn 1984 as a result of diagnostic testing undertaken at the Middlesex Hospital by Dr Richard Tedder of samples of blood sent to him of patients of Dr Ludlam at the Edinburgh haemophilia centre. Given that investigations showed that the Edinburgh haemophilia patients had been infected by Scottish factor concentrates (in November 1984), this was an unequivocal confirmation that HIV had entered the donor population in Scotland. A question therefore rises for the Inquiry as to why there was such a delay between diagnostic tests for anti-HTLV-III being available and the roll out of a mass screening test for blood donations in Scotland. Even

[934] Statement of Dr McClelland to the Penrose Inquiry @ PRSE0002627_0003
[935] PRSE0003524_0010
[936] Statement of Dr McClelland to the Penrose Inquiry @ PRSE0002627_0003

amongst the transfusion directors, there was little confidence that the existing donor exclusion measures would prevent infections. This was why Dr McClelland described testing as the "cornerstone of safeguarding the blood supply".[937] The feeling amongst senior transfusionists that, notwithstanding the practical problems including issues with the reliability of the test kits, there was a need to move as quickly as possible.[938] The need for a screening test was of the utmost importance in preventing further transmission of this fatal disease.

2.5 Evidence is available to this Inquiry which demonstrates that infections occurred over this period and indeed after it. We are aware from evidence presented to the Penrose Inquiry that two haemophilia B patients were infected with HIV in Glasgow from domestically produced factor IX. One was infected in 1985 and one in late 1985 or 1986 as a result of receiving these domestic products.[939] These patients did not have the same protection, as the SNBTS DEFIX product was not heat-treated until October 1985. These patients were therefore likely to have been infected by an unheated product, infected by a donor who was not excluded by donor selection measures in use at the time and before donor screening was introduced in October 1985. Further, evidence provided to the Penrose Inquiry shows that patient were infected from blood transfusions over this period. Of the 18 confirmed infections, one was infected in September 1985 (patient 16).[940] This is likely to have been as a result of a blood donation made before mass screening was introduced. Earlier screening could therefore have prevented this infection occurring. The fact that there were two infections in Scotland in 1986 indicates that the tests were not reliable in preventing infections at that time.[941] It is possible that these were window period infections. The antibody testing regime along with donor screening measures in 1986 did not prevent these infections.

---

[937] Penrose Inquiry transcript for 29/09/11 (day 50); 8 (8 to 16) (Dr McClelland); [PRSE0006050_0008]
[938] Penrose Inquiry transcript for 29/09/11 (day 50); 8 (23) to 10 (1) (Dr McClelland); [PRSE0006050_0008 to 0010]
[939] See Penrose final report, table 3.17, patients G10 and G11
[940] See Penrose final report, table 3.20
[941] Ibid.

Decision making structures

2.6 The structural arrangements relating to decisions to introduce mass screening of blood in Scotland were complex and did not work in the best recipients of the end users of blood and blood products. Ultimately, the decision-making and funding for such a project would have been within the remit of the SHHD at this time, acting in its role as the body controlling the health service in Scotland. Advice would have been provided on such matters from Professor Cash as national medical director of the transfusion service, acting along with his fellow directors within SNBTS. In this area, as in others similar to this, there was a significant requirement for DoH buy-in in relation to initiatives which might be taken to improve the safety of the blood supply, given the fact that the Scottish Office/ SHHD and the DoH were all part of the same government. At a meeting of the haemophilia reference centre directors on 10 December 1984, Professor Cash expressed the concern that there was no central body organising the introduction of routine anti-HTLV III testing. This was before the formation of EAGA, which did not meet until early 1985 (see below). This concern was echoed at that meeting by Dr Richard Tedder, who had a central role in the development of tests and diagnostic testing at that stage. There was also concern expressed about the extent to which funding would be made available from the DHSS for the testing programme.[942] That meeting was attended by Dr Alison Smithies of the DHSS who reported back to the department on matters raised.[943] The meeting was not attended by anyone from the SHHD.[944]

2.7 Many of the issues regarding the routine introduction of anti-HIV testing were identified by this point in time. At the meeting on 10 December 1984 the issues of (a) cost (b) necessary equipment and (c) counselling were recognised.[945] Further, the issues of counselling, false positivity, the possibility of members of high risk

[942] PRSE0000890_0003
[943] PRSE0000890_0002
[944] PRSE0000890
[945] PRSE0000890_0002

groups attending donor sessions for diagnostic purposes were also recognised at a department of health meeting on 14 January 1985.[946] On the latter point it was noted that the views of the expert advisory group (which had not yet met) would be particularly helpful.[947]

2.8 The apparent lack of a proper national structure for these important matters to be handled was confirmed by Professor Cash in his letter to Dr Bell at the SHHD dated 24 January 1985. The extent of his dissatisfaction about the way in which the AIDS crisis (including decision making about routine testing) was being handled on a national level is clear.[948] He identified the fear in England at this time that Scotland would move unilaterally on routine testing. In Scotland, moves had been made towards getting routine testing introduced by this time including (a) efforts to obtain test kits from US companies (b) technical staff investigating how the tests could be implemented in existing establishments (c) the ability to conduct the western blot confirmatory tests (d) discussions with communicable diseases experts about care for positive donors (including both counselling and treatment) and (e) financial planning to accommodate all of this.[949] This had all been done against a background where Professor Cash did not want to move unilaterally unless it proved necessary.[950] As is discussed in more detail below, it appears that despite (a) these concerns about progress at a national level and (b) steps taken to make progress to counter these problems in Scotland, the SNBTS were required by the SHHD to follow the processes being undertaken in England. This was a further example of the fallacy of administrative devolution. Scotland appears to have had the willingness and capacity to take steps which it considered necessary in early course. Its ability to do so was an illusion in reality.

2.9 This was a complex and largely dysfunctional structure which did not work well in the interests of those who relied on the safety of blood. Decision making was cumbersome and lines of responsibility were not clear. This system was not fit for

---

[946] PRSE0004578
[947] PRSE0004578_0002
[948] PRSE0004386
[949] PRSE0004386_0002
[950] PRSE0004386_0003

purpose. The head of the SNBTS made the point in his statement on this issue that it was not clear at this time who had the duty of care to ensure that blood and plasma was safe in Scotland.[951] Such a viewpoint highlights the lack of any clear lines of responsibility at the relevant time.

2.10 The groups most at risk from being infected with HIV at this time were those in receipt of blood transfusions, those being treated with cryoprecipitate (which included children) and others in receipt of products derived from blood which had not been heat treated or otherwise virally safe – ie anything derived from human blood other than Scottish factor VIII concentrates, albumin and immunoglobulins. Those suffering with haemophilia B in receipt of factor IX concentrate produced at the PFC continued to be at risk as the factor IX was not heat treated until later in 1985. Even at this time, the safety of the Scottish factor VIII concentrate had not been established and so its safety could only be deemed to be theoretical. Thus, there was a need for urgent measures to be taken to introduce routine screening for anti-HTLV III of all blood donations in Scotland.

The advisory structures available to government

2.11 In April 1984 it was announced by Gallo that the virus which was thought to be causative of AIDS had been isolated. By November 1984, the NBTS Advisory Committee's Working Group on AIDS had advised that routine testing throughout English blood transfusion centres should be introduced as soon as possible.[952] By January 1985, the US test kits were available. The theoretical advice of the Working Group required to be put into practice. The evaluation process started on the same date as the first EAGA meeting on 29th January 1985 (see the letter to the pharmaceutical companies referred to below). That group therefore had no opportunity to give advice on whether an evaluation needed to be done at all. No strategy had been put in place to deal with the kids of matters which the

[951] PRSE0003395
[952] PRSE0001693_0002

government had already identified as potentially problematic aspects of the routine testing programme. By this time, countries such as Norway had already set up a system for offering diagnostic tests to individuals on a confidential basis.[953] In our submission, the earlier setting up of this expert advisory group would have enabled expert advice to be rendered, decisions taken and strategies formulated which would have enabled the evaluation and introduction process to progress more smoothly and quickly once the US kits became available. The failure to do so resulted in the consideration of the issue of AIDS testing being considered in a piecemeal fashion in 1984 with little real preparation or co-ordination being achieved. Groups which considered AIDS included the UKHCDO, the CBLA, the English and Scottish Blood Transfusion Services (the former of which had a Working Group on AIDS), the Medical Research Council, the Advisory Committee on Dangerous Pathogens and the Communicable Disease Surveillance Centre ("CDSC"). This was a startlingly diverse and unstructured collection.

2.12 The Expert Advisory Group on AIDS ("EAGA"), set up to give advice to the government of AIDS related matters including the possibility of routine testing for anti-HIV, did not meet for the first time until 29th January 1985.[954] AIDS had been known about since 1982. Its connection with blood transfusion had been accepted by most by the spring of 1983, at the latest. Its sexual transmissibility and hence its ability to grow from one infection into a wider public health problem was well understood from an early stage as was the likelihood that it would kill its victims, as is discussed in more detail above. The severity of the disease, the lack of treatment and the public health implications were all well understood by 1984.[955] When EAGA did have its first meeting, it was noted that the CMO (who had invited the membership of the group) wished unequivocal advice about the introduction of a screening test to the NBTS.[956] Even then, there was no apparent reference to the timing of that advice or urgency with which it was required.

---

[953] PRSE0002030
[954] PRSE0002734
[955] PRSE0001693_0002
[956] PRSE0002734

The decision to evaluate US tests kits

2.13 By the start of 1985, there was a clear failure to appreciate the likely severity of the AIDS epidemic in the UK. Despite the knowledge which was available about the disease, the fact that it proved fatal in many cases, its sexual transmissibility (and hence potential to grow into a huge public health problem), the known period between infection and AIDS manifesting itself (the prodromal period) which increased the likelihood of the unwitting spread of infection, government officials and ministers continued to monitor the development and spread of the disease by reference to confirmed AIDS cases. There was focus only on incidence and not risk.[957] It appears that no robust epidemiological advice was taken that this was not a reliable marker as to the likely extent of the problem. Thus, the reaction to the spread of the disease by blood and blood products was unnecessarily and unjustifiably slow. In addition, the evidence available to the Inquiry demonstrates that the importance of screening was not appreciated as the threat of AIDS had been seen as a problem related to imported blood products and not one which related to the domestic system as well. This had been a problem which had prevented effective government involvement in decision making in response to the threat before this point. It continued to be a problem in connection with the need to prevent infection via the domestic blood supply in 1985. The minister of State for health was not aware that patient had been infected by blood products produced from UK donated blood in Edinburgh in 1984.[958] He was not clear as to why it was necessary to afford the protection of heat treatment of blood products and screening of blood as well. The latter was of course necessary to provide protection to those in receipt of blood transfusions who had already been infected in 1983 and 1984 in Scotland, as is shown by SNBTS statistical information analysed

[957] See para 7.46 of WITN0758001 (statement of Lord Clarke) – he was of the view that the outlay of £2 million on HIV testing was not justified based on the fact that "there were so few AIDS cases".
[958] para 7.67 of Lord Clarke statement @ WITN0758001

elsewhere in this submission. These matters are discussed in more detail elsewhere in this submission, in connection with the response of government to the emerging threat of AIDS via transfusion or the use of blood products.

2.14 It is apparent from the documentation available to the Inquiry that the DoH did not, in fact, have any statutory authority at this time to insist that US companies have their tests undergo a local evaluation at all. The approach which was devised within the Department was to encourage them to participate with the carrot that their involvement may result in their kits being recommended by the DoH and hence become more attractive to the lucrative UK market. It does appear, however, that the local evaluation was not a formal legal requirement from a licensing perspective.[959]

2.15 Test kits from the USA became available in the UK in January 1985. They were subjected to a lengthy UK-wide evaluation process. The kits had been approved and licensed for export by the Food and Drugs Administration ("FDA") in America. From an early stage, it was envisaged that, despite this FDA licensing and the fact that the US kits would have required to undergo assessment there to be licensed, the UK evaluation would be in 2 stages. The initial evaluation would be into the accuracy of the kits as tests and the second stage would involve field trials of the kits in order to ascertain their usability in UK centres.[960] The first stage of the UK evaluation took a significant time to complete and was the main cause of the delay in introducing routine anti- HTLV III testing in the UK until October 1985. Greater reliance could and should have been placed on the test kit evaluation process which had been undertaken by the FDA on the very kits which underwent such a lengthy UK evaluation. This would have resulted in a significantly earlier introduction of routine anti-HTLV III testing in the UK. Dr Robert Perry was a member of the Advisory Committee on the Virological Safety of Blood later in the 1980s which advised the UK government on matters including the introduction of testing for the presence of antibodies to hepatitis C. In his evidence to the Penrose Inquiry he stated that the UK and other European countries relied on the FDA

[959] PRSE0003002 (a note emanating from the Department of Health dated 30 January 1985)
[960] PRSE0003002

licensing of tests to give "a high degree of comfort that it had been through a rigorous regulatory process."[961] Far greater comfort should have been taken from the FDA licensing of the anti-HTLV III kits and that the lengthy first stage evaluation process in the UK was unnecessary.

2.16 Professor Cash gave evidence to the Penrose inquiry concerning serious delays which occurred even before the US test kits became available for evaluation. There was a clear preference in 1984 for an RIA test to be developed in the UK, despite the fact that the ELISA technology in this area was known to be further advanced. Professor Cash clarified in his statement that time had been wasted by this approach which had led to "internal civil service wrangles" in 1984, causing delay when the evaluation of the US assays (already under the scrutiny of the FDA) could have been underway.[962]

2.17 The requirement of evaluation in the locality where the tests were to be used therefore became the principal concern of transfusionists in January 1985. Dr Perry gave evidence to the Penrose Inquiry to the effect that local evaluation of testing kits was needed as there required to be consideration of the possibility of there being a difference in local epidemiology, compared to the kits' place of origin. However, he accepted that local evaluation would be deemed to be overkill now. It does not justify an unlimited delay, especially against a background that there was no testing system in place at all to prevent transmission of a lethal disease and donor selection methods were known to be limited in utility due to the emergence of infections caused by UK blood and UK produced blood products by this time.[963] Blood used for transfusions in Scotland and human plasma-derived, non-concentrate bleeding disorder therapies such as cryoprecipitate had no heating regime applied to prevent HIV transmission in 1985. Against this background, there was a very real risk that the disease could be transmitted via these routes. The introduction of routine testing required to be treated as a matter of the utmost urgency. It was not.

---

[961] Penrose Inquiry transcript for 23/11/11 (day 68); 43 (8 to 12) (Dr Perry); [PRSE0006068_0043]
[962] PRSE0003395_0002
[963] Penrose Inquiry transcript for 23/11/11 (day 68); 119 (7 to 14) (Dr Perry); [PRSE0006068_0119]

2.18 If local evaluation of the US test kits was indeed necessary, this could and should have been done much more quickly, in particular taking account of the data already available about the kits from the FDA. It seems likely that this could have been achieved through local evaluations done by transfusion centres such as the team in the west of Scotland (see below). Indeed, the evaluation process (against this background) could have been undertaken substantially after the formal start of testing. At least as an interim measure US test kits could have been used pending the development of more reliable tests – some protection from an FDA approved test kit was better than none. This approach can be contrasted with the apparent faith that was placed by the ministers in the DHSS in the FDA in 1983 when seeking to reassure the users of imported US concentrates that the new regulations to donor selection which they had introduced in the spring of 1983 would have the effect of making US concentrates safe or at least safer from the risk of AIDS transmission.

2.19 The process of evaluation of the US test kits started before EAGA met for the first time in January 1985. The failure to convene this expert group earlier (as is set out above) resulted in the consideration of the issue of AIDS testing being considered in a piecemeal fashion amongst various diverse groups in 1985 with little real preparation or co-ordination being achieved.

Basis for concerns about the US tests

2.20 The principal concern relating to the test kits which were available early in 1985 from the US was false positivity (low specificity). It was feared that this would give rise to the problems of many donors testing positive on the antibody test who, in fact, were not infected with HIV and would not develop AIDS. This would cause unnecessary concern to them.[964] There do not seem to have been many concerns at this time about false negativity (low sensitivity) meaning that the concern did

[964] PRSE0002030_0002; and PRSE0002453_0003 to 0004

not seem to be that positive donations would still get through the system, despite the test kits being used.[965] In the letter published by the blood transfusion directors in the Lancet in March 1985 expressing these concerns about false positivity, the authors (a) gave little detail about the basis on which these concerns about "likely" false positivity with the US kits are based and (b) appeared on the same page as an article by US authors who suggested that their research has shown that the use of an ELISA with a confirmatory test should not cause too many false positivity issues.[966]

2.21 This concern (a) was misplaced in that the false positivity rate could be offset by confirmatory testing which would not result in many donors being given false positive results and (b) again, inappropriately prioritised the position of donors (who would be affected by false positivity) over end users (who would be affected by false negativity which was not a concern). Confirmatory testing using the western blot technique would be relatively easy to achieve using existing techniques in the PHLS laboratories and in the west of Scotland, in particular in light of the low number of positives which would be expected.

2.22 There is an inherent tension on the position of the government/ the medical establishment in this regard between (a) the asserted understanding that HIV infection was likely to be limited in the UK and hence few positives would be discovered and (b) delays and concerns about issues like donor counselling and confirmatory testing which would (on that logic) not have required major efforts due to the relatively limited numbers of ELISA positives which were to be anticipated and, in the case of counselling, the limited number of confirmed tests by western blot. In any event, one would have been entitled to assume that with an effective system of diagnostic testing in high risk groups (as opposed to amongst blood donors) the numbers who would test positive as a result of donor screening would have been even fewer.

---

[965] PRSE0002030_0002

[966] PRSE0002453_0003 (2 March 1985)

Scottish evaluation

2.23 By December 1984, domestically produced heat inactivated factor VIII concentrate started to be made available by the SNBTS. That step forward for the safety of blood products was achieved before it was in other countries, including England, who did not have a domestically produced factor VIII concentrate at that time. The SNBTS operated independently from the BTS in England and Wales, as is demonstrated by the earlier advances with the heat treatment of factor VIII concentrate so as to inactivate HIV at the PFC. By this time, the risk of HIV transmission through blood or blood component transfusion was well known. It had been since the emergence of the details of the infection of a baby in San Francisco, which was reported in the MMWR in December 1982. Further details of the risks from blood transfusion, in particular the risk to infants due to their unsophisticated immune systems, were known by 1984.[967]

2.24 In light of these known risks and the transmission of HTLV III to Scottish haemophiliacs via domestic products produced at the PFC, within Scotland efforts were made to facilitate the introduction of the routine testing of blood for the presence anti-HTLV III. Professor Cash gave evidence at the Penrose Inquiry to the effect that he was happy that an evaluation of US test kits could and should be undertaken in Scotland in order to facilitate as early an implementation of routine testing in Scotland as possible. Arrangements for access to test kits had been arranged by the time Professor Cash wrote to Dr Bell at the SHHD on the subject of routine testing on 24 January 1985.[968] Professor Cash pointed out that the team in the west of Scotland were "quite outstanding by international standards" when it came to the evaluation of kits.[969] Dr McClelland confirmed that the Glasgow centre was very experienced in this kind of work.[970] There seems little doubt that the Glasgow team could have carried out this evaluation to a high standard and so

[967] See PRSE0002758 - Lancet article dated 22/29 December 1984, in particular the reference to the reports of the infection of 4 infants with HIV in Australia from blood
[968] PRSE0004386_0002
[969] Penrose Inquiry transcript for 01/12/11 (day 72); 116 (24 to 25) (Professor Cash); [PRSE0006072_0116]
[970] Penrose Inquiry transcript for 29/09/11 (day 50); 7 (9 to 10) (Dr McClelland); [PRSE0006050_0007]

there was no need for Scotland to await the outcome of the evaluation being done in England. Scotland had carried out its own evaluations of the RIA HBsAg test kits and had introduced such a testing regime unilaterally.[971] On 21 January 1985, it was indicated that the Abbott kits were already being evaluated in the west of Scotland.[972] The west of Scotland team, had the experience and materials available to carry out its own evaluation of the US test kits in early 1985. Again, the theory of the ability to follow its own path in the interests of patients appears to have become a reality that that required to wait for a routine introduction throughout the UK. This would be a recurrent theme in connection with testing, as is explored in some detail below, in connection, in particular with the introduction of anti-HCV testing.

2.25 Professor Cash gave evidence to the Penrose Inquiry that Scotland having control of its own evaluation would have meant that routine testing could have been introduced in Scotland more quickly as the evaluation would have been completed earlier. He took the view that it could have been achieved in Scotland by the same time as it was achieved in other countries, like Australia and the Netherlands, ie by April/May 1985.[973] Professor Cash was of this view even in light of the various practical steps which would have required to have been taken to organise confirmatory testing, counselling etc. Support for this proposition can be found in the fact that even by the time of Professor Cash's letter to Dr Bell on 24 January 1985, significant steps had been taken towards the introduction (unilaterally if necessary) of routine testing in Scotland and the apparently extensive experience within Scotland of carrying out such evaluations for large scale testing.[974]

2.26 In the event, the proposed separate Scottish evaluation was not proceeded with. Professor Cash gave evidence to the Penrose Inquiry of having communicated to the SHHD that it was his intention to undertake a Scottish evaluation of the test kits. It was his position in evidence that he was told by Dr Archie McIntyre within

---

[971] PRSE0004386_0003

[972] PRSE0004472

[973] Penrose Inquiry transcript for 27/09/11 (day 48); 185 (7) to 187 (15) (Professor Cash); [PRSE0006048_0185 to 0187]

[974] PRSE0004386_0002

the SHHD that he was not allowed to do so. In a statement provided to the Penrose Inquiry on this matter, Dr McIntyre refuted Professor Cash's version of events. In his recollection, the decision to await the results of the UK wide evaluation was made by the transfusion directors and not by him.[975] Professor Cash pointed out that the evaluation which he had proposed be done by the west of Scotland team was "banned" by Dr McIntyre who ordered that it all be centrally controlled.[976] He also expressed the view in his statement that this topic had been accorded an apparently low priority within SHHD, given that the individual nominated to act as liaison between the SHHD and the DoH on the issue had no experience of transfusion matters at all.[977] He expressed the view that matters such as this had been devolved by SHHD to the DHSS which is why his suggestion that Scotland carry out a separate evaluation of the kits was stopped.[978] As noted above, Professor Cash pointed out that the team in the west of Scotland were "quite outstanding by international standards" when it came to the evaluation of kits.[979]

2.27 On this matter, the contemporaneous documents and other evidence appear consistent with Professor Cash's version of events. A proposal for a Scottish evaluation of US test kits had been made very early in the period. They were available for evaluation by an internationally recognised team with a clear track record in this area. Thinking about what might be necessary to contemplate was already formulating in the early stages. It seems odd against this background that that process would have been stopped by the transfusion directors. The lack of appreciation of the apparent severity of the threat from the UK blood supply appears to have been a theme of the DHSS's and the minister of State's approach. Politically it would have been difficult to explain Scotland going first. There is other evidence of the lead having been taken by the DHSS on such matters, both earlier and late than this. The important point is that Scotland had made preparations for the evaluation of test kits by the time Professor Cash wrote to Dr Bell on 24 January

---

[975] PRSE0004124_0005 to 0006
[976] Penrose Inquiry transcript for 01/12/11 (day 72); 114 (18 to 22) (Professor Cash); [PRSE0006072_0114] and PRSE0003395_0003, para 2.08
[977] PRSE0003395_0003
[978] Penrose Inquiry transcript for 01/12/11 (day 72); 116 (1) (Professor Cash); [PRSE0006072_0116]
[979] Penrose Inquiry transcript for 01/12/11 (day 72); 116 (24 to 25) (Professor Cash); [PRSE0006072_0116]

1985.[980] Scotland had previously tested the RIA HBsAg kits and had introduced testing unilaterally, as well as having its own donor leaflets in 1983 to try to exclude high risk donors for AIDS (though this was subsequently replaced by a nationally-approved version available later) and had developed its own HIV-safe factor VIII concentrate.[981] The next day, Dr Mitchell was instructed to undertake testing of commercial kits by Professor Cash.[982]

2.28 The SHHD were in discussions with the DHSS at time of this letter at which time the need to co-ordinate with England and the DoH was noted.[983] At the SNBTS directors meeting on 19 February 1985, the plan which had been set out by Professor Cash in his letter to Dr Mitchell was departed from and it was agreed that the UK wide evaluation would be followed.[984] By 21 February 1985 (after the SHHD representatives had met with the DoH ones at the beginning of the month, as referred to in the 21 January memo), it suggested that Scotland should avoid the early introduction of testing.[985] Given that the SHHD had the ultimate control over these matters, we can see no reason to doubt that it was made clear to SNBTS that Scotland would be expected to follow the UK wide programme.

2.29 It is important to note at this point that by this point in time, a clear tension between the officials within SHHD and those within SNBTS (in particular the outspoken Professor Cash) was starting to emerge which would only worsen over the subsequent years. In a statement to the Penrose Inquiry, Professor Cash made it clear that the lack of a clear structure as to the responsibilities of the SNBTS and SHHD which became apparent over this issue was the cause of "significant operational difficulties" which lasted well beyond the period covered by this topic.[986] He also identified the cause of these problems as a "lack of clarity and reluctance on the part of SHHD to engage in dialogue directed towards resolution".[987] This working relationship deteriorated further subsequently, to the

---

[980] PRSE0004386_0002
[981] PRSE0004386_0003
[982] PRSE0001075
[983] PRSE0004472 (21 January 1985)
[984] PRSE0003378_0007
[985] PRSE0003266_0003
[986] PRSE0003395
[987] PRSE0003395

detriment of the safety of patients in receipt of blood and blood products in Scotland. The lack of clear lines of responsibility between the SNBTS and SHHD within the management structure of these two organisations was a matter on which the Penrose Inquiry heard evidence from Mr David McIntosh, who was appointed to the post of general manager of the SNBTS in 1990. He recognised this structural deficiency and acted to try to improve it at that time. The lack of clear lines of responsibility, the political deference of the SHHD to the DHSS despite the apparent freedom of administrative devolution and the deteriorating communication and relationships between these two key organisations made a significant contribution to the failure in clear decision making in connection with the evaluation of US test kits in Scotland in 1985 and also in connection with subsequent key events, such as the possibility of introducing surrogate testing and the ability unilaterally to introduce anti-HCV testing. Instead of learning from these experiences, it is clear from the testimony of Professor Cash that the problems manifested by examination of this topic were not resolved for many years, if at all.

2.30 In addition to the possibility of US kits being evaluated in Scotland, Dr Perry had mentioned around his time the possibility of an evaluation of evaluating the test kits which had been developed by the Institut Pasteur (along with access to LAV material to use in heat treatment experiments in the development of safe factor concentrates).[988] It seems that one of the results of the decision not to proceed with a Scottish test kit evaluation was the loss of an opportunity to consider a test from the French cell line. This may have been of interest, given that the different source of that test may have meant that it did not have the same problems as the US test kits developed from the Gallo cell line. Of course, it subsequently transpired that the Gallo cell line was responsible for a degree of false positivity in the tests developed from it, as was explained in evidence by Professor Robin Weiss to the Penrose Inquiry.[989]

---

[988] PRSE0002253_0002 (8 February 1985)

[989] Penrose Inquiry transcript for 27/09/11 (day 48); 165 (24) to 167 (8) (Professor Weiss); [PRSE0006048_0165 to 0167]

Running an evaluation alongside the introduction of testing as opposed to before it

2.31 In a letter from DHSS to regional transfusion directors dated 15 March 1985, it was pointed out that the intention was to carry out (a) an initial evaluation at the PHL and then (b) tests in the field.[990] In the letter, the DHSS pointed out that it was keen that screening tests should not be used until the evaluation process was completed. The fact that this is stated seems to make it clear that it would have been possible for testing to start before the evaluation at the PHLS had been done. Dr McClelland was of the view that the failure to start testing from the early months of 1985 (when kits became available) with the evaluation running in parallel may well have been one of the reasons for the overall delay.[991] As pointed out above, the DHSS had no legal power to insist that the evaluation take place. Further, in hie evidence to the Penrose Inquiry Professor Leikola made it clear that starting routine testing with one test would not preclude switching to a better one once it became available.[992]

2.32 The evaluation could have substantially taken place after the routine commencement of testing. In the absence of other effective measures to exclude positive donations, such an approach would have been appropriate.

Delays in the actual process

2.33 The decision having been taken that Scotland would not perform an independent evaluation of the US test kits available in early 1985, the safety of Scottish blood became dependent on the efficient running of the UK wide evaluation being done in England. Letters were sent out to companies which might produce the tests by the Department of Health on 21 January 1985.[993] It is clear from this letter that the

[990] PRSE0003427
[991] PRSE0003157_0013
[992] PRSE0001087_0003
[993] PRSE0003452

process would be controlled by the Department of Health who would make recommendations to the NHS about which tests should be used. The need to avoid unnecessary delay is emphasised. It was not observed.

UK commercial interests

2.34 The efficient progress of the UK wide evaluation was seriously compromised by the priority given in decision making to maximising the chances that a UK produced kit would be used for the routine testing of UK donated blood for anti-HTLV III.

2.35 Dr Alison Smithies discussed the test kit evaluation in an internal DoH memo dated 21 January 1985.[994] She considered the issue of whether the US test kits would require to be approved by the FDA for consideration in the evaluation of test kits. It was stated that such a stipulation would not be "in Wellcome's best interests in the short term". Professor Cash made it clear in his evidence to the Penrose Inquiry that he thought that a different emphasis was placed on the significance of FDA approval in connection with the evaluation of the US anti-HTLV III kits than there was later during the evaluation of kits for routine anti-HCV testing. This was based on the fact that the government were controlling the rules (which were not a normal legal requirement of the licensing regime before this time) to suit the interests of the Wellcome assay being available for consideration in 1985.[995]

2.36 From the start, the whole genesis of the test kit evaluation scheme was clearly bound up with the desire to maximise the interests of Wellcome and the UK produced kit. This was confirmed by Professor Cash at Penrose, who stated that the policy at this time appeared to be designed around "allowing Wellcome Diagnostics to catch up".[996] In fact, the very first matter mentioned at the first meeting of EAGA in connection with routine testing was an update from Professor Weiss on the progress with the Wellcome test.[997]

---

[994] PRSE0002849
[995] Penrose Inquiry transcript for 01/12/11 (day 72); 133 (14) to 134 (6) (Professor Cash); [PRSE0006072_0133 to 0134]
[996] PRSE0003395_0003
[997] PRSE0002734_0004

2.37 From early on in 1985 it appears that the need to get US companies to agree to be involved in a test kit evaluation (despite the lack of provision in the licensing system) and the consequent need to have the evaluation be appraised at a site which had no connection with UK commercial interests in order to maximise the chances of US participation were recognised within the DoH.[998] The "necessity" for there to be a British test was minuted at a meeting of the CBLA on 1 February 1985. Dr Gunson was of the view that it was necessary as the introduction of routine testing with a US enzyme-based test (ELISA) would "pose serious problems for the continuation of RIA testing" in the UK.[999] Patient safety does not seem to have featured in this technical discussion. The Wellcome test which was eventually developed was an ELISA in any event. In an internal DoH memo dated 30 May 1985, it was clearly indicated that it would not be preferable for a timetable to be issued for the availability of the Abbott kit (which by that time was in routine use in the US) as it would be preferable that a British test would progress to the second stage of the evaluation process.[1000]

2.38 By the time of the meeting of the screening test sub-group of EAGA on 10 June 1985, there was discussion of the possibility of letting the 3 commercial kits due to have been evaluated by the end of June proceed to the field test stage. However, the view that it was better to allow PHLS Colindale to evaluate more tests (including the Wellcome test) appears to have prevailed.[1001] An opportunity to make progress was presented and it was not taken due to the need for more evaluation of the UK test.

2.39 These commercial pressures compromised safety. As Professor Cash had recognised when he made moved to undertake a Scottish evaluation, speed was of the essence to minimise the chances of transmission of what was known to be a fatal disease which could be spread through blood and blood products. The US tests were the first to become available. The quickest route to getting routine

---

[998] PRSE0003002 (30 January 1985)
[999] PRSE0003354_0006
[1000] PRSE0004288
[1001] PRSE0002694_0002

testing started was to get the evaluation of those kits underway. Patient safety might be otherwise be compromised.

Concerns about donor screening being used for diagnostic testing

2.40 The introduction of routine anti-HTLV III testing was clearly delayed due to a concern about the risk that donor sessions would become a place where members of high risk groups would come for a diagnostic test. It was realised that this might be an issue at a department of health meeting on 14 January 1985.[1002]

2.41 Not enough was done to ensure that alternative diagnostic testing venues would be in place to minimise the chances that such high-risk donors would come to donor sessions. The need for public health protection for at risk groups separate from donor sessions was clearly a pressing need which required effort and investment in any event. As is noted below, such systems were put in place in other countries (such as Norway) very early in this period.

The evaluation

2.42 The first stage of the evaluation was not conducted with an appropriate degree of urgency. This is perhaps best summed up by the fact that on 27 June 1985, Kenneth Clarke (who had been briefed by the CMO[1003]) told the House of Commons that routine testing would be introduced "within a few months" and that evaluation was ongoing at the PHL.[1004] This announcement was made in the same week as the public call for an immediate introduction of testing by three senior haemophilia clinicians in the BMJ (see below). As was pointed out by Professor Cash in his evidence to the Penrose Inquiry (when talking about the anti-

[1002] PRSE0004578
[1003] PRSE0000686
[1004] PRSE0001110

HCV test evaluation), there is a need in these matters to resist the suggestion that there might be a "holy grail" of the perfect test. Professor Cash acknowledged in his evidence that false positivity was an issue with every test but that it was one which just required to be handled.[1005]

2.43 That the introduction of the tests was left at the mercy of the detailed scientific evaluations going on within the laboratory at the PHL was not a recipe for the speedy, and safe, introduction of testing. What was needed was applied research related to getting the testing up and running and not merely biological research, according to Professor Cash.[1006] At this point in time, the evaluation was being done by individuals with no experience of large scale donation testing, according to Professor Cash, which caused the evaluation to take significantly longer than it should have done.[1007] Further, there must be serious doubts as to the value which the phase 1 study actually added the fact that it was making large scale assumptions based on studying only a limited number of donations.[1008]

Confirmatory testing and simultaneous introduction throughout the UK

2.44 The availability of confirmatory tests and the need for simultaneous introduction of routine testing across the UK seem to have played a significant part in delaying the introduction of anti-HCV testing, as is discussed below. These factors do not seem to have caused great concern in connection with anti-HIV testing initially though they did in practice play a part in the delay. A Department of Health Memo (a) indicates that confirmatory testing using the western blot technique would be relatively easy to achieve using existing techniques in the PHLS laboratories (the availability of western blot technology was also noted by Professor Cash in his 24

[1005] Penrose Inquiry transcript for 27/09/11 (day 48); 78 (25) to 79 (4) (Professor Cash); [PRSE0006048_0078 to 0079]
[1006] Penrose Inquiry transcript for 27/09/11 (day 48); 29 (10) to 30 (2) (Professor Cash); [PRSE0006048_0029 to 0030]
[1007] PRSE0003395_0004, para 2.09
[1008] PRSE0003395_0012

January 1985 letter to Dr Bell) and (b) anticipated the possibility of introducing routine testing in certain "high risk" areas before others.[1009] By the time of the meeting of screening test sub-group of EAGA on 10 June 1985, a venue appears to have been decided upon for confirmatory testing.[1010] One assumes that this was due to the fact that it was likely that there would be relatively few positives for confirmation compared to HCV. In our submission, these factors do not appear to have been legitimate reasons for any significant delay in the introduction of routine anti-HIV testing.

The known consequences of delay

2.45 In 1985, haemophilia directors (in Scotland and elsewhere in the UK) lived with the reality of HIV infection amongst their patients. As Dr Mark Winter stated in his evidence, he was called upon to be the nominated AIDS doctor for his region. This was due to his first hand experience with the disease.

2.46 In a letter from Professor Bloom (then Chairman of the UKHCDO) to the DoH dated 31 May 1985, he recommended that routine anti-HIV testing be introduced immediately.[1011] He stated that his fear about testing not coming in quickly enough (which he appeared to have anyway) had been compounded by the fact that there was a recent article about the increasing prevalence of HTLV III infection in London. He expressed the fear that haemophiliacs using cryoprecipitate, those with leukaemia and those have open heart surgery may be at a real risk of infection. He recommended that one or more of the FDA approved tests should be introduced immediately. By this time, the PHL stage 1 evaluation had not been completed. In fact, there was little difference between the position in May 1985 and in January 1985 when the test kits became available in terms of the advancement in knowledge about them. This would suggest that the tests could

[1009] PRSE0002239 (31 May 1985)
[1010] PRSE0002694_0002
[1011] PRSE0004380

have been introduced far earlier in the year and that Professor Bloom was not overly concerned about the results of the UK evaluation against a background of FDA approval. He makes it clear that retesting, confirmatory testing and donor counselling could be dealt with later after the donation had been discarded after an initial positive result. This approach seems to balance the urgency of the situation as far as the protection of recipients is concerned whilst also recognising that donors need to be considered too. He suggested that donors would be happy with that arrangement as they were potential recipients of the blood too.

2.47 These views were expressed in the BMJ of 22 June 1985 by Professor Bloom and others, including Professor Forbes of Glasgow.[1012] The article pointed out the dangers from cryoprecipitate use and also the fact that there was no heat-treated factor IX by this time. The authors indicated that they no longer considered cryoprecipitate to be safe due to the increasing numbers of infected persons who may be donors. They rated the current risk for blood transfusion patients exposed to blood, cryoprecipitate, red cells, platelets etc at around 1 in 20 (as they may be exposed to around 50 donors). They were of the view that the small risk of false positives was not enough to prevent the immediate introduction of testing with one of the 3 approved FDA test kits. The risk of false positivity was also addressed. It was not considered big enough to justify the non-introduction of tests. Further, this could be dealt with by confirmatory testing and counselling being implemented at a later stage. This was clearly a question of the balance between the needs of recipients and the risks of false positivity and the interests of donors. This balance is addressed in more detail elsewhere in this submission. However, at this point, those who required to look after at least some of the recipients (those with bleeding disorders) felt strongly enough that the balance was not being struck appropriately that they expressed their view in this public way.

2.48 This plea for urgency was not taken on board by the by the DoH. The dangers of infection from blood which were hardly really news anyway. This had been known for some considerable time within the DoH.[1013] One might have expected,

---

[1012] PRSE0001917
[1013] PRSE0001783_0002

however, that the identity of those who were expressing these views might have had a significant impact on the Department's attitude. It took 5 months after Professor Bloom's letter for routine testing to be introduced in the UK. The response within the DoH suggested that they required to wait for the PHL evaluation as it was not clear whether the supplier would be able to produce tests on a large scale and which would still be reliable.[1014] As noted above, Professor Cash was of the view that the PHL evaluation on a limited number of donations appeared unlikely to give very satisfactory answers about this large scale issue in any event. These were the same test kits already in use in the US and elsewhere. It is interesting to note that this memo takes no issue with the proposition that false positives would cause only "a relatively small quantity of blood" to be wasted.

2.49 The consequences which were warned about by the haemophilia directors became reality. The Penrose Inquiry heard oral testimony from a witness who was known by the same "Amy". Her son was infected with HIV as a result of a which was the blood transfusion which he received as a baby in summer of 1985.[1015] Further, that Inquiry also heard evidence from "David", a haemophilia B patient who was in receipt of factor IX when he was infected in Glasgow in 1985. Another haemophilia B patient was infected in Glasgow to have been infected in 1985 or 1986. Both were infected by PFC factor IX concentrate. Their infections are likely not to have occurred had screening been introduced earlier, given the low prevalence of HIV in the Scottish donor population.

2.50 The Inquiry heard evidence that the risk of HIV infection from cryoprecipitate was a reason why a previously a untreated haemophilia patient might be given a factor VIII concentrate as opposed to cryoprecipitate which carried a greater HIV risk (albeit still low) and much lesser chance of infecting the patient with NANB hepatitis. The earlier introduction of routine anti-HTLV III screening in the period between January 1985 and October 1985 would have made the use of cryoprecipitate a more attractive alternative and may have reduced the incidence of hepatitis C infection in minimally treated patients with bleeding disorders

---

[1014] PRSE0000105 (10 June 1985) and PRSE0002789 (8 July 1985)
[1015] PRSE0004003

treated with concentrates over that period. Despite the oft declared mantra that practices became more focussed on patient safety in the period after HIV came along, this certainly does not appear to have been the case in relation to anti-HIV screening.

Conclusions

2.51 Dr McClelland expressed the view that the delay was purely financial.[1016] By 1 March 1985, the FDA had licensed the Abbott test kit. By April 1985, routine anti-HIV testing had been introduced in the USA using the Abbott kits. It had been introduced in Australia[1017] and Finland[1018] by May 1985. Professor van Aken gave evidence to the Penrose Inquiry that in Holland testing was started at "the beginning of 1985".[1019]

2.52 In the UK, unnecessary delay was caused by (a) the decision to conduct an evaluation of test kits in the UK prior to the introduction of testing (b) the priority given to the UK test kit (c) the failure to proceed with a Scottish evaluation of the test kits and (d) the way in which the UK evaluation was conducted. The way in which the routine introduction of anti-HIV testing was handled was not in the best interests of the recipients of blood and blood products.

2.53 There was significant reluctance within the DHSS, in particular on the part of the minister of state for health Kenneth Clarke to introduce donor screening for anti-HIV at all. This was due to a misunderstanding on his part as to the nature of the threat which the disease posed in 1985 and the groups for whom screening was required. Consistent themes of the evidence heard by the Inquiry about the approach of the government to the threat of AIDS were as follows:

[1016] IBI transcript for 28/01/22; 62 (Dr McClelland)
[1017] PRSE0001509
[1018] PRSE0000490_0003
[1019] Penrose Inquiry transcript for 15/09/11 (day 47); 82 (2 to 12) (Professor van Aken); [PRSE0006047]

a) The threat was thought to emanate only from imported products and the risks of the virus which caused the disease entering the donor population in the UK was completely missed or at least greatly under-appreciated;

b) As a result of this misunderstanding, the threat was thought to be only to haemophiliacs who received treatment with foreign concentrates. The minister of state for health appeared unaware in early 1985 that there were proven cases of HIV having been transmitted to large numbers of haemophiliacs treated exclusively with domestically sourced products (for example the Edinburgh infections which were known about in October 1984). The corollary of this mistaken impression was that it was erroneously thought by the DHSS that the problem with the transmission of AIDS to haemophiliacs would and had been solved at the point when heat treated factor VIII concentrate started to become available. Technological innovations in this area did not provide any protection to the groups mentioned above, who required screening as real protection against the limitations of donor selection to exclude the risk of HIV transmission from blood and blood products manufactured in the UK. This misunderstanding (that the problems if AIDS had not been solved by the arrival of virally attenuated factor VIII concentrates either from commercial sources or domestically in December 1984 and April 1985 from PFC and from BPL respectively) underpinned the government's lack of commitment to and lack of urgency in implementing anti-HIV screening in the UK;

c) There was a consistent misunderstanding of the difference between the epidemiological risk of the disease spreading and the incidence of it, in particular in a disease like AIDS with a long latency period; and

d) There was a failure to appreciate the wider public health, epidemiological considerations of allowing infections to occur with a disease which could be spread like wildfire via sexual transmission. The belief that the risk from blood and blood products occurred in only limited populations of those with bleeding disorders took insufficient account of the ability of that population to spread the disease more widely in society. It was not known that the methods of heat treatment applied to factor VII concentrate would prevent all infection – indeed, it did not. The failure to appreciate that infections could and did occur beyond

those in receipt of virally attenuated factor VIII concentrates by extension underestimated the number of potential vectors of the disease who could be created in the absence of anti-HIV screening.

e) Inherent in the decision making around the introduction of anti-HIV screening was a theme which would continue to run throughout decisions made in relation to the introduction of screening tests for the presence viral threats in blood, namely the need for uniformity at all costs as a perceived defence to any threat of litigation based on an asserted failure to introduce the test quickly enough. The practice of ensuring uniformity in this regard had predated the decisions in 1985 and appears to have had its origins in decision making around the introduction of HBV screening. The stated need for uniformity in that regard had been "the possible medico-legal significance of this procedure".[1020]

3. Surrogate testing for NANBH

General – overview

3.1 The failure to introduce surrogate testing for HCV as an example of the lack of regard for the safety of the recipients of blood and blood products as a priority. Surrogate testing for markers which would indicate that donors were at risk of being infectious for NANBH could have been introduced at any time before the introduction of routine anti-HCV testing in September 1991. The importance of such a testing regime became more pressing as time progressed but was never introduced in Scotland or in the UK more widely. The requirement became more pressing as the prevalence of NANBH in the donor population became greater. It was known from the work which went into the paper by Fletcher et al, published in 1983 that the prevalence of NANBH in the UK donor population had meant that the perceived benefit of voluntary donation had been lost. Pooled factor VIII products were likely to be infective on first infusion whether of domestic or

[1020] PRSE0003817_0005 - Minutes of UK RTD meeting on 11 March 1970

commercial origin due to the number of positive donations having reached the point that each batch would be infective (even though domestic products were made from smaller donor pools). The increased number of NANBH positive donations in the UK (including Scotland) was the reason for that, coupled with the inadequate protections against the spread of the disease afforded by donor selection practices (as discussed earlier in this submission). In addition, over the period before September 1991, there was an increasing amount of information becoming available about the severity of post-transfusion NANBH. From the late 1970s, it was or ought to have been known that there was a form of hepatitis which was being transmitted by transfusion which was not being prevented to any extent by the HBsAg screening tests which were in place to try to prevent the spread of HBV. Increasing evidence of the possibility that the resultant infection could become chronic in a high proportion of cases and that it could be serious or even life-threatening also became available, as is analysed elsewhere in this submission. The increased incidence of spread, the increased awareness of the potential severity of transmission and the ongoing inadequate protections to prevent this all meant that more needed to be done by way of prevention. As Dr McClelland had told the Penrose Inquiry, testing was "the cornerstone of safeguarding the blood supply".[1021]

3.2 As is discussed in more detail below, surrogate testing regimes were introduced in other countries to combat this increasing risk, showing that there was, in those countries, (a) a realisation of the significance of hepatitis risk posed by blood and blood products given the severity of infection with NANBH (b) scientific means by which prevention could be achieved by means of surrogate testing and (c) a more patient orientated risk/ benefit analysis of the right regime to use, in light of the cost and donor deferral implications (discussed below).

3.3 There is discussion above of the reliance placed by ministers and civil servants on medical advice received from experts and medical officials as a means of evading responsibility for inaction, in particular in relation to steps which might have been taken to combat the threat of AIDS being transmitted by blood or blood products.

[1021] Penrose Inquiry transcript for 29/09/11 (day 50); 8 (8 to 16) (Dr McClelland); [PRSE0006050_0008]

In the period after it became apparent that significant numbers of infections had been or were likely to have been caused by blood or blood products in the UK from around 1984, a more cautious approach to the possibility of serious disease being transmitted by these routes was certainly merited, given the severity and extent of the HIV infections which occurred. More attention required to be paid to expert advice which counselled that such preventative measures could or even should be taken to prevent similar such transmissions of other potentially serious diseases like NANBH. Given that there was advice from experts that surrogate testing should be introduced (expressed publicly by SNBTS directors in 1987) the government's position was inconsistent with the position it took when explaining its response in the earlier stages of the HIV crisis (namely that the ministers simply relied on the medical evidence). This shows the fallacy of the government's position. Over this period, it was keen to elicit and follow advice which advocated taking no action and spending no money. Advice which it did receive to take action, such as from the likes of Dr Spence Galbraith in connection with AIDS, in relation to the need for surrogate testing for NANBH or for the earlier introduction of routine anti-HCV testing was conspicuously not acted upon.

<u>The context in which surrogate testing was actually considered in Scotland</u>

3.4 Surrogate testing for NANBH could have been introduced at any time during the 1970s or 1980s, given the increasing availability of knowledge about the severity of the condition and the need for protection against it. However, as the evidence considered below reveals, it was given some active consideration in the mid 1980s, the context of which is important as regards the risks from blood or blood products. In his evidence at the Penrose Inquiry, Professor Thomas agreed with the proposition put to him that the approach of haemophilia clinicians was perhaps based on an underestimation of the severity of NANB hepatitis based on the fact that screening techniques minimised infections with hepatitis B by

1981[1022]. At least as far as pooled product were concerned, the approach to treatment was not sufficiently cautious and did not take account of the known potential risks associated with infection with either HBV or the cumulative risk along with NANB hepatitis. The issue of surrogate testing was actively considered in the aftermath of fatal hepatitis B outbreaks, including the infection of a number of recipients of blood in the renal unit of the RIE in 1969.[1023] This showed that the donor selection techniques alone had proven to be limited protection against such catastrophic outcomes.

3.5 Further, decisions about surrogate testing were taken in the aftermath of infection of patients throughout Scotland with HIV, both in the haemophiliac and transfused communities. That was a virus with a prodromal phase, similar to NANB hepatitis, as was HBV. The attitude generally (and specifically in connection of surrogate testing) was insufficiently urgent and demonstrates that little had been learned by the government in Scotland or the United Kingdom about the threats posed by viral contamination of blood and blood products. Surrogate testing, as its name would suggest, represented a non-specific detection method for the presence of HCV in donated blood and therefore would not eradicate the virus. Prior to the isolation of the virus responsible, something needed to be done to prevent the spread of this sub-clinical virus. The opportunity to introduce surrogate testing (anti-HBc) for HTLV-III had been inadequately considered and missed. Lessons had not been learned.

3.6 In his evidence to the Penrose Inquiry, Dr McClelland made it clear that the AIDS experience had made him more conscious that there could be something in the Scottish donor population which was there for years before they realised with the result that, in his own practice, he became aware of the need to be more proactive. The need to be proactive was, in his view, more pressing as (a) they knew there was something there and (b) they had known for quite a long time that

---

[1022] Penrose Inquiry transcript for 11/10/11; 143 (18) to 144 (2) (Professor Thomas); [PRSE0006052_0143 to 0144]

[1023] Penrose Inquiry transcript for 12/05/11 (day 24); 30 (16) to 31 (3) (Dr Boulton); [PRSE0006024]

something bad was happening.[1024] Unlike AIDS, this did not come out of the blue. NANBH had been known about since the 1974 Prince paper, making the failure to take preventative steps all the more culpable. Whilst the HIV experience had clearly influenced Dr McClelland who was a keen advocate of surrogate testing, lessons had not been learned by others, including those in government in Scotland, who had a far from proactive approach.

Lines of responsibility of in connection with the possible introduction of routine surrogate testing for NANB hepatitis in Scotland

3.7 The subject of the lines of responsibility for decision making about screening of blood donations in Scotland over the 1970s and 1980s is discussed in detail above. The decision making in this area was part of the responsibility of the SHHD, the department within the Scottish Office which dealt with health matters in Scotland. Though there is evidence that the SHHD was concerned that the SNBTS may introduce testing unilaterally, in reality this was unrealistic. Such a move would have required political support and funding – in essence it was a policy as opposed to an operational matter. This is shown by the evidence that SNBTS provided advice on the issue to SHHD. The evidence above also demonstrated that the consensus of SHHD was necessary, as it had been for the introduction of anti-HIV testing in 1985.

3.8 The lack of clear lines of responsibility between the SNBTS and SHHD within the management structure of these two organisations and the poor operational relationship between the two bodies caused significant problems at least from the time of the debate over the introduction of anti-HIV testing, as is examined above. David McIntosh was appointed to the post of general manager of the SNBTS in 1990. He recognised this structural deficiency and acted to try to improve it at that time. This lack of clear lines of responsibility and the deteriorating communication

[1024] Penrose Inquiry transcript for 16/11/11 (day 64); 26 (19) to 27 (6) (Dr McClelland); [PRSE0006064_0026 to 0027]

and relationships between these two key organisations (one in charge of policy and one the key expert advisory body on transfusion) made a significant contribution to the failure in clear decision making in connection with the evaluation of US test kits in Scotland in 1985 and also in connection with subsequent key events, amongst them the failure to introduce surrogate testing for HCV at any time and the significant delays in connection with the introduction of routine anti-HCV screening, discussed below. In addition, it was clear that the decision making within SHHD was undertaken without ministerial involvement.

3.9 The evidence available to the Inquiry shows that there was complete lack of ministerial involvement in this area. Despite his knowledge of the risks of viral transmission associated with the use of factor concentrates in the treatment of bleeding disorder patients, Lord Glenarthur on arriving in the Scottish office as health minister in charge of SHHD in 1986 appears to have taken no role in this area. He appeared completely unaware of the issue when he gave evidence on the subject to the Inquiry, just as he was also unaware of the ongoing issue of the lack of HCV factor VIII concentrate in Scotland over his period in office.[1025] The issue of the lack of ministerial involvement in decision making in this area in Scotland and the responsibilities of civil servants are discussed below. His successor, Lord Forsyth gave evidence to the Inquiry to the effect that within SHHD it was thought that SNBTS was doing a good job. He clearly had little or no involvement in transfusion matters in the late 1980s and early 1990s.[1026] The lack of ministerial involvement in the surrogate testing issue demonstrates that it was never considered seriously enough to be a realistic proposal by the civil servants within SHHD, despite the advice they received on the matters from the transfusion experts. Though on the subject of anti-HCV testing (to which the same principles applied) Lord Forsyth explained that as the DoH had the resources, the Scottish Office was not in a position to replicate investigations into matters such as testing, which was why it was important that there be departmental "collaboration" on

[1025] IBI transcript for 23/07/21; 155 to 156 (Lord Glenarthur)
[1026] Lord Forsyth witness statement (WITN7126001) @ para 30.1

such matters.[1027] We submit that what collaboration meant in practice was total policy subordination on all such matters. He saw it as a matter of common sense that testing should be approached on a UK basis.[1028] We submit that it was a matter of common sense that if the administrative devolution arrangements made it possible for Scotland to make progress alone in the interests of minimising infections (as they did) those powers should be exercised to facilitate that goal being achieved.

3.10 The possibility of surrogate testing appears to have been considered in the United Kingdom from the early 1980s (though it had been in place in other countries long before that) until the isolation of the virus which gave rise to the possibility of the introduction of routine anti-HCV testing, not achieved in the end until September 1991. Over this period the SNBTS was controlled and operated by the directors of each of the national blood transfusion centres, Professor Cash (the national medical director) and latterly also by a general manager (Mr David McIntosh). The SHHD was headed by the health minister within the Scottish Office. The minister would be dependent on receiving "strong, clear, consistent and well argued advice".[1029] The implementation of surrogate testing would have required funding to be found and allocated specifically for the purpose by the SHHD.[1030] Funding was allocated for measures such as this in response to the submission by SNBTS of financial requests in the form of Public Expenditure Surveys ("PES") which prospectively nominated the purposes for which funding was to be used in the overall SNBTS budget. The amount of money which would have been required to implement routine surrogate testing for HCV markers in Scotland could not have been found from the general SNBTS budget without such a specific allocation for this purpose. The PES documents to which the Inquiry has access make it clear that applications were made for funding to be allocated for this purpose in the budgets for the years commencing April 1987 and April 1988 (and subsequently). Funding could have been made available for the introduction of surrogate testing, had it

---

[1027] IBI transcript for 20/07/22; 134 (Lord Forsyth)
[1028] IBI transcript for 20/07/22; 101 (3 to 10) (Lord Forsyth)
[1029] Penrose Inquiry transcript for 15/11/11 (day 63); 133 (9 to 10) (Dr McClelland); [PRSE0006063]
[1030] Penrose Inquiry transcript for 15/11/11 (day 63); 132 (14 to 22) (Dr McClelland); [PRSE0006063]

been recommended and adopted in principle. In his statement to the Penrose Inquiry on this subject, Duncan Macniven pointed that the reasons why surrogate testing was not introduced were "largely non-financial".[1031] The reasons for the failure to introduce surrogate testing were, therefore, not rooted in the absence of funds but in the perception that it was not a worthwhile step, as is discussed in more detail below.

3.11 As far as medical expertise was concerned, there were medically qualified employees within the SHHD who would give advice to the administrative staff on the medical aspects of proposals such as surrogate testing. Ultimately it would be for the administrative officers to make recommendations to the minister, either independently or as part of a funding allocation within the PES system. As far as the medical staff within SHHD was concerned, medical advice was available from the chief medical officer, deputy chief medical officers and principal medical officers. Although certain of these individuals had responsibility for dealing with transfusion matters (including the possibility of introducing surrogate testing) none of the medical staff at SHHD over this period had any specific experience of or training in transfusion matters. They were generalists and expected to deal with advising on matters arising across a number of different disciplines.[1032] The experienced, internationally renowned experts in transfusion in Scotland were to be found within the SNBTS including Professor Cash and Dr McClelland.

<u>The potential utility of surrogate testing for NANBH</u>

3.12 As is discussed above, that the risk of transmission of NANBH from even domestic concentrates was known by the early 1980s, as was the potential severity of the resultant condition. The inherently non-specific nature of surrogate testing was unlikely, it would appear, to have reduced the prevalence of HCV in the donor pool used to make concentrates sufficiently to make it likely that patients treated with

[1031] PRSE0002324_0002

[1032] Penrose Inquiry transcript for 21/11/11 (day 66); 94 (15 to 24) (Dr Iain Macdonald); [PRSE0006066_0094]

concentrates (made from large donor pools) would have escaped infection. This was Dr McClelland's evidence to the Penrose Inquiry.[1033] Bleeding disorder patients would, however, have benefitted from such a regime (a) in that the reduction of the viral load within the donor pool is likely to have reduced their exposure to the potentially harmful virus and (b) patients treated with low donor products (cryoprecipitate) would have benefitted as a certain number of positive donors' blood would be excluded from the plasma collected from the donor pool thus reducing the risk from cryoprecipitate as a potential source of infection.

3.13 Recipients of blood transfusions would have benefitted as a group from surrogate testing which would have reduced the number of positive whole blood transfusions transfused into such patients. In his Penrose evidence, Dr McClelland did not agree with the proposition that even by 1986 NANBH was rarely transmitted by the parenteral route.[1034] He accepted the terms of the description of the standard textbook on blood transfusion by Professor Mollison (published January 1983, seventh edition) which is what most people would have read at the time.[1035] He accepted the passage which stated that NANB hepatitis was deemed to be prevalent following transfusion.[1036] The risk of transmission of NANB hepatitis through blood transfusions should have been well known in the 1980s both to the government in Scotland (in particular to the medical officers) and to the transfusion doctors working within SNBTS. Although many of the studies available were on people with haemophilia who had received blood products, there were also others which considered the transmission and progression of the disease in blood transfusion recipients.[1037]

3.14 As to the severity of the disease which could thereby have been prevented, Professor Thomas stated in his evidence to the Penrose Inquiry that what was being discovered and reflected in the studies in the late 1970s up to 1982 (and certainly by the time of studies in 1985) was that NANB hepatitis was a progressive

---

[1033] Penrose Inquiry transcript for 16/11/11 (day 64); 35 (2 to 7) (Dr McClelland); [PRSE0006064_0035]
[1034] Penrose Inquiry transcript for 15/11/11 (day 63); 23 (14 to 19) (Dr McClelland); [PRSE0006063]
[1035] Penrose Inquiry transcript for 15/11/11 (day 63); 30 (8 to 14) (Dr McClelland); [PRSE0006063]
[1036] Penrose Inquiry transcript for 15/11/11 (day 63); 27 (6 to 7) (Dr McClelland); [PRSE0006063]
[1037] Such as PRSE0004118 and PRSE0001451

disease with more patients being found to have developed to the stage of chronic active hepatitis which has a worse prognosis than chronic persistent hepatitis (though both were of course chronic conditions with the unknown potential for further development and extra-hepatic harm).[1038] This meant that one should have treated evidence of the numbers infected with some caution on the basis that (a) a certain number of patients would remain sub-clinical before being identified as sufferers and (b) the severity of symptoms could not be taken in the early stages as indicative of how the serious the symptoms might become. Professor Thomas also pointed out that this research answered the question of whether post transfusion hepatitis was a benign condition we did not have to worry about.[1039] It was not. Professor Ludlam also accepted at Penrose that the evidence which emerged in 1985 (in particular the Sheffield paper by Preston & Ors) showed that one could no longer treat NANB hepatitis as something which "needn't concern me".[1040] By 1986, the rates of progression amongst haemophiliac patients progressing to the chronic phase of the disease had been echoed by a West German paper by Schimpf and Ors.[1041]

3.15 Dr Forrester was the key medical officer within SHHD at the time when surrogate testing was being actively considered. Despite the picture about severity being clear amongst the medical literature and in the minds of key medical experts by the first half of the 1980s, it appears that this information had not permeated the minds of the key medical advisors within SHHD. In a memo dated 12 June 1986, Dr Forrester stated that the NANBH was not as a rule serious.[1042] He described it in a note of a meeting held on 26 June 1986 as "generally mild (except in pregnant women)".[1043] In minutes of joint meeting at which Dr Forrester reported on the WP TAH meeting in November 1986, he reported again that NANB hepatitis was "relatively benign".[1044] In a memo written by him to other staff within the

---

[1038] Penrose Inquiry transcript for 11/10/11; 128 (22 to 23) (Professor Thomas); [PRSE0006052_0128]
[1039] Penrose Inquiry transcript for 11/10/11; 137 (10 to 14) (Professor Thomas); [PRSE0006052_0137]
[1040] Penrose Inquiry transcript for 13/10/11; 95 (15 to 17) (Professor Ludlam); [PRSE0006054_0095]
[1041] PRSE0000149_0002 (The Lancet, 8 February 1986)
[1042] PRSE0000857
[1043] PRSE0000017 (30 June 1986)
[1044] PRSE0002769

department dated 26 January 1987, he described NANB hepatitis as "relatively benign".[1045] After he gave evidence to the Penrose Inquiry, Dr Forrester saw fit to submit an email with testimony additional to his oral evidence on this matter.[1046] He sought to draw a distinction between what one might describe as the normal meaning of the word "benign" and a specific medical meaning which applied "if one form of a fatal disease takes much longer to prove fatal and does so in fewer cases than another".

3.16 This was an attempt to deflect criticism from himself. It was an attempt to try to explain away his underestimation of the probable severity of the disease by relying on an excuse akin to the "conclusive proof" line discussed elsewhere. It is inconsistent with the contemporary evidence about the possible or indeed likely severity of the disease. What was required at the time was an appropriate, patient-centred assessment of risk. Dr Forrester failed to appreciate the risk. In any event, the phrase was used by Dr Forrester in material to which non-medical colleagues as well as medically qualified ones would be exposed. For example, the manuscript annotations on PRSE0001376 clearly show that this document was considered by non-medical SHHD staff. Used in isolation the phrase "relatively benign" without any detail would be likely to have been understood as meaning that the condition was not one to be concerned about. It was the administrative staff who would be reading such advice who would ultimately have made the decision whether or not to elevate the matter to the minister. This line of advice was misleading.

3.17 As is referred to elsewhere in this submission, the evolution in the Sheila Sherlock textbook between the 6th and 8th editions (the latter one being published in 1989 but composed 2 or 3 years before that) is instructive as regards the development in the general thinking about the potential severity of NANBH. In his evidence at the Penrose Inquiry, Professor Thomas accepted that once the data from the studies up to 1985 started to become available, one would not take what comfort existed in the sixth edition of the Sherlock text.[1047] Had Dr Forrester sought

---

[1045] PRSE0001376 (26 January 1987)
[1046] PRSE0002991
[1047] Penrose Inquiry transcript for 11/10/11; 139 (4 to 9) (Professor Thomas); [PRSE0006052_0139]

appropriate expert advice by 1985 at the latest he would have been told that it was understood that NANB hepatitis was a progressive, potentially lethal disease. It was no longer considered to be "relatively benign". His failure to understand that and the impact of his assessment of the severity of the disease on decision making within SHHD is considered further below.

3.18 It is significant to recall that these comments were made in circumstances where significant investment had been made at BPL in their heat treatment regime to eradicate from blood products manufactured there this condition, which Dr Forrester seemed to think would be benign. Similar efforts were being made to catch up to the success of the English 8Y product at PFC. It is hardly surprising in circumstances where the need for significant efforts to be made to achieve a NANBH safe factor VIII concentrate in Scotland in the period before April 1987 that little government impetus was lent to either (a) the development of the safe product or (b) the procurement of a safe alternatives, such as a supply of 8Y from England, given that the key SHHD advisor on blood and blood products appeared not to have any insight into the urgency of the situation.

The international perspective

3.19 The Inquiry has evidence that the State regularly paid for key medical personnel to attend medical conferences on matters about the risk of disease from blood and blood products. Examples are discussed elsewhere in this submission. Literature was regularly accessed and available such that international perspective and comparison was both possible and appropriate. The German and Italian blood services introduced ALT testing in 1965 and 1970 respectively. In Germany, one estimate of its likely effectiveness was that it had reduced NANB hepatitis by around 29% with 1.2% of donors being lost.[1048] This provided important safety and statistical context. Surrogate testing was practically possible (in terms of the

[1048] PRSE0000571_0002 (Professor Weise)

technicalities and the loss to the blood supply which it would involve) and worked. The extent of loss to the blood supply in a similar Western, industrial nation could be calculated and planned for.

3.20 Further, in the USA and France surrogate testing (ALT and anti-HBc) was introduced in 1986 and 1988 respectively. US and some French studies carried out by May 1987 indicated that a significant proportion of transfusion related NANB hepatitis would be prevented. It was further observed at a Council of Europe European Health Committee meeting that the evidence already published rendered the ethics of further randomised studies questionable.[1049] Surrogate testing was instituted in other countries as well, as recorded by Burton J in the case of A v National Blood Authority.[1050]

3.21 There was awareness of this in Scotland. The SNBTS claimed theirs to be a system at the forefront of international blood transfusion practice. It was noted by the SNBTS directors at their meeting on 25 June 1986 that surrogate testing was being introduced in the US and several European countries at that time and that Professor Cash was concerned that pressure would be forthcoming from clinicians for such a regime to be introduced in Scotland.[1051] The only response at that time was to note the possibility of a "limited" study into donors in Edinburgh, a possible study involving the gastroenterology unit in Aberdeen and that a study into the "feasibility and practicability" of such a testing regime was to be conducted in England. The limitations on the Edinburgh study, given its scale and focus on donors is discussed in more detail below. The prospect of the Aberdeen study happening seems remote. The English study was not local and it was restricted to matters of practicality. No positive action was taken and no consideration noted of the reasons why these other countries were taking this step at this time, including the local data available for these places which justified such a move and the applicability of that data to Scotland. There is no note here of any real consideration having been given to the likely benefits of surrogate testing for Scottish blood recipients. One would have expected the SNBTS directors to have

[1049] PRSE0000571_0003 (Dr Habibi)
[1050] PRSE0003333_0068
[1051] PRSE0002641_0005

considered the matter fully long before clinicians started to call for the move. However, no such consideration appears to have been planned noted though Professor Cash seemed to consider the possibility of such calls from clinicians to be imminent.

3.22 The introduction of testing in the USA seems to have had some influence on the SNBTS directors' position by the time of the meeting on 3 March 1987 (see below). However, that influence is not minuted as due to anything other than the fact that fractionators in the USA were now undertaking surrogate testing.[1052] This is despite the fact that Professor Cash made it clear in his evidence that the positive attitude of some of his other European colleagues (such as the Dutch) had indicated to him that testing needed to be instituted and that the UK "had gone to sleep" on the issue.[1053] International opinion had led to the blood services moving far more quickly on this issue. The UK (and Scotland in particular) was being left behind as far as safety was concerned, despite the lessons which could and should have been learned from the HBV and HIV disasters.

Research into the prevalence of NANB hepatitis and the potential effectiveness of surrogate testing

3.23 As is discussed below, the lack of what was deemed sufficient relevant research to support the introduction of surrogate testing was eventually deemed to be a reason why it should not be introduced. This was akin to the "conclusive proof" arguments which had been used to justify inaction in the medical community and by the government over the emerging AIDS crisis. However, the reasons why a large-scale prospective study involving both donors and recipients into (a) the prevalence of HCV in the donor population and (b) the likely effectiveness of surrogate testing in reducing the transmission of Hepatitis C was never undertaken in Scotland or the UK merit consideration. Had it been and had an eye been kept

[1052] PRSE0004163_0005
[1053] Penrose Inquiry transcript for 29/11/11 (day 70); 172 (5) to 175 (13) (Professor Cash); [PRSE0006070]

on the need to protect recipients of blood and blood products against NANBH (as well as AIDS), a clear evidence base could and should have been available to support the argument for the benefits of such a regime.

The purpose of such a study

3.24 The importance of such a study was, in the first place, that it would have given insight into the likely prevalence of NANBH (against which there was little or no protection in the transfusion system) in the donor population and therefore the likely number of infections (particularly in the recipients of whole blood and single donor components like cryoprecipitate) which could be prevented by instituting testing of donor samples (the likely incidence of PT NANBH). Secondly, it would have been able to provide an assessment of the likely usefulness of surrogate testing in the prevention of the spread of PT NANBH. It was particularly important that such a study be undertaken in the local population in order to ascertain answers to these prospective queries for the local population. Further, it was important, as Dr McClelland pointed out in his evidence to the Penrose Inquiry that the study would be prospective rather than observational in nature.[1054] At this Inquiry, Dr McClelland made it clear that a study akin to the US TTV study should be undertaken in Scotland from at least the early 1980s.[1055]

3.25 In the United States, such large-scale prospective studies had been underway for a number of years by the start of the 1980s. The severity of the NANBH problem was realised there, based both on the acquired knowledge about the severity of the resultant disease but also the lack of protection in the system against the NANB condition. The Transfusion-transmitted virus study ("TTVS")[1056] and a similar study by the National Institute of Health ("NIH") in Maryland reported in 1981.[1057] The TTVS had been carried out between 1974 and 1979. The attack rate for PT

[1054] Penrose Inquiry transcript for 15/11/11 (day 63); 3 (15) to 4 (23) (Dr McClelland); [PRSE0006063]
[1055] IBI transcript for 28/01/22; 107 (Dr McClelland)
[1056] PRSE0001650
[1057] PRSE0002216

NANBH was 10%. The incidence of NANB transmission was linked to the ALT levels of donors. At lower ALT levels the transmission rate was 6% and at higher levels the attack rate was 45%. It was concluded that around 40% of cases of post transfusion NANB hepatitis observed in the study could have been avoided if donations with raised ALT had been discarded. It was thought that this would have resulted in 3% of total blood donations being rejected.[1058] The NIH study found that ALT testing of donors could prevent 29% of PTH at a loss of blood to the donor system of 1.6%.[1059] The studies continued into the mid 1980s. An updated version of the NIH study was published in 1985 and included details of the prevalence of NANB hepatitis in studies for both volunteer and non-volunteer blood transfusions.[1060] Further papers from the NIH which tended to favour the introduction of surrogate testing and which considered the position in a volunteer donor population appeared in 1986.[1061] It is important to note that these studies provided evidence relating to the feasibility, utility and likely impact of the blood supply in voluntary donor populations. Given that a similar study had not been introduced in Scotland, these studies provided a scientific basis (albeit not local) to support surrogate testing in Scotland by the mid-1980s, in the absence of a Scottish of British TTV-style study.

<u>The attempts made to institute such a study in Scotland</u>

3.26 Dr McClelland gave evidence to the Penrose Inquiry about efforts he had made dating back to 1981 to instigate a large-scale prospective study into the prevalence of NANB hepatitis in the UK. In 1981, he had proposed to the MRC working party on Post-Transfusion Hepatitis that a large-scale prospective study (along the lines of the TTVS), including the follow up of recipients, be carried out into PT NANBH in the UK. His proposal did not receive particular support from the other members

[1058] PRSE0001650_0005
[1059] PRSE0002216_0005
[1060] PRSE0004333
[1061] PRSE0000340 and PRSE0001533

of the Working Party which, in any event, was disbanded in 1981, after its second meeting. It seemed that certain members of the group, in particular Professor Zuckermann, thought that there was no need for the study as these matters had been looked at in earlier studies.[1062] However, as Dr McClelland pointed out when he looked at the earlier MRC study it did not tell him what he needed to know at all as it had been done over the period of hepatitis B screening being introduced.[1063] There was a clear imperative for such a study to be instituted at that time. That it was not was a significant error.

3.27 Further, in 1982/1983 Dr McClelland proposed to the joint BTS working party on Transfusion Associated Hepatitis that a (more modest) prospective study be carried out, again including the follow-up of recipients. The WP TAH met on 27 September 1983 (when most of the discussion concerned AIDS) and did not meet again until late 1986. The proposal was not taken forward. The disbanding of the MRC working party and the apparent failure of the BTS WP TAH to meet more regularly over this crucial period appear to have played resulted in there being no clear forum in which this important issue could be discussed and resolved. The lack of clear advisory structures around this time contributed to the lack of proactivity about this important issue. Further, as Dr McClelland stated in his Penrose evidence, in the period after this things were taken over by the need to deal with the AIDS crisis.[1064] The opportunity which could have been taken on either of these occasions in the early part of the 1980s was missed. Also, the failure to see AIDS and PT hepatitis together and thus their cumulative risk from 1983 appears to have played a part in sight being lost of the risks of NANBH transmission and the need for measures to be taken to prevent it.

3.28 It was a mistake that the very worthy proposals of Dr McClelland to institute a large-scale prospective study were not properly considered and ultimately therefore were not accepted. The lack of interest in his proposals seems hard to understand when similar US studies had been done into this subject since around 1974. It may be the case that it was considered, as had been the case with the

---

[1062] Penrose Inquiry transcript for 15/11/11 (day 63); 64 to 67 (Dr McClelland); [PRSE0006063]
[1063] Penrose Inquiry transcript for 15/11/11 (day 63); 71 (3 to 7) (Dr McClelland); [PRSE0006063]
[1064] Penrose Inquiry transcript for 15/11/11 (day 63); 89 (18) (Dr McClelland); [PRSE0006063]

emergence of HTLV III, that the transmission of NANB hepatitis was a predominantly a foreign problem, of concern in countries which relied on blood from paid donors. From the time of the Prince study it had been realised that NANBH was a problem. Increasing evidence of severity mean that steps towards instituting such a study should have been instituted in the 1970s and certainly by the time Dr McClelland was raising the issue in a more practical sense in 1981. The failure to undertake such research in the post HBV screening era in effect meant that the system had no real insight into the nature and extent of the PT NANBH problem in the UK. It had no effective protection against the problem from door selection of screening. The system had turned a blind eye to the problem. At this time the research which culminated in the Fletcher et al paper in 1983 was revealing that the condition had become so prevalent in donors that the protections afforded by the voluntary donor regime had been lost, at least in pooled products. Yet, when the proposal for surrogate testing came forward in around 1986, lack of specific evidence was prayed in aid to reject it by the very system which had failed to obtain such specific evidence.

3.29 Such a study would take a number of years to complete. Either it needed to have been instituted by the early 1980s at the latest or what evidence that there was needed to be acted upon from 1986. It was entirely feasible that such a study could have been instituted with the right backing in Scotland. The appropriate scientific expertise could be found in a number of places, in particular either in Edinburgh (Dr McClelland) or the west of Scotland (Dr Follet et al). This would have given particularly useful local data. Such a study would ideally have been done on a multi-centre basis in order to ensure the kind of enrolment necessary to maximise the study's value (like the US studies). It would have required time and significant financial input and therefore government support to find the most useful answers.[1065] The government were not even asked to institute such a study in the early 1980s. Dr McClelland's entirely sensible proposals had fallen on the deaf ears.

[1065] Penrose Inquiry transcript for 16/11/11 (day 64); 41 (25) to 43 (12) (Dr McClelland); [PRSE0006064_0041 to 0043]

Small studies

3.30 There were a number of small studies done (in Scotland and in England) relating to the issues of the prevalence of NANB hepatitis in the local population and the possible utility of surrogate testing. One such study was reported in an article in the Lancet by Anderson & Ors on 18 April 1987.[1066] In this article it was pointed out that the combined surrogate testing had been required for accreditation to the American Association of Blood Banks from 30 November 1986. That requirement had been instituted on the basis of information that 7% of recipients of volunteer donor blood contracted post transfusion NANB hepatitis and that around half of those went on to develop to the chronic stage of the disease.[1067] This was based on the ongoing study by Alter and Ors, the latest part of which had been published in 1985. The Anderson study assessed only 186 cardiac surgery patients (recipients) for signs of PT NANBH between 1981 and 1983. As was noted in the Anderson paper, a further US study by Korzoi and Holland expressed the view that the incidence of PT NANBH could be reduced by around 40% in the US by the introduction of testing for the presence of anti-HBc (although there had been no prospective study to confirm that figure).[1068] That study also suggested that a further 30% of PT NANBH cases could be prevented by excluding donors with a raised ALT. The study also noted a very low number of reports of PT NANBH from hospitals where the blood which the authors collected had been used (a low incidence) since 1974. There had been no reports of cirrhosis having resulted from transfusion.

3.31 Little reliance can be placed on a system based on reporting of cases of post transfusion hepatitis where no detail is given of the robustness of the obligation to report and one is dealing with a disease whose symptoms are sub-clinical for

---

[1066] PRSE0001216
[1067] PRSE0004333
[1068] PRSE0001533

some time. The Anderson study proposed that a large domestic trial was needed in the UK in order to assess the likely incidence of PT NANBH in the different regions of the UK and the severity of the sequelae and consequently whether surrogate testing would be cost effective. This was the type of study which had been in Dr McClelland's mind from at least 1981.

3.32 Two Scottish studies were reported in the Lancet on 13 June 1987.[1069] The first (Dow & Ors) was based on a study of reports of PT hepatitis in the west of Scotland (23 such reports). The usefulness of this data is limited in the same way as the reported data in the Anderson paper. The report itself suggested that 99% of hepatitis cases are not reported. Further, it is interesting to judge the likely accuracy of the reporting system by the fact that only 5 of the reported 23 cases were users of Scottish factor concentrates. It is widely accepted that all recipients of Scottish factor VIII concentrates would have been infected with NANB hepatitis on first infusion by at least 1983 and so the fact that there had only been 5 reported cases shows that those reported cases in this population represented only a tiny proportion of those actually infected in that group. An assessment was done of the donors who had given the blood transfused into the 15 patients for whom a report of PT NANBH had been made and who had not been excluded from the study as having other risk factors for infection (drug use and concentrate exposure). 51 donors had given blood to which these patients had been exposed. Only 5 would have been excluded by surrogate testing and so 5 cases would have been prevented. The reliance in this study on reporting to identify patients whose donors could be studied means that this analysis is really of little value, as was accepted in evidence by the expert in this area, Dr McClelland in his evidence to the Penrose Inquiry. The study also recommended a large scale domestic trial. In addition, like the Anderson letter, it analysed the value of surrogate testing in terms of its cost effectiveness. In the post HIV era, prevention was not something which could be judged solely on the basis of cost, as A v NBA would later show. It is of interest to note that one of the signatories to this letter, Dr Mitchell, was also

[1069] PRSE0002104 (one by Dow and Ors and the other by Gillon & Ors)

a signatory to the letter (discussed below) dated 4 July 1987 which recommended the introduction of surrogate testing.

3.33 The second of the June 1987 letters (Gillon & Ors) detailed a study of blood donors only in the east of Scotland. It had no recipient component. The conclusion of the study was to raise doubts as to the prevalence of PT NANBH in the donor population and the link between positive surrogate tests and NANBH infection. Only 33 of the 42 donors with a raised ALT returned to allow further tests and analysis to be done on them (circa 21% did not return). One might think that those who did not return may have been more likely to have risk factors for NANBH infection, explaining their reluctance to participate further. It is not clear what proportion of the donor population the number of donors involved in the study represents. A significant number of the donors who tested positive on the ALT test in the trial had other risk factors for raised ALT (such as obesity or alcohol ingestion). The study seems to have assumed that where there were other risk factors, these (and not NANB hepatitis infection) were the reason for the raised levels of ALT. The conclusion that "most of the excluded donors would not be NANB hepatitis carriers" (indicating a low specificity) is therefore of dubious accuracy. Once again, value for money appears to be the test used to measure the need for surrogate testing.

3.34 As these studies themselves accepted, given that they tended to recommend that a larger study be carried out, the findings of these small studies were limited and were of little value in reaching conclusions about the likely prevalence of PT NANBH in the UK or indeed in Scotland as a whole, its likely severity or the likely utility of surrogate testing in preventing it. The value of the studies is also extremely limited for the reasons listed above. What was needed was an assessment based on the large scale studies from other countries, in particular the US. The evidence from the studies like Fletcher meant that there was not as significant a difference between the US and UK systems as had been thought in terms of risk. The US data, in particular the elements derived from a voluntary donor population were therefore of relevance to decision making in the UK. They had been compiled over years and were on a large scale. That could not be achieved in the UK by the mo=id 1980s. In effect, making the need for such a study

a suspensive condition of surrogate testing meant that it would never be introduced. The laudable desire for scientific certainty about prevalence and the utility of a contemplated testing regime which was expressed in the smaller studies ought not to have been confused with the political necessity for something to be done based on the data which did exist, even if it was not perfect. The same head in the sand attitude to justify inaction which had been so common in relation to HIV continued to prevail.

3.35 Despite the limitations of the small, local studies, it is clear that a good deal of the thinking within SHHD, in particular on the part of Dr Forrester, was based on these limited studies and, in particular, the work led by Dr Brian Dow in the west of Scotland. Dr Forrester's Note of 12 June 1986 on the subject of surrogate testing is derived mostly from the Dow PhD thesis of 1985.[1070] It contains a reference to information which he had from Dr Dan Reid to the effect that cases of NANBH were probably under-reported by clinicians and hence he had little confidence in his figures. He states (on the basis on the Dow work) that in association with blood transfusion NANBH is very uncommon in the west of Scotland. This comment is not qualified by limitations on reporting or the known sub-clinical nature of the early stages of the disease. He states that Dr Dow found no evidence of any substantial NANB hepatitis problem in haemophiliacs. This would appear to be very much contrary to contemporary evidence on both the incidence and the severity of the disease in that population. Dr Forrester's note on the meeting of 26 June 1986 was clearly once again based on the reasoning in the Dow PhD thesis [1071]. By the time of this note, Dr Forrester appeared to have forgotten the advice given to him by Dr Reid that the condition was probably underreported meaning that one could not have confidence in figures about incidence, whether as a result of transfusion or not. Further, in his evidence at the Penrose Inquiry even Dr Dow expressed surprise that his research was being used by the SHHD in decision making on the issue of surrogate testing.[1072]

[1070] PRSE0000857

[1071] PRSE0000017 (30 June 1986)

[1072] Penrose Inquiry transcript for 22/11/11 (day 67); 65 (19) to 66 (4) (Dr Dow); [PRSE0006067_0065 to 0066]

3.36 A large scale prospective study would have been a useful indicator of the likely utility of surrogate testing and the scale of infection which it could have prevented. It should have been commissioned by around 1981. Focus on its value was lost when the AIDS crisis emerged as the risk were not seen as cumulative. However, as time progressed into the second half of the 1980s, the utility and hence the need for such a large-scale study was superseded by the emergence of other relevant information about the severity of the disease. Against the backdrop of AIDS, the lack of protection against NANBH should have resulted in screening steps being taken. A failure to appreciate the urgency of the situation which appeared wilful led to a lack of ministerial involvement and thus a lack of any political appetite for steps to be taken in the interests of safety. The absence of such a study did not leave transfusionists with no information relevant to the question of the likely prevalence of NANB hepatitis in the local population. Some assistance could be gleaned from foreign studies (discussed further below) and there was the fact that it was considered highly likely that the recipients of unheated locally produced factor concentrates would contract the disease, meaning that recipients of blood components were also increasingly at risk. Although those individuals were being exposed, some deductions could be made about the prevalence of the disease in the local donor population. Transfusion and cryoprecipitate infections and the viral load in concentrates could have been reduced. The smaller studies referred to above could not be relied upon to give an accurate picture to assist with the issue of surrogate testing. They themselves indicated that a larger prospective study would be needed for any local conclusions based on research to be able to be drawn with confidence. The failure to commission one earlier meant that it became increasingly less feasible to do so.

Working Party on Transfusion Associated Hepatitis in November 1986

3.37 Dr McClelland also gave evidence to the Penrose Inquiry about the meeting of the WP TAH in November 1986. He was a member of that group. The paradox of the

November 1986 meeting appears to be that it was (a) the meeting at which Dr Gunson presented material which formed the basis of the Lancet letter from the SNBTS directors of July 1987 (see below) about the likely benefits of surrogate testing as well as being one of the reasons why Dr McClelland became convinced that the time had come to recommend that testing be instituted in Scotland and at the same time (b) the meeting which recommended further research involving looking at donors only. The material presented by Dr Gunson is considered in more detail below. Dr Gunson had other pressures on him as he was the principal advisor to the DHSS on blood transfusion matters and (as will be seen from elsewhere in this submission) there was no great appetite for surrogate testing in England and Wales at that time.

3.38 As for the outcome of the meeting is concerned, it was clear from the evidence heard by the Penrose Inquiry that the research proposed at the meeting would have added little to the discussion about whether surrogate testing should be introduced on the basis that it looked at donors only. Any study into the likely transmission of NANBH and the utility of surrogate tests as markers to prevent the possible spread of the disease would have had to have considered the position of recipients as well, in particular the number who appeared to contract the disease and whether the fact of infection would have been avoided or the viral load reduced had the donor in question been excluded on the basis of positive surrogate testing. It is clear that though Dr McClelland participated in the meeting, he did not concur in principle with either the likely usefulness of such research or any further delay in introducing surrogate testing. It is interesting that Dr Forrester's memo (considered in more detail below) refers to speaking to Dr Gunson as if that were the same as reflecting the view of the group.[1073]

3.39 It is clear that the preference for this limited research was a means of delaying a decision having to be made about surrogate testing. Such a delay, according to Dr McClelland, was not justified at that time. The approach of this committee and its preference for research are important as they subsequently formed a significant part of the basis upon which administrative staff within SHHD did not recommend

[1073] PRSE0003801_0002

surrogate testing be introduced in Scotland. The attitude that this matter could be kicked into the long grass was, however, an attitude the time for which had passed. The proposed research came too late given what was happening in other countries, the diminished value of research anyway due to the increased relevance of the US material in the UK and the fact that the research which was being proposed here was actually research which would not solved the conundrum of surrogate testing anyway due to its limited scope.

3.40 A report of the meeting was prepared by Dr Forrester[1074] to his colleagues within SHHD (Dr McIntyre, Dr Scott and Mr Murray and others whose names can be seen in manuscript) in a memo. There are a number of difficulties with his report, indicative of the fact that the SHHD was making decisions on a false basis at that time. The preference expressed at the meeting for there to be further research was later relied upon heavily by the administrative staff within SHHD in not recommending surrogate testing. Dr Macdonald made it clear that the decision of the SHHD to reject the March 1987 recommendation by the SNBTS directors was heavily influenced by the report by Dr Forrester of this meeting.[1075]

3.41 In the first place, on the first page, he refers to anti-HBc testing as having "some association with the risk of transmitting NANBH". This is not very informative about the potential effectiveness of this form of surrogate test. In his evidence to this Inquiry Professor Tedder was of the view that "hepatitis B was the best analogue illness for what we saw in the 18 June MMWR report for AIDS".[1076] By the early 1980s he had already published on detecting and measuring anti-HBC causing a one-step simultaneous competitive radioimmunoassay.[1077]

3.42 Secondly, Dr Forrester clearly stated that the US experience of a 40% reduction in PT NANBH would not be replicated in Scotland based on "such [unspecified] evidence as exists". This recognises the limitations on the current UK evidence, without giving any detail of it. The fourth paragraph recognises that a large-scale prospective study would be needed to reach similar conclusions. However, this

---

[1074] PRSE0003801
[1075] Penrose Inquiry transcript for 21/11/11 (day 66); 74 (21 to 25) (Dr Macdonald); [PRSE0006066_0074]
[1076] WITN3436003 @ paragraph 37
[1077] WITN3436003 @ paragraph 168

was not going to be done and instead a small-scale donor study was proposed. No comment is made on the likely usefulness of such a limited study on assessing the benefits of surrogate testing or on the advances on the current evidence which this new study is likely to make, if any.

3.43 On the second page, Dr Forrester indicated that he had asked Dr Gunson as to whether he would introduce surrogate testing if it were free of cost and that he replied that he would not. This must be inaccurate reporting of Dr Gunson's position, in particular in light of the material which he presented to the meeting upon which some reliance was placed by Dr McClelland. This cannot realistically have been his position, in any event, as this would be tantamount to saying that no benefit would be offered by surrogate testing at all, which simply was not the case. This statement must, however, have been a powerful indictment of the benefits of surrogate testing for the readership within SHHD. In light of this and the consistent focus on the determination of this meeting in subsequent correspondence, this inaccurate statement must have influenced views within SHHD considerably. Further, it is unlikely that the membership of this group would have recommended research which they accepted was "of no great significance or scientific interest". In any event it is interesting to note that the research was supported by the staff of SHHD despite this comment. The final sentences tried to downplay the significance of the disease on then available evidence and failed to appreciate that the disease was known to be sub-clinical in its early stages.

3.44 It is worthy of note that Dr McClelland (who arrived late at the meeting) was quite surprised by the content of the note, in particular the point about recommending research to "shut people up".[1078] However, he did agree that research on donors would not have added very much to their ability to make a rational decision on what to do.[1079] Dr Dow (who attended the meeting in place of Dr Mitchell) did not recognise the business detailed in the memo to the point that he wondered in his evidence whether this was in fact the meeting which he had attended.[1080] He also expressed surprise at the report that Dr Gunson said that he would not have

---

[1078] Penrose Inquiry transcript for 15/11/11 (day 63); 118 (21) to 119 (6) (Dr McClelland); [PRSE0006063]
[1079] Penrose Inquiry transcript for 15/11/11 (day 63); 119 (7 to 12) (Dr McClelland); [PRSE0006063]
[1080] Penrose Inquiry transcript for 22/11/11 (day 67); 71 (14 to 15) (Dr Dow); [PRSE0006067_0071]

introduced surrogate testing for free.[1081] It is important to note that though the outcome of the meeting is noted, the detailed material presented to the meeting by Dr Gunson which had an impact on Dr McClelland's thinking was not reproduced with the memo.

Evidence of the incidence of PT NANBH (blood transfusions)

3.45 There is one further matter about the discussions at the meeting which is, in our submission, worthy of note. At a joint meeting of the transfusion directors and haemophilia directors on 9 February 1987, Dr Forrester reported on what had been discussed at the meeting. In particular, he pointed out that NANBH was transmitted in between 5% and 25% of blood transfusions in the US. Further, he pointed out that in the UK the transmission rate with blood transfusions was 2.5%. It is interesting to note that the material provided by Dr Gunson at the meeting suggests that he had stated under the subject of "Incidence of transfusion associated NANB hepatitis in the UK" that "the best estimate of incidence from published data is 3%"[1082], a little higher than Dr Forrester's commentary suggests. Little commentary is given in the minutes as to the source of this figure on the incidence of blood transfusion associated NANBH. It appears that little account was taken of this figure which suggests that the incidence of PT NANBH is really quite high, although not in relative terms. As will be seen below, Dr McClelland (the main advocate of surrogate testing) appears to have taken the figures discussed at that meeting as being indicative of the need for routine surrogate testing to be introduced based on the number of cases of PT NANBH which he thought could have been prevented by it. He was right. In calculations done by Dr McClelland for the assistance of the Penrose Inquiry, he used recent data to suggest that one might expect there to be around 36,875 patients receiving one

[1081] Penrose Inquiry transcript for 22/11/11 (day 67); 72 (5 to 10) (Dr Dow); [PRSE0006067_0072]
[1082] See PRSE0003729_0011 (the Dr McClelland statement to the Penrose Inquiry which reproduces the text of the note by Dr Gunson);

or more blood components in a year. The application of a transmission rate of 2.5% to that figure would suggest that around 922 (at 2.5%) and around 1,106 (at 3%) would contract PT NANBH. As Dr McClelland stated in his Penrose evidence, this estimate of incidence was of course an estimate. In the absence of the virus having been isolated, however, these estimates derived from the advice of experts about a potentially very serious disease ought to have been taken seriously. In circumstances where (a) this was a best estimate provided by the UK national medical advisor on transfusion matters (b) it would take several years for a full scale prospective study to be done to give a better figure than this best estimate and (c) no such study as being proposed, as the meeting had resolved to recommend a study on donors only, far more weight should have been given to this figure as a starting point for the consideration of the introduction of surrogate testing.

Scottish participation in the proposed research

3.46 The extent to which Scottish participation in the proposed research was planned is an interesting question as it would be likely to affect the relevance and hence utility of its results in Scotland. In April 1987, Dr Gunson wrote to Dr Cash about the recommendation made by the SNBTS directors that surrogate testing should be introduced (discussed below).[1083] There had been some suggestion at the SNBTS directors' meeting on 3 March 1987 that Scottish centres would not be included in the research proposed by the WP TAH in November 1986[1084]. Dr Gunson pointed out that Edinburgh was to be involved although the involvement of Glasgow had been cancelled. He pointed out his dismay at the possibility that testing might be introduced before the study which had been proposed had been completed. It was later noted, however, that the Scottish component would

[1083] PRSE0001289
[1084] PRSE0004163_0005

require to be abandoned.[1085] Despite this, it seemed to be the case that the directors still thought that Edinburgh would participate[1086] though Dr Forrester had pointed out that the necessary funding application was "lame".[1087] It appears to have been refused by 13 November 1987.[1088] Despite this, there did not seem to be any alternation of the thinking within SHHD of the value of the study (this is considered more fully below) even though it was not to have a Scottish element.

The March 1987 recommendation

3.47 At a meeting of the SNBTS directors on 3 March 1987, a decision was taken to make a unanimous recommendation in the following terms:

> *"to recommend to the SHHD that surrogate testing for NANBH should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres."*[1089]

3.48 The meeting was attended by all of the then directors and Dr Forrester from the SHHD. It is clearly anticipated in the minutes that separate funding would be required for this initiative. Directors are asked to provide costings for their region. Little explanation is given in the minutes as to the reason why this unanimous recommendation was made at this time, apart from the mention of surrogate testing having been started by plasma collectors in the USA and pressure possibly coming from the Haemophilia Society for it to be instituted here. To the extent that any explanation is given, it relates to the possible pressure to have surrogate testing of plasma used for the production of fractionated blood products.

[1085] PRSE0001191 (14 May 1987)
[1086] PRSE0000633_0006 (10 June 1987)
[1087] PRSE0003211_0002 (12 June 1987)
[1088] PRSE0000359
[1089] PRSE0004163_0005

3.49 Dr McClelland took the lead on the issue of surrogate testing within SNBTS. Professor Cash referred to his "leadership" on this issue[1090] and the fact that he very much left Dr McClelland to get on with this issue[1091]. This was also acknowledged by Dr Mitchell.[1092] He gave evidence to the effect that he had become convinced by March 1987 that the time had come for surrogate testing to be introduced in Scotland. The factors which had persuaded him that the time for this measure had arrived were as follows:

- The decision was all about the safety of the blood. It was "the factor" in his consideration.[1093] He was convinced by this time that blood would have been materially safer as a result of surrogate testing.
- The early studies from the US had, in his view, been based on a donation system too different from the one in Scotland for the conclusions about prevalence of NANB hepatitis in the donor pool and the likely effectiveness of surrogate testing in preventing its transmission to be of value here. However, by 1987, Dr McClelland had become convinced that greater regulation in the blood donor system (meaning changes in the profile of the donors[1094]) made more recent US data more persuasive in Scotland in the absence of large scale prospective studies here.[1095] It was confirmed in the evidence of Professor Leikola at the Penrose Inquiry that by the mid-1980s the US blood banks were generally collecting blood for transfusion from voluntary donors only.[1096] The US studies published in the mid-1980s are considered above. It was this material which, in an article in Nature regarding the introduction of surrogate testing in the US, had led the President of the American Association of Blood Banks to say that the tests were "essential to increase the safety of the blood supply".[1097]

[1090] Penrose Inquiry transcript for 16/11/11 (day 64); 169 (22) (Professor Cash); [PRSE0006064_0169]
[1091] Penrose Inquiry transcript for 29/11/11 (day 70); 164 (22 to 25) (Professor Cash); [PRSE0006070]
[1092] Penrose Inquiry transcript for 17/11/11 (day 65); 62 (1 to 5) (Dr Mitchell); [PRSE0006065_0062]
[1093] Penrose Inquiry transcript for 15/11/11 (day 63); 143 (23 to 25) (Dr McClelland); [PRSE0006063]
[1094] Regulations designed to exclude high risk donors in the US had been initiated in March 1983 by the FDA – see PRSE0004408
[1095] Penrose Inquiry transcript for 15/11/11 (day 63); 141 (16) to 142 (10) (Dr McClelland); [PRSE0006063]
[1096] Penrose Inquiry transcript for 30/11/11 (day 71); 14 (15 to 22) (Professor Leikola); [PRSE0006071]
[1097] PRSE0001774 (4 September 1986)

- The smaller UK studies (referred to above) which did not concur with that recommendation were not really studies which he found to be very convincing in the general argument on this subject.[1098]
- The figures presented by Harold Gunson at the WP TAH meeting in November 1986 based on the information which was available at the time made an impression on him as to what the benefits would be for patients in introducing surrogate testing.[1099] The material which was presented by Dr Gunson is reproduced by Dr McClelland in his Penrose Inquiry statement.[1100]

3.50 Had the SHHD thought to ask the SNBTS for further specification as to the reasons why the recommendation had been made and why surrogate testing was now necessary, it is likely that it would have been Dr McClelland to whom they would have turned given that it was he who was taking the lead in this area. These are likely to have been the reasons he would have given them. Indeed, in response to questioning about negative responses to the position taken by the SNBTS directors, Dr McClelland considered the approach of others who favoured delay to be inconsistent with the precautionary principle and unscientific.[1101]

The Lancet letter

3.51 Subsequent to the recommendation having been made to the SHHD by the SNBTS directors at the meeting in March 1987, the directors wrote a letter to the Lancet relating to the need for surrogate testing to be introduced in Scotland.[1102] The letter was drafted by Dr McClelland[1103] and was entitled "Testing blood donors for NANB hepatitis - irrational, perhaps, but inescapable", though a rationale for its

---

[1098] Penrose Inquiry transcript for 15/11/11 (day 63); 147 (2 to 8) (Dr McClelland); [PRSE0006063]
[1099] Penrose Inquiry transcript for 16/11/11 (day 64); 116 (15) to 117 (22) (Dr McClelland); [PRSE0006064_0116 to 0117]
[1100] PRSE0003729_0011
[1101] Penrose Inquiry transcript for 15/11/11 (day 63); 145 (16) to 146 (21) (Dr McClelland); PRSE0006063]
[1102] PRSE0001444
[1103] PRSE0001527_0003 (16 June 1987)

introduction was set out in the article and further explanation of the reasoning was given by Dr McClelland in his evidence, as detailed above. In the article it was argued:

- Despite the value which would be gained by a large-scale UK prospective study, the time for that had passed as it would take 3 - 4 years for such a study to be carried out. This time period is not a matter which is considered in any of the small-scale study letters, discussed above.
- The strict liability provisions of the impending consumer protection legislation was considered and it was argued that the producer of a product would be liable to a consumer who had contracted NANB hepatitis unless it could be shown that all measures were taken to avoid the risk of the disease being contracted. This nature and extent of the strict liability obligations and the resultant cost implications of a breach are not matters which are considered in any of the small-scale study letters, discussed above.
- Though advanced specifically in the context of blood products, it was argued that some improvement in the quality of the product (which surrogate testing would afford) is better than none. This is not a point which is considered in any of the small-scale study letters, discussed above.
- The argument was made that products from abroad were subjected to surrogate testing and that would put the UK products at a competitive disadvantage in the eyes of the consumer (testing having been instituted in Germany, France and the USA). Though this seems to relate predominantly to the production of blood products it recognises (a) the number of large countries which had adopted surrogate testing and (b) the requirement to look at safety from the point of view of the consumer, which was at the heart of the new legislation. The number of countries which used surrogate testing and the requirement to view products from the points of view of the consumer are not points which are considered in any of the small-scale study letters, discussed above.
- It was also argued (using, it would seem, figures derived from the material presented to the WP TAH meeting by Dr Gunson) that the value for money which

surrogate testing would represent would be better than the value offered by other blood testing regimes. Such a comparative assessment of the value for money argument is not considered in any of the small-scale study letters, discussed above.

3.52 The reasons set out here are not exactly the same reasons as were given for the recommendation of surrogate testing by Dr McClelland in his Penrose evidence. Dr McClelland stated that this was because he thought that the arguments in the letter might work.[1104] There appears to be an emphasis in this letter on blood products, though in the tables it produced relating to cost effectiveness it recognises that transmission in fractionated plasma products may be irrelevant to this debate due to the impending arrival of heat treatment. There was no reference to the relevance of the more recent US data. The source of the assumptions used to calculate the cost effectiveness of testing (it would appear the US data, as used by Dr Gunson at the WP TAH meeting) was not referenced. This apparent discrepancy, he explained, was due to the fact that the article (which he drafted) was intended to put forward the kind of argument which it was thought would be most effective in persuading the government that this was the correct way forward. The fact that the full range of arguments was not put clearly to the SHHD is considered elsewhere in this submission. It appears that the lack of communication between the SNBTS directors and the SHHD on this issue played a part in the failure to introduce surrogate testing.

The timing of the recommendation

3.53 It should be noted that certain of these arguments could have been made considerably earlier than this. The fact that surrogate testing would have at least

[1104] Penrose Inquiry transcript for 15/11/11 (day 63); 144 (6 to 8) (Dr McClelland); [PRSE0006063]

some safety benefit had been known for many years. Testing had been introduced abroad many years previously (as set out above) and in the US from November 1986. If consideration of what consumers of the product would reasonably expect had only been initiated by the introduction of the impending legislation, we would argue that this should have been the predominant attitude for many years in any event. Consumers in receipt of blood transfusions and blood products would have assumed (quite reasonably) that all available steps were being taken to protect them. No alternative to the blood on offer was available. As is discussed elsewhere in this submission, it was almost invariably the case that haemophiliacs were not offered any alternative to the SNBTS concentrate. Further, the impending products liability legislation had been on the radar since 1985, the date of the EC Directive. The fact that a large-scale study was unlikely to happen and the fact that it would be likely to take several years to be completed had been the position for some time before the publication of this letter. The more recent US studies indicating the likely benefits of surrogate testing there had been available since 1985/86. The small-scale studies done in the UK over previous years were always known to have been too small to have made any real impact on the argument. On this basis, we would argue that the recommendation to introduce surrogate testing should have been made at least a year before this. That this could have happened is also suggested by the fact that in 1986, in their budget request to the Scottish Office, the SNBTS sought £810k to introduce surrogate testing for NANBH in 1987/88. In our submission, there is no basis upon which to suggest that a recommendation made in 1986 could not have been implemented by 1987.

<u>The actual prospect of surrogate testing being introduced in Scotland in 1987/1988</u>

3.54 Despite the title of the Lancet letter published in July 1987, there was a clear reasoning behind the recommendation that surrogate testing be introduced. However, the likelihood that it would be introduced (as far as the SNBTS directors were concerned) was another matter. In the aftermath of the meeting on 3 March

1987, Dr Gunson wrote to Professor Cash expressing some concern that surrogate testing would be introduced in Scotland where there was no intention to do so in England at that time and without waiting for the outcome of the donor study which had been agreed upon at the WP TAH meeting (of which Dr Gunson was the Chairman) in November 1986 (referred to above).[1105] Professor Cash replied on 27 April 1987 to the effect that he should not take the recommendation too seriously at this stage and that it was made principally for the purpose of securing funding.[1106] It is interesting to note that he suggests that the outcome of the research is unlikely to have an effect on future operational practice anyway. This would appear to reflect an attitude that the government would be unlikely to introduce surrogate testing in any event. This exchange appears to be indicative of a familiar dichotomy between attitudes being adopted by Professor Cash in his dealings government and his English colleagues. The Cash dichotomy is discussed in more detail in connection with the introduction of anti-HCV testing below. However, for present purposes it should be noted that Professor Cash appears to have been in favour of surrogate testing from a scientific point of view, but when faced with the possible issue that such a move would create for England which did not intend to introduce such a testing regime, he responded to Dr Gunson with a kind of fatalism about the possibility that SHHD would introduce the move anyway. This was a common pattern. What this evidence appears to demonstrate is that there was a political embargo on such a move being taken in Scotland when no such equivalent move was being contemplated in the rest of the UK. This was a figment of the fallacy of administrative devolution addressed elsewhere in this submission. It was not in the interests of patients in Scotland. It contravened expert scientific advice. However, the Cash dichotomy cannot have helped matters. No doubt, Professor Cash was trying to navigate the political ramifications of his scientific advice in the UK context. However, on this and other occasions this apparent inconsistency in his position resulted in his scientific advice having far less clarity and apparently less conviction than they actually did. This can only have

[1105] PRSE0001289 (21 April 1987)
[1106] PRSE0002017

had the effect of undermining the robustness of his scientific advice, in particular in the minds of those within SHHD and the English BTS who were naturally inclined to oppose such a move.

3.55 In his evidence to the Penrose Inquiry, Professor Cash confirmed that it was his attitude that Dr Gunson need not worry as he did not think that the SHHD would approve anything which was not going to be done in England anyway.[1107] We take this (along with the fact that directors saw fit to write a letter to the Lancet in the terms that it was written on this subject) as an indication that the directors thought that there would be little likelihood that surrogate testing would be acceptable to the government. This is likely to be the reason why little effort was made to communicate the precise reasons for the recommendation to the SHHD and little effort was made in preparing practically for surrogate testing (see submission below, for example, about no algorithm having been worked up). This was a mistake. It meant that the officials within SHHD did not have access to the full information and reasoning which they would have needed to make the recommendation to the minister that surrogate testing be introduced in Scotland. It gave them the impression that, despite the recommendation, the directors did not have clear reasoning or did not really support the idea. Dr Macdonald gave evidence to the effect that the medical officers within SHHD tended to have problems knowing whether the directors were going to hold their position.[1108] As the evidence of Dr McClelland shows, there were good reasons for this measure to be introduced and their reasoning should have been explained clearly and the implementation of testing pursued vigorously by the SNBTS directors. If anything, the position adopted by Professor Cash in his correspondence with Dr Gunson demonstrates that the anticipated resistance within SHHD to surrogate testing would mean that all the more clarity was required in the recommendation. Further, as subsequent correspondence written by administrative staff within SHHD indicated, the removal of the research option (by then practically impossible given the time it would take and the pressing need for the move) would have made

[1107] Penrose Inquiry transcript for 29/11/11 (day 70); 184 (25) to 185 (14) (Professor Cash); [PRSE0006070]
[1108] Penrose Inquiry transcript for 21/11/11 (day 66); 144 (3 to 7) (Dr Macdonald); [PRSE0006066_0144]

pressure to introduce surrogate testing "irresistible".[1109] This suggests that a clear argument as to the limited utility of the proposed research would have resulted in surrogate testing being introduced in accordance with the March 1987 recommendation as such a proposal would have become politically irresistible.

Clarity around communication regarding the severity of NANBH

3.56 One major reason for the non-introduction of surrogate testing in Scotland was a failure in communication between the SNBTS and the SHHD as to the reasons why the directors considered it appropriate for such a testing regime to be instituted. These reasons are discussed above. The reasoning adopted by the officials within SHHD are discussed below. There is a clear incongruity between the two. The responsibility for that state of affairs rests on both sides.

3.57 Additionally, as is indicated above, there clearly appeared to have been a limited understanding by officials within SHHD of the severity of the disease transmission of which surrogate testing would have been designed to prevent. By 1985 at the latest the accumulation of material relating to infection with NANB hepatitis indicated that it was not, as had previously been thought, a benign disease. Dr Forrester continued to maintain within SHHD that this was predominantly a benign disease. This was communicated to his colleagues in numerous places (see above). We do not feel that the severity of the disease was understood over this period within SHHD as it should have been and in accordance with the contemporaneous, well known literature. That he was under the impression that it was a benign disease should have been known to the SNBTS directors. At a joint meeting on 9 February 1987, Dr Forrester reported on the WP TAH meeting which he had attended in November 1987. He reported his impression that NANBH was "relatively benign".[1110] This was an opportunity for the SNBTS directors (and indeed the haemophilia directors in attendance) to communicate to him that the

[1109] PRSE0003515
[1110] PRSE0002769_0003

literature was not in accordance with his understanding and that his impression from the WP TAH meeting in November 1986 was not accurate. The emphasis on the benign nature of the disease will have tended to lessen the likelihood that steps would be required to prevent it, such as the institution of surrogate testing. However, the responsibility for the misunderstanding of the potential severity of the condition cannot be said to lie entirely with the SNBTS. Although we would have expected them to have brought this to his attention, it is clear that Dr Forrester had access to and used other sources of information to gain an insight into the severity of the disease. His memos show that he consulted Dr Dan Reid who had an infectious diseases background *inter alia* on the severity of the disease. There is reference in one memo to this individual consulting a textbook about the current thinking on the disease.[1111] The shortcomings of this approach and the limitations on the research upon the understanding of the disease are indicative of a substandard effort having been made to fully understand fully the severity of the disease. This resulted in incomplete information being used as a basis for decision making on prevention options, such as surrogate testing, within the SHHD.

<u>The communication of the reasons for the recommendation by the directors to institute surrogate testing</u>

3.58 The SNBTS directors were experts in matters relating to blood transfusion, including the current international practice and the risks of viral transmission. In particular, the fact that the position and therefore the attractiveness of surrogate testing had moved on was not communicated effectively. The discrepancy between Dr McClelland's expressed reasoning and the advice given is addressed above. As will be discussed in more detail below, the government maintained the

[1111] PRSE0000857

general position that more research was needed, which had been the position of the directors before March 1987.

3.59 Prior to the meeting on 3 March 1987, the position within SHHD is set out in certain evidence available to the Inquiry. At the SNBTS directors meeting on 26 March 1986 it was noted that the FDA advisory panel had published its recommendations on surrogate testing in February and that it looked likely that surrogate testing would be introduced in the US. Dr Forrester pointed out that he considered it to be highly unlikely that the UK departments of health would introduce testing based on the US data.[1112] This remained the interactable position. This remained Dr Forrester's position in February 1987 when he explained in an internal memo that UK evidence (by which he must have meant the small UK studies considered elsewhere in this submission) did not concur with the US data and advised not to adopt US practice blindly.[1113] Against this background, it should have been appreciated that a change in the directors' stance on this issue would require clear explanation to the SHHD, in particular where any reliance was being placed on the US data (as Dr McClelland had done).

3.60 As outlined above, the recommendation was made by the directors at their meeting on 3 March 1987. There is little detail of the full extent of the real reasons (as outlined by the expert Dr McClelland) for the recommendation having been made at that time. Dr Forrester was present and reported back to his colleagues, both medical and non-medical, within SHHD. There is no evidence of any further communication having been made either informally or formally by the directors to the SHHD as to their reasons for the recommendation.

3.61 In his Penrose evidence, Professor Cash accepted in his evidence that more could and should have been done to communicate clearly the reasons for the recommendation to SHHD.[1114] In particular, the increasing relevance of the study material from the US (as referred to by Dr McClelland) and the limited value of (a) the small local studies and (b) the research proposed by the WP TAH did not appear to have been explained as the directors' position either in the minutes of

---

[1112] PRSE0004769_0008 (26 March 1986)
[1113] PRSE0002803 (10 February 1987)
[1114] Penrose Inquiry transcript for 29/11/11 (day 70); 178 (10 to 19) (Professor Cash); [PRSE0006070]

the meeting on 3 March or the Lancet article on 4 July 1987. Equally, and in light of the scant reasoning in the minutes of the 3 March meeting, there is no evidence of any further request for any greater specification of the reasons for the recommendation having been made by anyone within SHHD. Dr Forrester indicated in his evidence that he thought that the reasons for the recommendation would be passed to the government through a channel other than himself and that he did not think that any further action on his part was required.[1115] Dr McClelland gave evidence at Penrose to the effect that communication of these matters would have been the responsibility of Professor Cash and through the documents produced surrounding the meetings.[1116] Taken at its height, this evidence appears to indicate a significant lack of clarity as to what procedure should be followed. The result of that lack of clarity was a communication failure on this issue of central significance to patient safety.

3.62 It is clear, however, that the working relationship between SNBTS and the SHHD had deteriorated significantly by this point. This may well be the reason for the limited communication, the effect of which was that the safety of the recipients of blood and blood products was undermined. Dr Macdonald, at that time the chief medical officer, accepted in his evidence at Penrose that the working relationship between SHHD and the SNBTS directors had become strained by late 1986 into 1987.[1117] The very fact that the directors saw fit to send a letter with their views on surrogate testing to the Lancet when they had not explained their reasoning for the recommendation clearly to the SHHD is indicative of a strained relationship. The correspondence from Professor Cash relating to his perception of the competence of Dr Forrester as the link between the two departments appears to suggest a serious problem[1118], as does the refusal of the SHHD to comply with his suggestion as to what to do about it.[1119] In particular (a) the

---

[1115] Penrose Inquiry transcript for 21/11/11 (day 66); 32 (1) to 33 (14) (Dr Forrester); [PRSE0006066_0032 to 0033]
[1116] Penrose Inquiry transcript for 15/11/11 (day 63); 105 (8 to 20) (Dr McClelland); [PRSE0006063]
[1117] Penrose Inquiry transcript for 21/11/11 (day 66); 143 (20) to 144 (9) (Dr Macdonald); [PRSE0006066_0143 to 0144]
[1118] PRSE0004596
[1119] PRSE0002521

reference by Professor Cash to the need for him to raise the issue "once again" suggests that this was an ongoing problem (b) the generality of his comment about lack of confidence suggests that his view does not relate to the specific matter which prompted this letter (c) the recommendation that Dr Forrester should no longer deal with the SNBTS demonstrates Professor Cash's strength of feeling and (d) the letter refers to a previous failure on the part of Dr Forrester to communicate information to Mr Morison properly. Professor Cash's own evidence throughout the Penrose Inquiry made it clear that he and the staff of SHHD did not work well together and took very different views as to how best to run the transfusion service. He resigned as consultant advisor to the SHHD in March 1986.[1120] He referred to "an almost complete disruption in professional relations between some important and senior members of SHHD's medical team and me which I suspect lasted for more than a decade".[1121]

3.63 The difficulties in the relationship between the experts and the decision makers in Scotland, was not conducive towards maximising the interests of patients. Further, it is of interest to note that Mr David McIntosh was keen to change the structure within SNBTS and clarify its working relationship with SHHD. He accepted in his evidence at Penrose that it was the responsibility of the SNBTS to give advice to the government, to be clear about it and to be clear about the consequences of not accepting it. He gave this evidence in the context of the introduction of routine anti-HCV testing, in connection with which he acted that this did not happen.[1122] This was clearly also the position with regard to surrogate testing, where the reasoning for the advice given were neither properly communicated by SNBTS nor understood by SHHD. The correspondence with Dr Gunson indicates that a recommendation had been made in a half-hearted way on the basis that, despite the fact that it was deemed right that it should be made, it was assumed that it would never be acted upon. This was a dysfunctional system.

[1120] PRSE0001514
[1121] PRSE0002223
[1122] Penrose Inquiry transcript for 29/11/11 (day 70); 85 (3) to 86 (6) (Mr David McIntosh); [PRSE0006070]

A testing algorithm

3.64 A testing algorithm had been developed by SNBTS in connection with the introduction of anti-HTLV III testing. No such algorithm was developed for NANB surrogate testing by the SNBTS. In the course of preparations for the introduction of anti-HTLV III testing in 1985, the SNBTS prepared an algorithm detailing the way in which the testing programme was to operate when a positive sample was detected.[1123] This was clearly the standard method by which the testing process was thought through and depicted graphically to ensure that careful planning was put into consistent practice. It was confirmed in the evidence of Dr McClelland at the Penrose Inquiry that at the time of the recommendation that surrogate testing be introduced in March 1987 no similar testing algorithm had been devised. This is indicative of the attitude described above within SNBTS that surrogate testing would not actually be introduced. The kinds of details which might have been included in such an algorithm and the importance of advice on these matters being given to the SHHD by SNBTS is considered in more detail below.

Loss of blood to the system which would have resulted from surrogate testing for NANBH

3.65 It is clear that any measures such to minimise the risks of viral transmission from blood or blood products, such as surrogate testing, would have resulted in a loss of blood to the donor system. This required to be a consideration which would be taken into account in decision-making about the institution of testing. It did not deter the directors from making their recommendation in March 1987. Therefore, there is no reason to think that this would have been a real impediment to surrogate testing at any time. The loss would not have been any different at any time. The ability to cope was consistent. Indications as to the level of loss which

[1123] PRSE0003524_0017

could be expected could have been deduced from the international evidence cited above.

3.66 It is also clear that the non-specific nature of the testing would have resulted in a degree of false positivity with the result that blood which was not contaminated with NANB hepatitis would be lost to the system. The Penrose Inquiry heard evidence from Dr McClelland[1124] and Dr Mitchell[1125] to the effect that the system could have coped with the loss of blood caused by the introduction of surrogate testing. It is worth noting in passing that the same logic could have been applied to the earlier introduction of both anti-HIV and anti-HCV testing, in connection with which false positivity of tests was an issue. Dr McClelland expressed the view that the combination of ALT and anti-HBc testing would have resulted in a loss of blood of around 4.5%.[1126] He pointed out that there was usually a surplus of red cells.[1127] As is noted above, the main population which would have benefited from surrogate testing were blood transfusion recipients of those red cells. Given the surplus of these, it seems inherently unreasonable that blood transfusion recipients would not get the benefit of surrogate testing in order to maintain the needs of plasma for fractionation. Of course, these are total amounts and it must be borne in mind that only a proportion of that total would have been "innocent blood" (false positives). As far as the Crawford paper referred to below is concerned, on ALT testing alone it was estimated that around 59% of the blood which tested positive was positive in anti-HCV testing.

3.67 It is significant to note that the possible loss of blood to the donor system was something upon which Dr Forrester commented in an internal memo dated 12 June 1986. In that memo he stated that "rejection of donations might reach 3 percent, a grave loss" if surrogate testing were to be introduced.[1128] He had earlier described his role as being one in which he did not express his own opinions but

---

[1124] Penrose Inquiry transcript for 16/11/11 (day 64); 51 (23) to 52 (2) (Dr McClelland); [PRSE0006064_0051 to 0052]
[1125] Penrose Inquiry transcript for 17/11/11 (day 65); 48 (3 to 22) (Dr Mitchell); [PRSE0006065_0048]
[1126] Penrose Inquiry transcript for 16/11/11 (day 64); 35 (24) to 36 (4) (Dr McClelland); [PRSE0006064_0035 to 0036]
[1127] Penrose Inquiry transcript for 16/11/11 (day 64); 51 (23) to 52 (2) (Dr McClelland); [PRSE0006064_0051 to 0052]
[1128] PRSE0000857

in which he gathered information from others and passed it on.[1129] He did not recall having asked the transfusion directors about their views on this. Despite this he felt able to express a view that the rejection of donations would constitute a "grave loss" in this memo. As indicated above, neither of the two main directors in Scotland thought that the loss of blood to the system could not be overcome.

3.68 Given that it would appear that temporary donor deferral was not considered, these estimates must have been based on permanent loss of donor with raised ALT to the system. A temporary deferral system to cope with the possibility of transient rises in ALT in non-infected donors would have eased this burden. Further, the predominance of the evidence available to the Inquiry was that the main pressure on the blood transfusion service in Scotland as far as volume was concerned was due to the need for plasma for fractionation. Given that the main groups for whom surrogate testing would have been of benefit would have been the recipients of blood other than the plasma product recipients, there may not have been such a supply issue for these groups even after a loss of blood due to surrogate testing as might have been expected. In any event, efforts could and should have been made to recruit new donors based on the need for testing due to the risk of viral infection in non-tested blood. Given that donors may themselves be recipients, at least of whole blood in future, one would have hoped that such effort would have led to an increase in supply. It is interesting to note that at the very meeting where the directors recommended that surrogate testing should be introduced, it was minuted that donors were not accepted under the age of 18 but that the directors appeared receptive to the possibility of younger donors being allowed. This would have been a method of increasing the blood coming into the system.[1130]

The accuracy of the testing mechanisms

[1129] Penrose Inquiry transcript for 21/11/11 (day 66); 11 (13 to 15) (Dr Forrester); [PRSE0006066_0011]
[1130] PRSE0004163_0009

Sensitivity and specificity

3.69 The likely sensitivity and specificity of surrogate tests (a) as tests in their own right and (b) as markers for NANB hepatitis and the appropriateness of the weight accorded to these factors require to be considered. The surrogate testing mechanisms which were considered in Scotland were testing for (a) raised ALT levels and/or (b) the presence of anti-HBc. There are two aspects to the question of whether these tests were specific enough to be used as a means of excluding blood which had been donated by NANB hepatitis positive donors. The first is whether the available tests were accurate in detecting the presence of a raised ALT and anti-HBc themselves. The second is whether these tests, no matter how accurate for detecting a raised ALT and the presence of anti-HBc, were accurate in marking the presence of NANB hepatitis.

3.70 As far as the first of these elements was, ALT tests had been conducted on people with bleeding disorders for many years by the second half of the 1980s. No weight appears to have been attached to this factor by the opponents of surrogate testing in the literature. It did not prevent surrogate testing being introduced in other countries (as outlined above). As far as the sensitivity of the testing as an indicator of NANB hepatitis was concerned, Professor Thomas gave evidence to the Penrose Inquiry to the effect that the antibody remained in those who had recovered from the disease as well as those who are chronically infected.[1131] It is only the presence of antibody and RNA which means that we know that the person is infected. In fact, the person who has recovered has a higher level antibody than the person who is chronically infected. This demonstrates that even anti-HCV testing is really only a surrogate test but it is a surrogate test for infectivity. The sensitivity and specificity of surrogate testing needs to be understood against the background (a) that no other form of testing was available (b) that testing (even for antibodies to the specific virus in question) would not be a complete answer to the problem.

[1131] Penrose Inquiry transcript for 11/10/11 (day 52); 40 (19) to 76 (6) (Professor Thomas); [PRSE0006052_0040 to 0076]

3.71 The presence of antibodies to the hepatitis B core antigen did not indicate the presence of NANB hepatitis antibodies. Instead, their presence demonstrated that the individual concerned had been exposed to the hepatitis B virus in the past. Professor Thomas gave evidence to the Penrose Inquiry regarding the differences and similarities between HCV and HBV.[1132] He noted that both were parenterally transmitted viruses. The rationale behind using anti-HBc as a surrogate marker for the presence of NANB hepatitis was that persons who had been exposed to the hepatitis B virus in the past were likely to have a high risk of having been exposed, and therefore possibly being infected, with NANB hepatitis. This was on the basis that, as both were parenterally transmitted viruses, those who had been exposed to hepatitis B through certain activities may also have been exposed to NANB hepatitis through the same activities.

3.72 Raised ALT was known to be caused by the presence of NANB hepatitis. It was used as a means of diagnosing NANBH and monitoring progression of the disease in haemophiliacs. Professor Thomas indicated in his Penrose evidence that the ALT level would be found to be raised above the upper limit of normal in those with acute infection and that that level would not go down under the upper limit of normal in patients who progressed to the chronic phase of the disease. However, raised ALT is simply an indicator of liver damage and not a specific indicator of the cause of that liver damage.[1133] The Penrose Inquiry heard oral evidence to the effect that a raised ALT level could be caused by alcohol use, drug abuse, exercise and medical conditions such as coronary heart disease. This might have rendered the use of a raised ALT level as an unsuitable test for the presence of NANB hepatitis. This risk is not something which rendered ALT testing an unsuitable method of donor exclusion for the protection of recipients against NANB transmission. This is because the loss of the donor who had a raised ALT but was not infected with NANB hepatitis (a false positive result) should not be deemed to be a great loss to the system where the causes of that raised ALT were predominately things which rendered the donor unsuitable for other reasons. It is

[1132] Penrose Inquiry transcript for 11/10/11 (day 52) (Professor Thomas); [PRSE0006052]
[1133] Penrose Inquiry transcript for 11/10/11 (day 52); 73 (13 to 21) (Professor Thomas); [PRSE0006052_0073]

clear from the practice of donor screening that blood was seen of variable quality and that certain types of donors were deemed to be too risky on the basis of certain traits to be allowed to give blood. Amongst these were practices which could have been the cause of a raised ALT level, including drug and alcohol use. This, combined with the system of temporary donor deferral advocated below, should, in our view, have meant that using ALT testing for the sake of safety should not have been deemed to be too inspecific a method of rendering blood safer.

3.73 ALT and ant-HBc tests were not specific tests for the presence of NANB hepatitis. In his evidence to the Penrose Inquiry, Dr Macdonald stated that one of the reasons that he was against the introduction of surrogate testing was the fact that it was not a complete solution to the problem.[1134] This is inherent in the nature of a surrogate test (and, as outlined above, even a specific antibody test). There can be no suggestion that the introduction of surrogate testing could ever or could have been expected to eradicate the transmission of hepatitis C through blood in Scotland. However, until a more specific test was introduced, surrogate testing would have made a significant contribution to that aim. The importance of doing something to minimise the spread of this potentially lethal disease was all the more pressing, given the fact that there were, during the 1980s, serious doubts about when the virus which caused NANB hepatitis would be found, if ever, enabling a more specific test to be developed. In the first paragraph of his statement to the Penrose Inquiry on this topic, Dr Mitchell noted that Dr Harvey Alter had entertained serious doubts as to whether the virus would ever be found.[1135] By May 1987, there was clearly no expectation that a specific test would be available any time soon.[1136] Something needed to be done.

3.74 There are three other elements which are worthy of consideration at this point. First, the very reason why two tests were under consideration was that it was the combination of positivity for both that would give rise to a more reasonable inference that a patient was NANBH positive. The raised ALT was indicative of liver damage. The positive anti-HBc test was indicative of a previous exposure to a risky

---

[1134] Penrose Inquiry transcript for 21/11/11 (day 66); 65 (9 to 12) (Dr Macdonald); [PRSE0006066_0065]
[1135] PRSE0001221
[1136] PRSE0000571_0005 (Council of Europe European Health Committee)

practice by which HBV would have been encountered, including IVDU by which NANBH could also be spread. This rendered it more likely that the raised ALT was caused by infection introduced by that route, rendering a combined positive test more likely to be accurate. Looking at each test in isolation is of little value. Secondly, as is expressed above, anti-HBc testing could and should have been introduced as a surrogate marker for HIV anyway. If it had been at that time, it would also have served the dual purpose of assisting with the identification of NANBH positive patients. The introduced of one new test (ALT) would have been all that would have been under consideration at this time, had that happened from around 1983. That would have led to the additional administrative burden being less. Thirdly, there is the issue of the donors. An issue which may have factored into the decision making was what to tell donors about the positive test. The uncertainty of this being a surrogate test was an issue in this regard. However, this was not necessarily a logical impediment to telling donors about their results, if that was considered necessary. It was unlikely that the reason for raised ALT was something which was good for the health of the donor, unless the rise was transitory (such as exercise). Thus, bringing the raised ALT to the attention of the donor was a positive public health development in that it would allow patients to be made aware of this element of their health and be counselled by their own doctors about what might be done about that, such as reduce alcohol intake or improve diet.

Temporary deferral of donors

3.75 There appears to be no evidence available to the Inquiry to suggest that the deferral of donors for a certain period was ever considered. In his PhD thesis in 1985, Dr Dow had suggested that raised levels of ALT are normally transient and that therefore there would be a strong argument based on his data against

permanent donor deferral.[1137] Thus, a donation should not have been accepted from a donor with a raised ALT level (and possibly positive anti-HBc) on a particular day at a particular donor session. However, consideration should have been given to temporary deferral to deal with the possibility that the raised ALT level was merely transient. Such a donor would not be one who should be lost forever to the system, whilst recognising the immediate risk posed by the raised ALT level.

The role of the government in Scotland in the failure to introduce routine surrogate testing

Communication failure

3.76 As submitted above, the working relationship between SHHD and SNBTS resulted in their being a communication failure surrounding the issue of the introduction of surrogate testing. Whilst the communication of their reasoning on this issue was part of the SNBTS directors' responsibility, we take the view that there were also errors in the way in which this matter was handled within the SHHD. Duncan Macniven gave evidence to the Penrose Inquiry the effect that it was regularly necessary for the SHHD staff to approach the SNBTS directors for clarification of their reasoning in support of their financial applications.[1138] No such approach appears to have been made in connection with the recommendation to implement surrogate testing which was, in effect, a financial application as the minute of the 3 March 1987 meeting makes it clear that separate funding would be necessary.[1139] This was despite the fact that Mr Macniven understood his department's representative at the meeting, Dr Forrester, to have been very

[1137] PRSE0003937_0137
[1138] Penrose Inquiry transcript for 17/11/11 (day 65); 152 (8 to 21) (Mr Macniven); [PRSE0006065_0152]
[1139] PRSE0004163_0006

surprised at the recommendation having been made and that it represented a change of the directors' previous position on this issue.[1140]

3.77 Following the meeting a series of memos was exchanged within SHHD. There was no evidence that any of the authors of these memos sought further advice from the SNBTS directors as to their reasoning for the recommendation. The authors seem to have been quite content to express their views as generalists on a recommendation made by experts in transfusion. The first of these is a Memo by Dr McIntyre dated 6 April 1987.[1141] In the Memo he suggests that surrogate testing was to be introduced soon in the USA. It had been introduced in the previous November. The reason for surrogate testing being introduced there is said to be "fear of litigation", as if that were an unjustified basis upon which to institute testing in Scotland and despite the advice received from Professor Cash about the impending consumer protection legislation (see below). He pointed out that the main causes of infectious hepatitis were hepatitis A and hepatitis B. Dr McClelland described the content of this memo as "dismissive".[1142] Dr McIntyre failed, in our view, to appreciate the increasing concerns about the severity of NANBH which had been clear in the domestic medical literature since 1985 at the latest. Further, the memo points out that the funding request for £810,000 which had been submitted by the SNBTS to introduce surrogate testing was refused as (a) a west of Scotland study (the study reports by Dow & Ors in the Lancet) had shown a low incidence of PT NANBH (b) the paper had suggested that surrogate testing would be expensive and (c) the paper had suggested that there would be false positivity and that testing would not eradicate PT NANBH. The limitations of the Dow paper are shown elsewhere in this submission. The cost effectiveness of surrogate testing is dealt with in the July 1987 Lancet letter from the SNBTS directors where it is argued that surrogate testing would, in fact, be a more cost-effective disease prevention measure than other existing forms of testing. Of course, the long-term financial implications of the failure to introduce testing appear never to have been considered within the financial system of spending reviews within government. No

---

[1140] Penrose Inquiry transcript for 17/11/11 (day 65); 142 (11 to 13) (Mr Macniven); [PRSE0006065_0142]
[1141] PRSE0000618
[1142] Penrose Inquiry transcript for 15/11/11 (day 64); 109 (5 to 7) (Dr McClelland); [PRSE0006063]

voice ever appears to have seen any funding application as anything more than something which had financial implications in the short to medium term. No consideration appears ever to have been given to the cost of treating and supporting sick patients in the future, who would become sick if testing were not introduced. Such strategic financial thinking was not part of the government way. The final argument in the memo entirely misguided. Surrogate testing was a non-specific form of testing which, by its nature, would involve a degree of false positivity. This should not have ruled it out as a useful interim measure aimed at achieving some prevention pending the arrival of a more specific test in a system which had little or no protection. If compete eradication were the standard by which testing measures were judged, no testing would ever be instituted.

3.78 In addition, Dr McIntyre pointed out that they wished to await DHSS thinking on the subject. This demonstrates a clear preference for following the English on this matter which is also addressed elsewhere in this submission. The memo concludes that it would be "logical" to participate in the research being proposed by the WP TAH before embarking on a surrogate testing programme. As discussed above, this was not a logical step as that research involved donors only and so would have provided little, if any, insight into the likely effectiveness of surrogate testing in preventing PT NANBH.

3.79 Dr Scott agreed with this approach in a memo dated 7 April 1987.[1143] He stated that they should do whatever they could to prevent the introduction of surrogate testing and that the SNBTS should not be allowed to blackmail them into providing funds. The reasons for this are perhaps not clear but he had indicated concern in an earlier memo about co-ordination with the English BTS on this issue.[1144] It is hard to understand why a measure proposed in the interests of patient safety should require any "blackmail" for funding to be provided for it. Mr Macniven agreed that research was the way to go in a memo dated 9 April 1987 [1145] as did Mr Moir by memo of 23 April 1987.[1146]

[1143] PRSE0002916
[1144] PRSE0004812 (16 October 1986)
[1145] PRSE0000784
[1146] PRSE0004370

3.80 None of these memos demonstrates an understanding of the reasoning why Dr McClelland, the leader on this issue within SNBTS, had made the recommendation that surrogate testing be implemented.

Proposed research

3.81 In February 1987, Dr Forrester showed that he understood there to be a divergence between UK evidence (by which he must have meant the small UK studies considered elsewhere in this submission) and the US data and advised not to adopt US practice blindly.[1147] The usefulness of the small-scale local studies as a basis for decision making in this area is addressed elsewhere in this submission. The exchange of memos referred to above suggests that the position within SHHD in 1987 was (a) that small local studies had demonstrated the limited incidence of PT NANBH in Scotland and the limited utility of surrogate testing in its prevention and (b) that the research proposed by the WP TAH was the way to go at this stage. This attitude is further exemplified by a memo from Mr Duncan Macniven (the assistant secretary with responsibility for blood transfusion in SHHD) dated 2 October 1987.[1148] In this memo to Dr Forrester, Mr Macniven reiterated his preference for research by saying that "the worst of all worlds is that research cannot get off the ground." In those circumstances he feared that they would come under increasingly irresistible pressure to spend the money and introduce surrogate testing for the sake of improving the safety of blood and blood products (at any price). It should be borne in mind that it was known within SHHD that HBsAg and anti-HTLV III testing had been introduced in Scotland without any prior research. Further, it was also known within SHHD that certain haematologists and other clinicians had thought that the introduction of anti-HTLV III testing was slow (even without a delay for research) and that they felt the same way towards delay

[1147] PRSE0002803 (10 February 1987)
[1148] PRSE0003515

surrounding NANBH surrogate testing.[1149] This shows that the prevalent attitude within SHHD was that research should be undertaken so that a decision about the introduction of surrogate testing could be delayed. But for the research, the political pressure for testing would have been "irresistible" according to Mr Macniven. As we have stated above the limited likely utility of the research proposed by the WP TAH had not been appreciated by SHHD. This preference for unnecessary delay was entirely consistent with their desire not to do anything before England (see below).

3.82 SHHD was partly responsible for its failure of understanding of the SNBTS directors' reasoning on the surrogate testing issue. It did not ask for any such reasoning. It seems on the evidence that it can reasonably be inferred that if the limitations of testing were spelled out more clearly that that crutch could not be lent on to kick the issue into the long grass. It was the SHHD's responsibility to take all of the advice it could and inform the minister about the advantages and disadvantages of the proposal. The memo by Mr Macniven demonstrates that the overwhelming desire within SHHD was to kick the issue of surrogate testing into the long grass, irrespective of the advice from the experts in the SNBTS directors group that the time had come for its introduction. Indeed, in a letter to Dr Smithies at the DHSS, Dr Forrester expressed the hope that the message both north and south of the border would be "research first, action later" on this issue.[1150] In his written evidence to the Penrose Inquiry, Dr McClelland pointed out that the multi-centre study into donors (originally proposed at the November 1986 WP TAH) and which was not reported until 1988 was, in his view, an "irrelevance". However, he made it clear that it was the focus of many, including those within SHHD. The time could have been better spent analysing what evidence there was which challenged the belief that NANBH was a non-serious condition rarely transmitted by transfusion.[1151]

[1149] See comments of Dr Forrester notes at PRSE0004769_0008 (26 March 1986)
[1150] PRSE0000738 (17 October 1986)
[1151] Penrose Inquiry transcript for 16/11/11 (day 64); 27 (20) to 28 (7) (Dr McClelland); [PRSE0006064_0027 to 0028]

The understanding within SHHD of the likely severity of NANB hepatitis

3.83 The understanding of the government in Scotland of the potential severity of NANB hepatitis influenced decision making regarding surrogate testing for NANB hepatitis in Scotland. As is examined in detail above, it appears that the understanding of the generalist medical advisors of the current understanding on the severity and progressive nature of the disease in the second half of the 1980s was inaccurate. This misguided understanding is likely to have been a contributory factor in the non-introduction of surrogate testing in Scotland.

Financial considerations

3.84 Funding does not seem to have been a major impediment to the introduction of surrogate testing. Little, if any, consideration appears to have been given within SHHD to potential savings in care costs resulting from prevention of infection. The discussion of the issue was all about the annual budget and not the longer-term picture. Internationally, more consideration was given the potential effectiveness of surrogate testing in the reduction of costs involved in the treatment of chronic hepatitis and the importance of balancing this factor in decision making about incurring the cost of testing.[1152] Further, the relative cost effectiveness of surrogate testing compared to existing forms of testing in disease prevention was specifically addressed by the authors of the letter to the Lancet on 4 July 1987. This does not seem to have been considered in any detail either within SHHD.

The delaying of a decision on surrogate testing

[1152] PRSE0000571_0003 (Dr Habibi)

3.85 The SHHD's approach was to delay making a decision about the introduction of surrogate testing by favouring research as proposed by the WP TAH in November 1986. The desire within SHHD was not to take steps not being taken in England. Professor Cash pointed out that he had learned from Dr Gunson that there was no real appetite for surrogate testing within the DHSS.[1153] In light of this political stance, one can more easily understand the paradox of the November 1986 at which Dr Gunson presented information which assisted in persuading Dr McClelland that surrogate testing should be implemented whilst also recommending research which Dr McClelland described as "irrelevant" to the surrogate testing question.

3.86 Dr Macdonald suggested to the Penrose Inquiry that the introduction of surrogate testing in Scotland but not in England would be "extremely difficult to explain" when different approaches were being taken within the same government.[1154] He later added that the DHHS would have taken the lead on major matters and SHHD would have been required to fit its policy around the DHSS view.[1155] This appears to be what happened with surrogate testing. Mr Macniven suggested that there was a degree of hesitation in accepting the recommendation of the SNBTS directors in March 1987 because there were a great many finger posts pointing in different directions, including people within SNBTS.[1156] This failed to recognise that the recommendation made by the SNBTS directors, the local blood transfusion experts, in March 1987 was unanimous. To the extent that there were others within SNBTS (such as Dr Gillon and Dr Dow) whose studies did not square with the recommendation precisely, the limitations of their studies as a basis for decision making are addressed elsewhere in this submission. Instead, it appears that SHHD were keen to appease the concerns of colleagues within the DHSS.[1157] Rather than listening to the unanimous advice of the SNBTS directors, as Mr

---

[1153] Penrose Inquiry transcript for 16/11/11 (day 64); 151 (2 to 3) (Professor Cash); [PRSE0006064_0151]
[1154] Penrose Inquiry transcript for 21/11/11 (day 66); 66 (3) to 67 (1) (Dr Macdonald); [PRSE0006066_0066 to 0067]
[1155] Penrose Inquiry transcript for 21/11/11 (day 66); 80 (22 to 25) (Dr Macdonald); [PRSE0006066_0080]
[1156] Penrose Inquiry transcript for 17/11/11 (day 65); 141 (7 to 9) (Mr Macniven); [PRSE0006065_0141]
[1157] PRSE0004562 (21 July 1987)

Macniven stated "we were conscious of the fact that the view of the BTS directors south of the border was against the introduction of surrogate testing".[1158]

3.87 In his evidence at Penrose, Dr McClelland indicated that he would not have had any compunction about recommending surrogate testing even if the English transfusion directors had no plans to do the same.[1159] More attention should have been paid within SHHD to the transfusion directors whose concern was the safety of patients and less to political pressure from Westminster.

Conclusion

3.88 There was a clear failure on the part of SNBTS to communicate effectively to the decision makers within SHHD the reasoning for their support for surrogate testing in March 1987. Equally, the staff within SHHD failed properly to clarify their reasoning and reached decisions in connection with this issue based upon apparently wilful misunderstandings of key issues and a desire to delay a final decision being taken on this matter. The possibility of surrogate testing had been raised by the SNBTS directors many months before their recommendation in March 1987. It was raised a meeting on 26 June 1986. In his note of the meeting, Dr Forrester was dismissive of the concept of surrogate testing and, in response to Professor Cash's views on product liability, he merely commented that all of this was just his way trying to get more money.[1160] This tin-eared approach remained the position of the SHHD throughout the period during which surrogate testing was being considered. It was this dismissive attitude which led Dr McClelland to draft the letter to the Lancet (eventually published on 4 July 1987) as, in an uncharacteristic move, he felt the need to "stir the pot a little".[1161] The attitude of the SHHD, in our submission, was conditioned by a political desire not to introduce surrogate testing before England did. Its limited consideration of the severity of

---

[1158] Penrose Inquiry transcript for 17/11/11 (day 65); 180 (14 to 16) (Mr Macniven); [PRSE0006065_0180]
[1159] Penrose Inquiry transcript for 15/11/11 (day 63); 132 (6 to 11) (Dr McClelland); [PRSE0006063]
[1160] PRSE0000017 (30 June 1986)
[1161] Penrose Inquiry transcript for 16/11/11 (day 64); 111 (12 to 23) Dr McClelland); [PRSE0006064_0151]

the disease and the likely benefits of research involving donors only (which they supported) led to a view being taken which was consistent with this political aim. It was not, in the best interests of patients.

The identity of those for whom surrogate testing may have been of benefit

3.89 Surrogate testing would have been of benefit to blood transfusion recipients and patients treated for bleeding disorders with cryoprecipitate whose infections over this period could have been avoided as a result. It would also have had the beneficial effect of reducing the viral load in patient who were treated with concentrates or were otherwise already infected by their treatment. This would have been particularly beneficial to children whose immune systems were still developing, to those already chronically ill with HCV or to those who had been infected with HIV, with the consequent reduction in immune function. Indeed, as the research of Dr Ludlam showed in 1984, even those not infected with HIV had reduced immune function if they had had been exposed to concentrates in their previous treatment. Thus, even of not infected with HIV, reduction in viral load for any such haemophiliac patient would have been of benefit before heat treatment from April 1987.

3.90 In his evidence to the Penrose Inquiry, Dr Macdonald (then CMO) stated that he thought that the recommendation had been made by the SNBTS directors in March 1987 due to the need to be able to compete on a level playing field with the US producers of blood products who subjected their plasma to surrogate testing.[1162] From this, we take it that the SHHD viewed surrogate testing at this as an issue relating to blood products only or predominantly and what you could say in the package insert as against the commercial products which could say that they had been made from plasma which had been subjected to surrogate testing. This simplistic approach missed the point completely. It was predominantly recipients

[1162] Penrose Inquiry transcript for 21/11/11 (day 66); 129 (3) to 130 (16) and 141 (15 to 20) (Dr Macdonald); [PRSE0006066_0129 to 0130; 0141]

of blood and blood products who are most likely to be uninfected on receipt of their transfusions and who were not protected at all, other than by the indirect effect of anti-HIV and HBsAg testing and limited donor selection measures.

3.91 The Inquiry heard no evidence that any consideration was given to addressing any concerns about efforts which would be required for routine surrogate testing to be implemented by subjecting only the blood which was due to be used in blood transfusion and in plasma used in the production of cryoprecipitate to surrogate testing. This approach would have maximised the chances of benefitting those who stood to benefit from surrogate testing without requiring a process to be scaled up and paid for to test every blood donation given in Scotland. Dr McClelland did not appear to support this as an option.[1163] However, we note that Dr Mitchell recorded in his note of the fifth meeting of the ACVSB that FDA would recommend testing single donor blood but not the blood for fractionated products and so this approach to testing some of the blood seems to have found some favour there.[1164]

Lack of ministerial involvement

3.92 Evidence was heard at the Penrose Inquiry from staff of the SHHD at the time when the introduction of surrogate testing was being considered, both on the medical and the administrative side. The matter was not referred to the health minister within SHHD as a specific matter being recommended for the minister's consideration[1165] but it was referred to him as part of the budget proposals referred to above. The member of the administrative staff who has responsible for dealing with this matter and making the decision not to make such a specific referral was Mr Duncan Macniven, the assistant secretary with responsibility for blood transfusion matters within SHHD at the time of the SNBTS directors'

[1163] Penrose Inquiry transcript for 16/11/11 (day 64); 99 (21) (Dr McClelland); [PRSE0006064_0151]
[1164] PRSE0001414_0010
[1165] Penrose Inquiry transcript for 17/11/11 (day 65); 139 (14 to 16) (Mr Macniven); [PRSE0006065_0139]

recommendation. In his evidence, Mr Macniven said that it would have been impracticable for all matters to be referred to the minister for his attention and that he and other staff required to exercise their judgement as to which matters would be referred to the minister.[1166] However, that judgement was exercised in this case incorrectly. The matter was a significant issue relating to public health, recommended by the expert advisors in the area. The decision not to elevate the matter to the minister was based on incomplete understanding of the issues involved and was blinded by the need for policy consistency with the DHSS. In his evidence to this Inquiry, Mr Macniven commented on the structural set up of the Scottish Office at the time which meant that there were relatively few ministers.[1167] The SHHD minister covered both health and home affairs, for example. This structural position led to there being a convenience to matters being maintained at official level and thus to wilful blindness to the cogency and urgency of the proposal. The logical flaw in Mr Macniven's position was that by deciding not to elevate the matter to the minister, he was depriving the minister of expressing a view and hence making the decision for him. This was undemocratic and in this instance unsafe.

3.93 Mr Macniven's successor in office, Mr George Tucker, said in a statement which he provided to the Penrose Inquiry that "if we had contradictory Scottish expert advice then ministers would have been consulted first".[1168] This policy, in our submission, seemed to recognise that ultimate responsibility lay with the minister for making decisions, that the medical advisors within SHHD were not experts and that expert advice needed to be accorded the appropriate weight and put to the minister. In connection with surrogate testing, there was a dispute amongst the experts as to whether it should be introduced. The SNBTS directors had taken one view. Others, like Dr Gunson and Drs Gillon and Dow (as indicated in their letters of June 1987 to the Lancet) had taken another. Given the fact that surrogate testing was an important safety issue about which there had been considerable debate within the transfusion services and the wider medical profession, the

---

[1166] Penrose Inquiry transcript for 17/11/11 (day 65); 140 (13 to 25) (Mr Macniven); [PRSE0006065_0140]
[1167] IBI transcript for 19/0722; 33 to 34 (Mr Macniven)
[1168] PRSE0002387_0004

matter should have been referred for the minister's consideration in line with the policy later adopted by Mr Tucker.

Donor considerations

3.94 The decision whether or not to instigate surrogate testing in Scotland, as with all such decision about testing, required there to be some degree of balancing between the rights and interests of blood donors and those of recipients of blood and blood products. In his Penrose evidence, Dr Macdonald stated that one of the reasons that he was against the introduction of surrogate testing was the fact that it would have had repercussions on the donors.[1169] There is no doubt that it was proper for the interests of both of these groups to weigh in the balance in making decisions like this. However, the interests of donors weighed too heavily in the balance. This was clearly demonstrated by the attitude of Dr Macdonald, the CMO, to surrogate testing in his evidence to the Penrose Inquiry. Even when faced with the hypothesis that surrogate testing could reduce PT NANBH by 30 to 40%, he still said he would have opposed it as he would have "put considerable weight on the possibility that donors would find it disturbing". He said that the interests of the donors required to be protected "almost at any cost".[1170] This attitude, as expressed the CMO of the time is instructive. On the issue of surrogate testing, it was clearly misguided, given the apparent prevalence of the virus in the donor population (estimated by Dr Gunson as 3%), the increasing evidence of the severity of the resultant disease and the pack of protection afforded by the system at that time.

3.95 However, the attitude is of more and even existential significance about the attitude of the medical community and government to the blood transfusion system. The need to have blood for transfusion in Scotland cannot be doubted. As

[1169] Penrose Inquiry transcript for 21/11/11 (day 66); 65 (12) to 66 (2) (Dr Macdonald); [PRSE0006066_0065 to 0066]
[1170] Penrose Inquiry transcript for 21/11/11 (day 66); 77 (8 to 20) (Dr Macdonald); [PRSE0006066_0077]

a principle, the sanctity of the blood supply was a principle which deserved significant respect, as did the donors who gave up freely of their time in pursuit of that principle. However, the total deference to the principle and the interests of the donors over those of the recipients of blood was unjustified and a root cause of the safety issues which the system encountered. The position expressed by Dr Macdonald is redolent of a system which worked on the presumption that any challenge to the sanctity of the donor should be resisted, however compelling. The system appears to have tolerated the production of the need for blood and the interests of the donor as trump cards which could justify any inaction on safety measures. Inaction was also convenient on effort and cost terms so it was likely not to cause difficult with ministers unless the results became press worthy but that would be tomorrow's problem. Transfusion doctors became the doctors of the donors not the recipients, the guardian of the sanctity principle. After all the recipients had their own doctors to look after them. The donors were volunteers and so any safety breaches could be explained away on the basis of the relative safety compared with other more commercial systems. This state of affairs gave rise to a system where action which would limit the risks was only ever expected to be taken where the advantage of doing so was completely irresistible based on conclusive proof. Even in circumstances where the like of Professor Cash and Dr McClelland (who whatever else one may say about them had devoted their lives to the transfusion system) said that the balance had been tipped in favour of action, the almost irrebuttable presumption against such action which might offend donors or result in less blood being collected. The presumption precluded the need to investigate more imaginative ways of maintaining the supply, looking after the donors whilst also pursuing safety. This was a system which had no real regard for the safety of the recipients as any priority.

3.96 As is touched upon above, the issue of the counselling of donors who had been found to have positive results on one or both of the surrogate tests appeared to have had a significant impact on the decision making process both from the point of view of (a) the efforts which would be needed to institute a system of counselling and (b) the problems associated with having to break the news of a positive test to a donor, who had only volunteered to give blood. These

considerations weighed too heavily in the decision not to introduce surrogate testing. As far as the practicality of introducing counselling was concerned, it is clear that staff within SNBTS had experience of counselling and had been trained in counselling techniques in connection with other testing programmes.[1171] Therefore, it does not seem that the introduction of counselling in connection with a positive surrogate test would have caused too many logistical problems. From the point of view of the requirement to break the news of a positive test to the donor, Dr Mitchell talked in his Penrose evidence about the importance of not turning donors into patients.[1172] This was entirely the wrong approach. It was based on an assumption that a donor would not want to know if there was something which might be wrong with him or her. It is based on a desire not to impose a practical burden on the health service in the short term (as such a patient may require some form of care) but ignores the fact that that short term care, which could only be offered if the patient were informed of the potential medical problem, could avoid longer term complications for the patient. Further, the premise appears to have been based on the assumption that the news of a raised ALT or the presence of anti-HBc would be bad news and would necessitate further medical treatment. Given that the presence of the latter in conjunction with a negative HBsAg would indicate that the individual had been in contact with hepatitis B but was not infected with the disease, this does not appear to be bad news. The risk of this indicting exposure to or infection with NANBH was a risk which was intolerable to a precautionary transfusion system but was not diagnostic of disease in the donor in these circumstances. It was argued by a number of the opponents of surrogate testing that it was too non-specific to be of use. It would seem illogical for those people to argue at the same time that a positive ALT test would necessarily indicate bad news on the basis that, as was pointed out, the test is a non-specific marker for the presence of NANB hepatitis. In any event, whatever the cause of the raised ALT level, informing the donor would enable them to do something about it if it was indicative of an underlying

---

[1171] PRSE0002641_0004 (25 June 1986) and the reference to the successful counselling training which had taken place in May 1986;

[1172] Penrose Inquiry transcript for 17/11/11 (day 65); 48 (21 to 22) (Dr Mitchell); [PRSE0006065_0048]

medical problem. Even if the donor were infected with NANB hepatitis, it would be more likely that early treatment would be effective than it would be likely to be if one waited potentially many years for the symptoms to manifest themselves. Internationally, it was thought in some quarters that ALT testing might represent a valuable contribution by the blood transfusion services to public health as donors would be identified and counselled.[1173] Further, it must be borne in mind that blood donors were also potential recipients of blood transfusions. It would be wrong, therefore, to have assumed that they would not want blood to be excluded from the system which might cause infection with NANB hepatitis.

3.97 The arguments of transfusionists and government officials that surrogate testing would have been too detrimental to the interests of donors represent a confusion between the interests of donors and their own interests. As outlined above, informing donors would not necessarily have been detrimental to their interests at all. It may have caused practical problems for the government and/or the transfusion doctors in having to devise and institute a system for this to be achieved and to break what might be perceived as "bad news" to donors but this should not have been an impediment to the introduction of surrogate testing.

3.98 The evidence given by certain of the transfusion doctors gave the impression that their principal concern was with the donors rather than the recipients of blood and blood products. We have referred to the evidence of Dr Mitchell at the Penrose Inquiry above as an example of this. It was the responsibility of the transfusion doctors to balance carefully the interests of the donors and the recipients of the blood equally in the discharge of their responsibilities. The government in Scotland also saw the interests of the donors as weighing more heavily in the exercise of their public health function. Equally, the proper discharge of that obligation required a careful balancing of the proper functioning of the highly valued national blood transfusion system (and hence of the interests of donors) and the prevention of the spread of disease through that system (and hence the interests of recipients).

[1173] PRSE0000571_0003 (Dr Habibi)

Practical considerations

3.99 The introduction of surrogate testing would have required there to be decisions made and action taken on the following practical matters:

(a) New equipment would have been required for the testing to be carried out on a national scale.

(b) Training would have been required for the staff responsible for carrying out the testing.

(c) A decision would have been required about ALT level which would result in a positive donation being excluded. The lower the ALT level the greater the likelihood of false positivity. The higher the ALT level, the greater the possibility of false negativity.

(d) The requirement for donor counselling, including training of staff required to carry this out.

(e) Donor recruitment measures would have been required for making up any loss of blood to the transfusion system which the introduction of surrogate testing would have created.

3.100 There is no evidence of clear advice on these matters having been communicated to SHHD by the SNBTS. This may be based of the application of the governmental presumption referred to above resulting in the idea never even getting off the ground, as Professor Cash had suggested to Dr Gunson (see above). It is clear that the analysis which SHHD required to carry out was a cost/benefit analysis involving "substantial patient safety/expenditure issues" as Mr Macniven phrased it in one communication.[1174] The application for funding was done via the normal PES application route. An initial application was made in the 1986 Public Expenditure

[1174] PRSE0003515 (2 October 1987)

Survey document for an initial sum of £810,000 for the year 1987/88.[1175] The application contained little detail about the reasoning for such testing to be introduced.[1176] Mr Murray pointed out in an internal note that they were not putting in a funding application for the year 87/88 for surrogate testing, despite the application.[1177] A further such application was made the following year with little if any additional information. [1178] These applications contained no detail about how the figures sought were arrived at and therefore, did not form a coherent basis upon which it could be assessed whether the sums sought represented reasonable estimates of actual likely expenditure or not. Given the delicate cost/benefit analysis which SHHD required to carry out, it is likely that the failure of SNBTS to communicate their position on these practical aspects (and the failure of SHHD to clarify in more detail the position in this regard) influenced the decision making process regarding the introduction of surrogate testing and the final decision that it should not be introduced.

3.101 Blood was being subjected to other testing in any event during the 1980s, including testing for HBsAg and anti-HTLV-III (the latter from October 1985). It seems reasonable to assume that the fact that donated blood required to undergo this testing anyway would have resulted in surrogate testing being able to be introduced relatively easily alongside the existing testing processes. It is interesting to note that the analysis of the likely effectiveness of surrogate testing done by various commentators in the Lancet between April and July 1987 (referred to in detail above) was done in terms of the cost effectiveness of the testing regime. It is clear that the statutory regime which was being implemented at around this time indicated that there required to be a move away from such a cost based approach towards a regime of strict liability based on the needs and interests of the consumer. None of the smaller studies referred to the impending legislation or to the cost effectiveness of having to care for those patients who were infected with PT NANBH as a result of the absence of surrogate testing or the

---

[1175] PRSE0001473_0004
[1176] PRSE0001473_0013
[1177] PRSE0002769 (21 October 1986)
[1178] PRSE0003941_0008 & 0013

cost of a breach of obligations under the Act. The requirements of the Act were, however, considered in the letter written by the Scottish transfusion directors published on 4 July 1987.

When surrogate testing for NANB hepatitis in Scotland could practically have been introduced

3.102 Dr McClelland gave evidence to the Penrose Inquiry to the effect that the SNBTS were experienced in rolling out testing programmes by the second half of the 1980s, having been responsible for instituting systems to test for both HBsAg and anti-HIV. These systems were up and running. Introducing a new testing system alongside would have been relatively straightforward. Dr McClelland was certainly of this view. He suggested that surrogate testing could have been started without a full counselling system in place and that it would have taken "a few months" to get all the practical matters in place, such as equipment and staff training.[1179] This suggests that the testing regime could have been rolled out fairly quickly after funding was secured and the wheels were set in motion. Infections could have been prevented quickly had the decision been taken other than it was.

The possible introduction of surrogate testing after the isolation and identification of the Hepatitis C virus

3.103 The announcement about the identification of the virus which caused NANBH was on 19 May 1988.[1180] This was merely the first step in progress towards a routine specific anti-HCV test being introduced in Scotland. Consideration of surrogate

[1179] Penrose Inquiry transcript for 16/11/11 (day 64); 20 (4) to 21 (5) (Dr McClelland); [PRSE0006064_0020 to 0021]
[1180] PRSE0004410 (19 May 1988) - Ezzell, 'Candidate Cause Identified of Non-A, Non-B Hepatitis', Nature; 19 May 1988

testing faded into the background after this time. Given the fact that it was clear from the isolation of the virus that it would take a considerable amount of time before routine anti-HCV testing could be implemented in Scotland, it was a mistake for the possible use of surrogate tests to have been disregarded. As was pointed out by the Lancet letter written by the SNBTS directors dated 4 July 1987, surrogate testing would be of value in preventing a certain number of cases of post transfusion hepatitis. Given that it took around 3 and a half years for routine anti-HCV testing to be introduced in Scotland, the arguments in favour of surrogate testing remained valid over that period. ALT testing appears to have been introduced in Switzerland after the isolation of the hepatitis C virus and in France an anti-HBc testing regime was added to the existing ALT testing regime on 3 October 1988. ALT testing was introduced in Queensland in April 1989. [1181] Further, there is evidence that certain countries continued to carry out surrogate testing even after anti-HCV testing was introduced.[1182]

3.104 Professor Leikola of Finland indicated in his evidence to the Penrose Inquiry that he did not think that surrogate testing required to be introduced, given that anti-HCV testing was available in 1990. However, anti-HCV testing was not introduced in Scotland until September 1991. Therefore, the period during which there was no testing at all in Scotland was significantly longer than his experience in Finland (which was one of the first countries to introduce anti-HCV screening, it being fully implemented in April 1990[1183]). Finland was not a member of the EEC at this time and so was not subject to the Council Directive which gave rise to the enactment of the Consumer Protection Act 1987 in the UK.

3.105 It is clear that the issue of surrogate testing did not disappear completely from the agenda after the isolation of the virus. However, even by the time of their meeting on 10 June 1987, the directors had noted the need for synchrony with England and Wales over surrogate testing.[1184] At the SNBTS directors meeting of 12 April 1988, it was confirmed that surrogate testing would not be introduced until it was UK

[1181] PRSE0003333_0068 (judgement of Burton J in A v National Blood authority)
[1182] PRSE0002888_0003
[1183] PRSE0003333_0086 (judgement of Burton J in A v National Blood authority)
[1184] PRSE0000633_0006

policy.[1185] By the time of the SNBTS directors meeting on 13 December 1988, Professor Cash announced that surrogate testing would not be introduced by the directors until SHHD and the DHSS supported and funded the project.[1186] In a memo from Mr David McIntosh to Dr McIntyre dated 12 March 1990, the issue of ALT testing was still being considered. The former was seeking from the latter a confirmation that ALT testing was not being introduced and that the SHHD and the DHSS still opposed it.[1187] By this time, it appears that the SNBTS directors (and Professor Cash in particular) had retreated from their previous policy of trying to persuade the SHHD into taking steps, like testing, to improve the safety of the blood supply, instead leaving matters entirely within the responsibility of the SHHD (see below).

3.106 It is clear from this correspondence that surrogate testing remained theoretically an option for some time after the virus was isolated. However, there appears to have been little, if any, real attempt to develop the current understanding of the likely benefits which such a testing regime would bring. As Dr McClelland pointed out at Penrose, the focus within SHHD was, for some time, on the multi-centre study which he considered to be an "irrelevance" as it focussed only on donors.[1188] A different attitude would have been of considerable benefit to the safety of blood and blood products.

Consumer Protection Act 1987

3.107 The legislation which was eventually enacted as the Consumer Protection Act 1987 forms, an important part of the backdrop to the consideration of surrogate testing. The issue of product liability in the context of blood transfusion was raised as early

---

[1185] PRSE0003650_0004
[1186] PRSE0001626_0004
[1187] PRSE0001626
[1188] Penrose Inquiry transcript for 16/11/11 (day 64); 27 (20) to 28 (7) (Dr McClelland); [PRSE0006064_0027 to 0028]

as November 1985 at a BTS meeting which was attended by Professor Cash[1189] and certainly one which was discussed within the SHHD and was regularly an agenda item at meetings of the SNBTS directors in the second half of the 1980s.[1190] It is clear from the material to which the Inquiry has access that Professor Cash raised certain concerns about the inclusion of blood and blood products in the definition of products to which the provisions of the legislation, in particular the strict liability provisions of the legislation, would apply. When he did so, it appears that his anxiety was considered by Dr Forrester to be a means by which he could obtain unlimited funds or seek to excuse even the most negligent or careless act.[1191] It is noteworthy that on the previous page of his note, Dr Forrester had dismissed the US introduction of surrogate testing as have been done understandably "to restrict their legal liabilities". Dr Forrester seems equally dismissive of Professor Cash's anxiety that similar legal liabilities may arise in Scotland. This was a completely misguided dismissal of the view expressed by Professor Cash on this issue.

3.108 The intended wording of the legislation was explained to the SHHD by the DTI in February 1987 in response to concerns raised by Professor Cash about the inclusion of blood and blood products within the statutory ambit.[1192] In particular, efforts were made to address the concerns which had been raised previously that there were viruses which were undetectable in blood and blood products and the concerns that liability would stem from that. It was pointed out that the Act would include a "state of the art" defence which would enable the transfusion services to escape liability if the virus causing infection were beyond the extent of contemporaneous medical knowledge. The government in Scotland failed to appreciate the nature of the argument being made by the SNBTS directors in the Lancet article concerning the impact of the legislation and the consequent need for action and also the comments made by Professor Cash surrounding the wording of the new legislation. When Professor Cash raised his initial objection to blood products being included within the definition of products to which the

---

[1189] PRSE0004796_0003
[1190] eg PRSE0004163_0005 (3 March 1987)
[1191] PRSE0000017_0002 (30 June 1986)
[1192] PRSE0001016 (9 February 1987)

legislation applied, he was effectively offering an expert opinion as to how the then current practices of the SNBTS might be interpreted if judged against the standards of the proposed legislation. He had made it clear that he thought that there would be no defence if blood and blood products were included within the statutory ambit.[1193] The state of the art defence would not apply as NANB hepatitis was known about. Therefore, whatever testing was available (including surrogate testing) required to be instituted in order to minimise the number of infections and the number of potential claimants under the strict liability provisions of the Act.

3.109 As was determined by Burton J in the case of A v The National Blood Authority & Ors[1194], the failure of the English BTS to introduce routine surrogate testing of blood donations there was a breach of the strict liability provisions of the Consumer Protection Act 1987 from the time at which those provisions came into force in March 1988. Given the fact that there is a clear history of the implications of the Act for the blood transfusion services in Scotland and also the specific warnings provided by Professor Cash about the potential exposure under the legislation based on the absence of a surrogate testing regime, it cannot be deemed reasonable on the part of the SHHD not to have implemented surrogate testing before March 1988 on the basis of its obligations under the legislation alone.

3.110 When asked at the Penrose Inquiry about the reasons for the recommendation to introduce surrogate testing in March 1987, Professor Cash indicated that part of the reason, at least, was the emergence of product liability and the whole question of patient safety.[1195] This would tend to imply that patient safety was a concept which had not always been at the forefront of thinking in the provision of blood and blood products. In our submission, patient safety should always have been the key consideration in decision making.

[1193] PRSE0002005

[1194] [2001] EWHC QB 446

[1195] Penrose Inquiry transcript for 29/11/11 (day 70); 175 (15 to 16) (Professor Cash); [PRSE0006070]

The consequences of the failure to introduce surrogate testing

3.111 The epidemiologist Dr Kate Soldan gave evidence to the Ross Committee to the effect that around 3,500 people were infected with hepatitis C as a result of blood transfusions in Scotland.[1196] The Inquiry's own expert statistical group has provided a different analysis of this number which has resulted on a total figure of 2740 being arrived at.[1197] On either view, surrogate testing would have been likely to have had a significant effect on the reduction of infection with hepatitis C.

3.112 Against this background, the Inquiry has access to a certain number of useful pieces of evidence in analysing the potential usefulness of surrogate testing in minimising the transmission of PT NANBH. Dr Dow gave evidence to the Penrose Inquiry that he thought that surrogate testing would have been likely to have reduced the incidence of PT NANBH in Scotland by 70%.[1198] He was an individual who was very familiar with this matter. Further, as was spoken to in evidence by Dr McClelland at Penrose[1199], the study done by Crawford & Ors on donors in the 6 months after the introduction of anti-HCV screening found that 0.088% of donors tested HCV positive and that 59% of those has ALT level above the upper limit of normal.[1200] Even amongst the 159 positive donors identified as anti-HCV positive amongst the 180,658 donors who were tested, that would have resulted in the west of Scotland alone in 94 positive donations potentially destined to infect a blood transfusion patient being excluded.

3.113 Dr McClelland was of the view in his Penrose evidence that this analysis needed to take consideration of a true prospective study of the value of surrogate testing, done between 1988 and 1992 in Canada.[1201] He was of the view that this was the best available evidence of the likely impact of surrogate testing on reducing the

---

[1196] Report of the Expert Group on Financial and other Support (March 2003) @ paragraph 4.8 - fgunsonhttp://www.scotland.gov.uk/Resource/Doc/47034/0024918.pdf

[1197] Expert group on statistics report @ page 29

[1198] Penrose Inquiry transcript for 22/11/11 (day 67); 34 (21) to 35 (4) (Dr Dow); [PRSE0006067_0034 to 0035]

[1199] Penrose Inquiry transcript for 16/11/11 (day 64); 33 (19) to 34 (3) (Dr McClelland); [PRSE0006064_0033 to 0034]

[1200] PRSE0000448

[1201] PRSE0004703

incidence of PT NANBH[1202] although he subsequently added a note of caution about its statistical significance.[1203] In this paper an analysis was done of the apparent transmission rates of PTH to patients based on whether the blood which they had received had been subjected to the two forms of surrogate tests (which were not routinely performed in Canada) or whether it was not surrogate tested. It is significant to note that these figures came from recipients of blood (a) before the introduction of routine anti-HCV screening and (b) which had been screened for anti-HIV. Therefore, all recipients benefitted from the incidental exclusion of donors who had hepatitis C and were excluded primarily to prevent HIV transmission. In the 397 patients who received non-tested blood, 8 were infected. In the 402 patients who received tested blood, only 2 were infected. Dr McClelland confirmed that the Canadian data (based on transfusion of blood collected and treated in a similar way to the contemporaneous Scottish blood collection system) would have resulted in a 70% reduction in the incidence of PT NANBH in Scotland. This is a safe assumption. Dr McClelland carried out certain calculations in a report submitted to the Penrose Inquiry on this subject based on a 50% reduction and the HCV prevalence rates amongst donors as reported in the Crawford paper, despite the fact that (a) the Canadian paper relied upon by him would have suggested a higher rate of reduction of PT NANBH due to surrogate testing (70%) and (b) the prevalence figures from the Crawford paper were lower than the rates used by other commentators, such as Professor Thomas who preferred a figure of around 0.5% based on the paper by Minor & Ors. This use of these alternative figures would result in (a) a higher rate of infection due to the higher prevalence and (b) a higher rate of prevention than the working hypothesis upon which Dr McClelland based his calculation.

Conclusions

[1202] Penrose Inquiry transcript for 16/11/11 (day 64); 40 (14 to 16) (Dr McClelland); [PRSE0006064_0040]
[1203] PRSE0002357

3.114 Routine surrogate testing should have been introduced in Scotland in 1987 as a result of information available about it in 1986 or at the latest in accordance with the recommendation made by the SNBTS directors in March 1987. Dr McClelland gave evidence to the Penrose Inquiry to the effect that the SNBTS had considerable experience in rolling out testing programmes by the second half of the 1980s and that he feels that once the decisions were taken, both types of surrogate testing could have been instituted "quite quickly". He also mentioned that the anti-core testing could have been instituted within days.[1204] This was the result of other similar testing systems already being in place. It would seem to be a reasonable inference from the evidence that the existence of other tests which would have made the introduction of surrogate testing practically easier is likely to have been a reason why it was, in fact, resisted by the government. It had been the attitude of Kenneth Clarke when minister of State when presented with the possibility of introducing anti-HIV testing in early 1985, the fact that money had already been spent on heat treatment meant that he was resistant to more being spent on screening.

3.115 In his evidence in the case of A v National Blood Authority & Ors, Dr Barbara expressed the view that around 10% of blood donors in England, under a similar voluntary donor regime to that in Scotland, should not have been accepted.[1205] As is submitted elsewhere, the evidence available to this Inquiry supports the contention that the system was in fact less safe in Scotland. This was blood being donated by the donors in a system which relied upon self-exclusion based on the assumption that donors were truthful. This faith was not appropriate and did not provide sufficient protection against the transmission of what was known to be a potentially lethal disease by 1986.

3.116 Dr McClelland gave evidence to the Penrose Inquiry to the effect that he took the view that if one could demonstrate that a particular safety measure would be of benefit, then it should be introduced. He contrasted the "Krever"" precautionary view based on patient safety with the health economic view, which was focussed

---

[1204] Penrose Inquiry transcript for 15/11/11 (day 63); 141 (2 to 12) (Dr McClelland); [PRSE0006063]
[1205] PRSE0003333_0062

primarily on cost.[1206] Patient safety was **the** factor in his consideration and his motivation as to try to get surrogate testing started by March 1987.[1207] At a meeting of the Council of Europe European Health Committee in May 1987, it was concluded that if blood were to have maximum safety then surrogate testing would have to be introduced.[1208] The legislative framework which was on the way at the time when surrogate testing was being considered imposed strict liability on producers of blood and blood products to ensure that these products were such that persons generally were entitled to expect.

3.117 In reality, there were two camps on this matter. There were those, like Dr McClelland, whose agenda was to "try and get testing started"[1209] in 1987. There were those who wanted to "buy time a bit".[1210] There was nothing else which could have been done at that time to minimise the risk of PT NANBH.[1211] Those in the latter category reached the view that delay was appropriate based on an incomplete understanding of the arguments and a preference for not making a difficult decision on an important patient safety measure. The delay which they advocated was unnecessary and harmful to patients.

4. Anti-HCV screening

General – overview

4.1 There was a delay between the discovery of the virus in 1988 and the introduction of routine screening for the antibodies to HCV in September 1991. As is explored elsewhere in this submission, the notional autonomy of Scotland the SNBTS along with its scientific capacity was limited by the political reality of being unable to

---

[1206] Penrose Inquiry transcript for 15/11/11 (day 63); 147 (13 to 23) (Dr McClelland); [PRSE0006063]
[1207] Penrose Inquiry transcript for 15/11/11 (day 63); 143 (23) to 144 (2) (Dr McClelland); [PRSE0006063]
[1208] PRSE0000571_0006
[1209] Penrose Inquiry transcript for 15/11/11 (day 63); 144 (2) (Dr McClelland); [PRSE0006063]
[1210] Penrose Inquiry transcript for 15/11/11 (day 63); 106 (18 to 19) (Dr McClelland); [PRSE0006063]
[1211] Penrose Inquiry transcript for 15/11/11 (day 63); 154 (2 to 8) (Dr McClelland); [PRSE0006063]

take steps which were clearly in the best interests of patients but which were not being implemented elsewhere. This is a theme which runs through the evidence heard by the Inquiry and manifested itself clearly in relation to the delay in introducing anti-HCV testing in Scotland. As with surrogate testing, this delay was determined by Burton J in A v National Blood Authority to have constituted a defect in the system of blood collection and use, as testing ought to have been implemented earlier. It ought to have been in the interests of patient safety. Infections occurred over this period which could and should have been prevented in this way. Despite the claims of the government and transfusion services that lessons were learned from the HIV crisis, similar manifestations of the pre-existing attitude to safety contributed to this unacceptable delay.

Decision making structure

4.2 The division of the responsibilities regarding decision making on blood transfusion matters in Scotland is dealt with above in connection with surrogate testing for NANBH. The basic decision-making structure remained the same in the period after the discovery of HCV in 1988. After that discovery, the introduction of anti-HCV testing became more of an imperative UK-wide and so there was a clearer national dimension to the decision-making process, as is explored below.

4.3 As far as the internal workings of the SHHD are concerned, the internal structure remained the same though different personnel had become involved in the important roles by 1988 than had been the case in the preceding years. As ever, the ministerial control changes periodically but the main decision-making role remained with civil servants anyway who only tended to involve the minister once a decision to proceed was all but fully formulated. The structure and the identity of the individuals involved within the SNBTS remained the same, other than the creation, for the first time, of the position of general manager, a post held from 1990 by Mr David McIntosh. His involvement in the decision-making process is discussed in more detail below.

Scientific developments

4.4 The virus which caused NANB hepatitis was isolated in the spring of 1988. The Chiron press release (dated May 1988) announcing the discovery of the hepatitis C virus made not only that announcement but also pointed out that a prototype assay which may lead to a screening test for the virus had already been developed.[1212] Details of the ELISA which had been developed to detect HCV antibodies were published in April 1989.[1213] As was the case with the introduction of anti-HTLV III testing following the isolation of HIV, the test which was proposed detected antibody to the virus. Following the isolation of the hepatitis C virus, huge international commercial efforts were made by pharmaceutical companies to develop an anti-HCV test which could be scaled up for mass production and sale on the international market. The FDA granted a licence to Ortho to export its anti-HCV ELISA in November 1989. It granted a domestic licence to Ortho for use of its anti-HCV ELISA in the USA in May 1990 and routine anti-HCV testing started there at that time, some 16 months before the UK.[1214] By that time, a confirmatory RIBA had also been developed to confirm the Ortho ELISA positives. In Scotland routine anti-HCV testing of blood donations was not introduced until September 1991. By the time Scotland introduced routine anti-HCV testing, many other countries in the world had instituted such a routine testing programme. Many considerations similar to those which were part of the debate post-1988 had been considered as part of the discussions around anti-HIV testing in 1985 and also NANBH surrogate testing throughout the decade. Thus, the concepts involved and the need for urgent action were not new. In addition, the no fault, strict liability culture which had been incorporated into the law under the provisions of the Consumer protection Act 1987 was designed to create a more end-user focussed approach

[1212] PRSE0004404
[1213] PRSE0001337_0004
[1214] Penrose Inquiry preliminary report, para 9.204

to these matters, which had been lacking in previous decision-making. This context rendered the dilatory approach to anti-HCV screening all the more culpable. As far as the responsibility for that delay is concerned, the decision making processes relating to this topic are analysed in more detail below. Professor Cash appears to have wanted to make it very clear from the outset that the decision making on anti-HCV testing was the responsibility of the SHHD and not the SNBTS.

4.5 As far as the structures within SNBTS were concerned, the Penrose Inquiry heard evidence that Professor Cash was able to impose his will that testing should be introduced in Scotland at the same time as in England (in accordance with assurances he had given to Dr Gunson).[1215] He wrote to Dr Gunson offering him the SNBTS directors' fullest support for the changes of the roll out date to 1 September 1991[1216] which, according to Mr McIntosh, it did not, in reality, have.[1217] The letter was not copied to the other directors. This was, in our submission, part of the "Cash dichotomy" described elsewhere in this submission and not an environment which was conducive to clearly reasoned decision making and proper advice being offered to government on matters of blood transfusion.

4.6 In his evidence to the Penrose Inquiry, Mr McIntosh described his efforts, at this time, to change the managerial structure in order to introduce what he considered as a necessary clarity to the dissemination of advice to ministers by those responsible for blood transfusion.[1218] In his view (as he had set out in correspondence at the time[1219]) the decision making processes were "shadowy" and required to be changed.[1220] He seemed to suggest that the involvement of advisory committees such as the ACVSB, which did not have any direct managerial responsibility, was not an efficient way of getting decisions made.[1221] He accepted in his evidence that it was the responsibility of the SNBTS to give advice to the government, to be clear about it and to be clear about the consequences of not

---

[1215] Penrose Inquiry transcript for 29/11/11 (day 70); 63 (9) to 64 (6) (Mr David McIntosh); [PRSE0006070]
[1216] PRSE0001382 (5 April 1991)
[1217] Penrose Inquiry transcript for 29/11/11 (day 70); 55 (12 to 24) (Mr David McIntosh); [PRSE0006070]
[1218] Penrose Inquiry transcript for 29/11/11 (day 70); 67 (4 to 14) (Mr David McIntosh); [PRSE0006070]
[1219] PRSE0000876 (30 August 1991)
[1220] Penrose Inquiry transcript for 29/11/11 (day 70); 81 (20) to 82 (5) (Mr David McIntosh); [PRSE0006070]
[1221] Penrose Inquiry transcript for 29/11/11 (day 70); 83 (16) to 84 (1) (Mr David McIntosh); [PRSE0006070]

accepting it which was not done in connection with the issue of anti-HCV testing.[1222] As is described in more detail below, this advisory responsibility seems to have been abdicated by the SNBTS by this time and exercised by the ACVSB in a wholly unsatisfactory manner. It should be noted that the role and function of expert advisory committees like SAGE have derived particular significance in more recent years since the COVID-19 pandemic. Consideration of the limitations of the advisory systems in the late 1980s and early 1990s still has resonance today.

Advisory committees

4.7 It is submitted above that the lack of clarity of expert advice had created delays and cost lives in connection with the HIV crisis, EAGA not having been formed until January 1985. In the years between 1985 and 1989, there was no government advisory committee with a clearly defined responsibility for providing government with advice, despite earlier viral disasters and the lack of advice having played a part in that. The Inquiry has heard evidence about the role of two particular advisory committees in the implementation of routine anti-HCV testing in the UK, including Scotland. These two committees were (a) the Advisory Committee on the Virological Safety of Blood ("ACVSB") and (b) The Blood Transfusion Service's Advisory Committee on Transfusion Transmitted Diseases ("ACTTD"). The remit of these committees was to advise the government on *inter alia* the introduction of routine testing for anti-HCV. The ACVSB was set up in April 1989, its first meeting having been on 4 April of that year. The Blood Transfusion Service's Advisory committee, the ACTTD first met on 24 February 1989. Further, other committees also existed to provide advice to the Departments of Health on issues which included testing blood donations to prevent the transmission of hepatitis C including (a) a BTS/NIBSC group whose remit it was to formulate guidelines for the

[1222] Penrose Inquiry transcript for 29/11/11 (day 70); 85 (3) to 86 (6) (Mr David McIntosh); [PRSE0006070]

standardisation of the safety of blood and blood products and (b) an Advisory Group on Hepatitis.

4.8 The existence of committees with overlapping remits and clear political tensions between them was not conducive to the government receiving clear and consistent advice on the issue of routine anti-HCV testing. In his Penrose evidence, Dr Perry accepted that over this crucial period, the boundaries between the ACVSB and the ACTTD became blurred.[1223] Dr McClelland gave evidence to the effect that it was essential that such clear, consistent advice was forthcoming for the government to take action on matters such as routine testing of blood.[1224] Whereas a multi-disciplinary approach to the solution of matters such as the prevention of the transmission of infectious diseases was appropriate in general terms, the existence of multiple committees with different priorities and agendas did not assist with clear and decisive action. The Penrose Inquiry heard evidence about the reality of the operation of these committees from Mr David McIntosh, who pointed out (a) that the ACTTD had been formed to enable the BTS to get some input from a practical standpoint into the matters with which the AVCSB had been charged[1225] and (b) that there was tension and conflict at this time.[1226] This could have been avoided by the creation of a single multi-disciplinary committee with a clear focus on the ultimate beneficiaries of testing, the recipients of blood.

4.9 The ACVSB was the main government advisory body. The make-up of the membership of the ACVSB also caused significant problems. This committee had the main policy formation role in this area. Dr Perry, who was a member, described at Penrose that committee as having the main policy role and the ACTTD as being more concerned in the implementation of that policy.[1227] The predominantly microbiological experience of the ACVSB, perhaps as far removed from clinical concerns of the end users of blood and blood products as one can imagine, seemed to focus throughout its meetings on the biological minutiae of developing

---

[1223] Penrose Inquiry transcript for 23/11/11 (day 68); 115 (22 to 23) (Dr Perry); [PRSE0006068_0115]
[1224] Penrose Inquiry transcript for 15/11/11 (day 63); 133 (9 to 10) (Dr McClelland); [PRSE0006063]
[1225] Penrose Inquiry transcript for 29/11/11 (day 70); 13 (9) to 14 (3) (Mr David McIntosh); [PRSE0006070]
[1226] Penrose Inquiry transcript for 29/11/11 (day 70); 14 (21) (Mr David McIntosh); [PRSE0006070]
[1227] Penrose Inquiry transcript for 23/11/11 (day 68); 8 (3 to 8) (Dr Perry); [PRSE0006068_0008]

understanding of the virus and not enough on the fact that there was no testing in place in the United Kingdom until September 1991 and therefore relatively little protection from the virus for the recipients of blood and some blood products. This was confirmed by Dr Perry in his evidence to Penrose who said that there was an emphasis in the committee on understanding the science rather than on saying that they must get a test introduced as soon as possible.[1228] It was noted at the SNBTS directors' meeting on 13 February 1990 that at the fifth meeting of the ACVSB (held on 17 January 1990), a decision to not to recommend the introduction of routine anti-HCV testing had been based on the advice of the microbiologists within the ACVSB.[1229] Dr Perry noted that the discussion on testing at the next ACVSB had been dominated by the academic virologists.[1230] He also noted that the decision to recommend further deferral was based, in part, on the perceived need to gain a "further understanding of the science".[1231] It is further worthy of note that the Penrose Inquiry heard evidence from Professor Lever who made it clear that **clinical** virology was only emerging as a discipline in the 1980s.[1232] This would appear to correlate with the suggestion from Dr Perry about the "academic" backgrounds of those who appear to have been wielding much influence on this extremely powerful committee at this crucial time. Dr Perry recognised that it might have been better to have an advisory committee with a greater public health perspective.[1233] Dr McClelland contrasted this committee with the Expert Advisory Group on AIDS ("EAGA") of which he was a member. He described that group as being one whose recommendations were well accepted in the professional community and identified the fact that it was well chaired, well-disciplined and was multi-disciplinary in nature (enabling it to look at things from a number of different angles) as reasons for that. He contrasted that with the relatively narrow membership and approach of the ACVSB.[1234]

[1228] Penrose Inquiry transcript for 23/11/11 (day 68); 33 (1 to 7) (Dr Perry); [PRSE0006068_0033]
[1229] PRSE0000205_0003
[1230] PRSE0004633_0002 (30 April 1990)
[1231] PRSE0004633_0003 (30 April 1990)
[1232] Penrose Inquiry transcript for 18/05/11 (day 27); 19 (1 to 7) (Professor Lever); [PRSE0006027_0019]
[1233] Penrose Inquiry transcript for 23/11/11 (day 68); 137 (24) (Dr Perry); [PRSE0006068_0137]
[1234] Penrose Inquiry transcript for 24/11/11 (day 69); 11 (12) to 12 (8) (Dr McClelland); [PRSE0006069_0011 to 0012]

4.10 Further, the ACVSB contained only two Scottish members (Dr Perry and Dr Mitchell) and was thus unrepresentative of the interests of Scottish patients. The minutes disclose little input from either of them. It is clear from the evidence available to the Inquiry that, as ever, there were different considerations regarding anti-HCV testing in Scotland than elsewhere in the UK. It was inevitable that this would be the result of having a wholly independent NHS and transfusion service in Scotland. The result of this was that the questions which arose would inevitably have a different context in Scotland based on scientific capacity, priorities, funding and hence attitudes. The creation of a main policy-making body in this area which excluded from its membership the national medical advisor, Professor Cash from its membership inevitably resulted in the problem that decisions would be made on policy lines to take which excluded the person with the main responsibility for providing advice on those lines in Scotland. Though Dr Perry (PFC director) and Dr Mitchell (director of a part of the Scottish BTS only) sat on the ACVSB, the main advisor, policy-making voice of Professor Cash was not heard. This made it inevitable that policy advice would be formulated in that committee without that voice being heard. This would (and did) inevitably lead to frustration and incongruity between the decision-making of that committee and the policy direction which Scottish advisors wanted to take. It led to a good deal of personal and professional frustration on the part of Professor Cash, which clearly manifested itself over this period.

4.11 Dr Perry confirmed that the main difference of opinion on the ACVSB was on the timing of the introduction of routine anti-HCV testing.[1235] He seemed to be trying, in his evidence, to refute the suggestion that there were widespread disagreements within the committee. Be that as it may, the question of timing was the key issue and the apparent disagreement on that is, in itself, if critical importance to a determination about the ability of that committee to function properly in the interests of patient safety.[1236]

[1235] Penrose Inquiry transcript for 23/11/11 (day 67); 66 (20) (Dr Perry); [PRSE0006068_0066]
[1236] Penrose Inquiry transcript for 23/11/11 (day 67); 66 (9 to 11) (Dr Perry); [PRSE0006068_0066]

4.12 This was not assisted by the confidential nature of the AVCSB proceedings. Ironically, this led to poor communication and co-ordination of an integrated strategy, with which patients had had to deal for many years. This was the result even though the confidentiality rule was not fully respected, as contemporaneous notes from Dr Perry to Professor Cash show.[1237] Indeed, Dr Perry described to the Penrose Inquiry that the requirement that things be kept on a confidential basis as being based on fears about public perception. He found that very frustrating and was not sure if important information got to people who needed it, such as within SNBTS.[1238] This demonstrates that the business of this committee (including its essential role in the issue of anti-HCV testing) was being handled according to an essentially political agenda and not with the best interests of patients at heart. It is also interesting to note that EAGA did not function on a confidential basis and Dr McClelland thought that its recommendations were well thought through and well accepted (see above).[1239]

4.13 The Penrose Inquiry heard evidence from David McIntosh that these committees had no locus in Scotland as far as he was concerned on the basis that they were advisory committees of the Westminster Department of Health.[1240] That this was his attitude to them is a cause for concern. There was a significant lack of clarity as regards the extent of the responsibility of these committees, in particular in Scotland. Mr McIntosh pointed out that the fact that anti-HCV testing was started in Newcastle by Dr Lloyd without the approval or authorisation of these committees demonstrated that the SNBTS certainly had the power to control matters relating to blood transfusion in Scotland.[1241] In Scotland, the SNBTS tried to make it clear that the introduction of anti-HCV testing was not their own decision to take. In doing this, it appears that the SNBTS had in fact ceded control of the anti-HCV testing issue to the Westminster committees, in particular the ACVSB. Despite this, Mr McIntosh made it clear that Scotland did indeed have the

---

[1237] PRSE0004633 (30 April 1990)
[1238] Penrose Inquiry transcript for 23/11/11 (day 68); 141 (22) to 143 (15) (Dr Perry); [PRSE0006068_0141 to 0143]
[1239] Penrose Inquiry transcript for 24/11/11 (day 69); 13 (7 to 9) (Dr McClelland); [PRSE0006069_0013]
[1240] Penrose Inquiry transcript for 29/11/11 (day 70); 14 (16) to 15 (2) (Mr David McIntosh); [PRSE0006070]
[1241] Penrose Inquiry transcript for 29/11/11 (day 70); 16 (7) to 17 (7) (Mr David McIntosh); [PRSE0006070]

power (in theory) to make decisions for itself and introduce anti-HCV testing if it thought that it was the best thing to do in the interests of the Scottish people.[1242] It was because of this that the then minister for health required to give his agreement to the very formation of the ACVSB, though this appears to have been notional and not a matter in which he had any real locus to object.[1243] This dysfunctional structural situation, whereby Scotland (and indeed other regions of the transfusion service in England and elsewhere) had the notional power to make decisions in the best interests of the patients under their care when at the same time political decisions in that area were being guided by the ACVSB over which the Scottish system and English regions had no control was a major cause of frustration, delay and ultimately infection. It was also the cause of further manifestations of what is described above as the Cash dichotomy. On the one hand, Professor Cash was horrified by the fact that he and Scotland had no voice on the main policy advisory body, that Scotland's ability and energy to move forward was thereby frustrated and made his views in that regard clear. On the other, he was cognisant of the dangers posed by a fragmentation of the transfusion system with certain parts moving before others, cohesion being lost and a potential postcode lottery being created. This is most evidenced in his vitriolic denouncement of Dr Lloyd in Newcastle. On the one hand he wanted Scotland to be able to move ahead. On the other he denounced someone else for doing just that. As ever, he reacted with characteristic vigour in support of both arguments. This was a paradoxical position to have taken and hardly provided the SNBTS with clear direction in the interests of patient safety. There appears to be little evidence of him seeking to reconcile these two opposite views, whether in his own mind or in practice. Whether did make efforts in that regard or not, there appears to have been little success in that regard. It seems that Professor Cash's overall approach was to give the impression of toeing the party line but actually at the same time taking steps to undermine it, perhaps in an effort to get the party line to advance. This is seen in various parts of the evidence which the Inquiry has

[1242] Penrose Inquiry transcript for 29/11/11 (day 70); 20 (16) to 21 (12) (Mr David McIntosh); [PRSE0006070]
[1243] PRSE0004464

seen and heard, for example in officially telling Dr Gillon not to undertaken an HCV Lookback in 1991 in accordance with the position of his political masters but enabling Dr Gillon to proceed with one as a "local study" instead.

4.14 In his evidence to Penrose, Dr Mitchell suggested that it was an advantage that the ACVSB had "people who were from the finance side of the departments and they had money to think about too".[1244] The title of this committee might have made one think that it was there to advise on the virological safety of blood and measures which might be adopted to increase it. Dr Mitchell's position creates the impression that its recommendations were tightly controlled by financial considerations. Clear evidence was available by 1982 and at the latest 1985 that the newly discovered HCV had for years been causative of a potentially lethal disease which was known to progress to a chronic state in a significant proportion of those infected. Indeed, by 1988, similar rates of progression amongst haemophiliac patients to the chronic phase of the disease as those found in the 1985 Sheffield study had been reported in a paper by Miller & Ors. This paper agreed that progressive liver disease was now a problem in haemophilia patients [1245] In addition, in his evidence at Penrose regarding the state of knowledge about the severity and prevalence of PT NANBH, Dr McClelland accepted the terms of the description of the standard textbook on blood transfusion by Professor Mollison (published January 1983, seventh edition)[1246], including the passage which stated that NANB hepatitis was deemed to be prevalent following transfusion.[1247] It should have been keenly appreciated by 1989 that a solution to the prevention of transfusion transmitted HCV infection was necessary for the State's moral and indeed legal obligations to be met. Financial limitations ought not to have been a priority. The role of these committees (in particular the ACVSB) and flaws in their decision-making processes were clearly the cause of unnecessary delay (as indicated by Dr McClelland in his Penrose evidence[1248]).

[1244] Penrose Inquiry transcript for 24/11/11 (day 69); 164 (9 to 15) (Dr Mitchell); [PRSE0006069_0164]
[1245] PRSE0004041_0004 (1988)
[1246] Penrose Inquiry transcript for 15/11/11 (day 63); 30 (8 to 14) (Dr McClelland); [PRSE0006063]
[1247] Penrose Inquiry transcript for 15/11/11 (day 63); 27 (6 to 7) (Dr McClelland); [PRSE0006063]
[1248] Penrose Inquiry transcript for 24/11/11 (day 69); 62 (21) to 63 (8) (Dr McClelland); [PRSE0006069_0062 to 0063]

The introduction of routine anti-HCV testing in Scotland

Regional variation in introduction

4.15 Before analysing the reasons for why the official start date was delayed until September 1991, the evidence of when testing actually started in Scotland needs to be understood. In Glasgow, anti-HCV testing commenced before it did elsewhere in Scotland. The reasons for this appear to be set out, to a certain extent, in a letter from Professor Cash to Dr Gunson dated 8 May 1991.[1249] The purpose of the letter appears to have been to set out a plan which Professor Cash had devised to deal with the "disaster" of testing having been commenced unilaterally in Newcastle by Dr Lloyd. In paragraph 5, Professor Cash suggested that a trial could be started with Newcastle (which was already using the Abbott kit) used as a test centre for that kit along with Glasgow which was the only Scottish centre which, at that time proposed to use that kit. Other centres could be found to test the Ortho kits.[1250] Thus, Glasgow, like Newcastle appears to have been able to start testing before the other centres in Scotland as it became part of this trial. It is noteworthy that in this letter Professor Cash recognised and rejected the possibility of other Scottish centres (Dundee and Inverness) being involved in the trial. By this point he should have been fighting to get testing started in Scotland by any means, including by proposing that other Scottish centres could be used in the trial. This may have provided a mechanism whereby he could have withdrawn Scotland from the ill-advised commitment to simultaneous introduction of testing, to which he had agreed with Dr Gunson (addressed in more detail below).

[1249] PRSE0001399
[1250] PRSE0001399_0002

4.16 The impetus to have testing started in Glasgow was not a concern for patient safety or principally a desire for further research feedback but, in the words of Dr Perry "to accommodate the activities of Newcastle".[1251] It seems that Professor Cash remained an official advocate for the policy though this did mean that using the Newcastle opportunity to undermine it further by arguing for an early introduction in Glasgow under the guise of it being a trial was beneath him. This demonstrates the extent to which the simultaneous start date had become an all-consuming political goal, despite the fact that by 1991 (as Dr Perry also indicated at Penrose) there were colleagues in Scotland who did not think that this was sustainable any longer.[1252] He also pointed that he that he thought that the national start date of 1 April 1991 had been removed from the ACVSB minutes of the meeting on 21 November 1990 [1253] and that the proceedings of the government's advisory committee, the ACVSB, were controlled by the circulation of papers in advance by the DoH[1254], the preparation of summaries of important material by DoH employees in advance[1255] and the apparently very heavy influence of the DoH members of the group over decision-making.[1256] It is hard to see how, in these circumstances, the advice being received by the department was truly independent at all. These factors indicate that the entire system which was responsible for the introduction of routine anti-HCV testing in the UK had become essentially a political exercise. These overriding political considerations resulted in a loss of focus on the safety benefits for patients which would have resulted from the swift and efficient introduction of routine anti-HCV testing.

4.17 Further still, it also appears from the evidence which the Inquiry has heard that routine anti-HCV testing may also have started in the south-east region of Scotland in July or August on the basis that, by this stage, Dr McClelland wanted to get

---

[1251] Penrose Inquiry transcript for 23/11/11 (day 68); 129 (10 to 16) (Dr Perry); [PRSE0006068_0129]
[1252] Penrose Inquiry transcript for 23/11/11 (day 68); 129 (17 to 23) (Dr Perry); [PRSE0006068_0129]
[1253] PRSE0000206_0002 and Penrose Inquiry transcript for 23/11/11 (day 68); 124 (18 to 25) (Dr Perry); [PRSE0006068_0124]
[1254] Penrose Inquiry transcript for 23/11/11 (day 68); 21 (3 to 11) (Dr Perry); [PRSE0006068_0021]
[1255] Penrose Inquiry transcript for 23/11/11 (day 68); 94 (16 to 19) (Dr Perry); [PRSE0006068_0094]
[1256] Penrose Inquiry transcript for 23/11/11 (day 68); 50 (10 to 14) (Dr Perry); [PRSE0006068_0050]

things started as quickly as he could.[1257] This suggests that the simultaneous start date, so important in the planning phase, had, in reality disappeared by this point. At long last, decisions were being taken which were focussed on patient safety, though only in certain places. In this context (where testing was in fact started earlier in some placed than others) it seems hard to understand why (a) simultaneous introduction (in practice abandoned at the end of the day) had been such a key element in the strategic thinking throughout and (b) Professor Cash saw fit to react as he did to the actions of Dr Lloyd.

4.18 As is discussed in greater detail below, the main plank of the simultaneous instruction policy was that any other approaches would result in a "postcode lottery" whereby the standard of care would be dependent on the place where one lived. It seems to be the case that the policy had been so dangerous that the transfusion directors simply took control themselves, apparently unconcerned by the postcode lottery argument. Dr Lloyd did so in Newcastle, Dr McClelland in the south-east of Scotland and Professor Cash facilitated an early introduction in practice in the west of Scotland, despite being an official advocate of the policy. As Dr David McIntosh pointed out in his evidence to the Inquiry, by this point there was no uniformity as certain places were already doing routine screening. He saw no reason why this plan could not simply have been followed everywhere in Scotland, with the result that all Scottish centres would have introduced testing at that time.[1258] The expert committee had been used to lend scientific credibility to a political policy, which was not in the interests of safety. As ever, the overriding concern appears to be legal, as non-uniform introduction would create the basis of a possible argument in areas where testing was not introduced sooner that it could and should have been. The overwhelming need to move together (a political policy) undermined safety. The policy stood in stark contrast to the system of regional and in the case of Scotland national autonomy which was designed

[1257] Penrose Inquiry transcript for 24/11/11 (day 69); 63 (16 to 23) (Dr McClelland); [PRSE0006069_0063]; see also IBI transcript for 28/01/22; 170 (Dr McClelland)
[1258] Penrose Inquiry transcript for 29/11/11 (day 70); 44 (6 to 9) (Mr David McIntosh); [PRSE0006070]

specifically to allow each region/ nation to develop its own strategies and capabilities in the interests of the patients.

Scotland's capacity to move earlier on anti-HCV testing

4.19 As is pointed out above, the context in this area is important. Scotland has already rolled out HBsAg and anti-HIV testing regimes and had given a lot of thought to the possibility of also screening for surrogate markers to NANBH. This had crested both experience, scientific knowledge, technical know-how and also certain facilities like laboratories and counselling which could be built upon in any new regime. At the Penrose Inquiry, Dr McClelland expressed the clear view that routine anti-HCV testing could have started in accordance with the start dates of other countries, even relatively small countries with poorer resources like Finland and the Netherlands.[1259] He gave evidence to the effect that SNBTS were, by the second half of the 1980s, experienced in rolling out testing programmes.[1260]

4.20 Thus, testing could have started in Scotland in 1990. Even later there were missed opportunities. Mr McIntosh pointed out at Penrose that everything was in place for anti-HCV testing to start in Scotland in April 1991.[1261] It was also suggested by Mr Tucker that funding could have been found whenever there was deemed to be a need for testing to be started. This is addressed in more detail below.[1262] The lengthy lead in period between the isolation of the virus and the availability of tests and the early consideration within SNBTS of how testing would work, combined with their experience of rolling out testing, would have meant that, had a case for earlier introduction been pushed more than it was, routine testing could have been introduced any time and, indeed, in the summer of 1990 in accordance with the timing achieved by many other countries worldwide.

[1259] Penrose Inquiry transcript for 24/11/11 (day 69); 6 (16 to 21) (Dr McClelland); [PRSE0006069_0006]
[1260] Penrose Inquiry transcript for 15/11/11 (day 63); 141 (2 to 12) (Dr McClelland); [PRSE0006063]
[1261] Penrose Inquiry transcript for 29/11/11 (day 70); 35 (11 to 13) (Mr David McIntosh); [PRSE0006070]
[1262] PRSE0002387_0006 (statement of SHHD assistant secretary Mr George Tucker)

4.21 This Inquiry has heard evidence from English Regional Transfusion Centre Directors who accepted that the introduction of anti-HCV testing could and should have started before it eventually did. Thus, even though it was the English transfusion service which was the source of the delay, it is clear that facilities did exist that would have permitted the testing to be introduced there before it was. Although some centres were 'dragging their feet', this led to a race to the bottom so that the slowest centre held all the others up. In light of the agreement to wait until all centres were willing and ready to commence testing, there was no impetus to speed matters up.

Cognisance taken of the screening regimes in other countries

4.22 Unlike the position as regards surrogate testing, there appeared to be relatively little debate as to whether the more specific anti-HCV testing should be introduced in Scotland (or indeed UK wide at all). Whereas the local applicability of data collected abroad as to prevalence of NANB hepatitis, the incidence of PT NANBH and the likely usefulness of testing for surrogate markers as a means of preventing PT NANBH were (to a point) legitimate concerns in connection with surrogate testing, relatively few such concerns could be deemed to have justified any delay in the introduction if anti-HCV testing. In principle, anti-HCV testing was a done deal.

4.23 The USA introduced routine anti-HCV screening on 2 May 1990. It was noted that testing was coming or had arrived in Italy, France, Belgium and Luxembourg at the sixth meeting of the ACVSB on 24 April 1990.[1263] It is interesting to note that this fact, though recorded, seems to play little part in the argument about introducing testing in the UK. For a transfusion service whose comparative international reputation was worn as a badge of pride, comparisons in relation to safety appeared to cause little change of attitude amongst key advisors. The observation

[1263] PRSE0002519_0003 (24 April 1990)

appears to be trumped in the reasoning by scientific concerns mentioned in the very next paragraph.[1264] Routine anti-HCV testing was introduced in many other countries before it was in the UK (including Scotland) as recorded in the opinion of Burton J in the case of A v National Blood Authority.[1265]

4.24 The views of those who were responsible for blood transfusion around the world were clearly available to those in the United Kingdom who were charged with decision making about routine anti-HCV testing. In a note of the Council of Europe Committee of Experts on Blood Transfusion in May 1990 (circulated by Professor Cash) it was the view of the meeting that the introduction of routine anti-HCV testing would increase the safety of blood, though it was realised that not all positive donors would be infective.[1266] Professor Leikola gave details of the system which was being adopted in Finland, which involved the deferral of patients who had tested positive with "two bands" in the Ortho RIBA test on the basis that a study which had been undertaken on cardiac patents (published in the Lancet on 21 April 1990[1267]) and which indicated that such a result correlated well with infectivity. This meant that 0.1% of donors were being deferred whereas 0.6% and 0.5% were testing positive on the ELISA test.[1268] This approach seems to balance the desire not to lose too many false positive donors but also the need to do something in a system which had no surrogate testing (like in Scotland) to prevent PT NANBH by testing.

4.25 In a letter to Dr Gunson dated 28 July 1989, Professor Cash had indicated that it would be a "wonderful idea" if the introduction of anti-HCV testing could be co-ordinated with other countries in Europe.[1269] As the tone of this letter suggests, that comment appears to have been made more in hope than in expectation. Relatively little account appears to have been taken of the fact that anti-HCV testing was being introduced throughout the world ahead of its introduction in the UK or indeed the scientific basis upon which its introduction there was deemed

---

[1264] PRSE0002519_0003 (24 April 1990)
[1265] PRSE0003333_0086 & 0087
[1266] PRSE0000522 (26 June 1990) and PRSE0003672_0004 (notes from May 1990)
[1267] PRSE0003455
[1268] PRSE0003672
[1269] PRSE0004845

justified. As noted above, the committees advising the government on these matters (in particular the ACVSB) appear to have prioritised technical matters and scientific detail over the general safety of the recipients of blood. The failure to take account of the fact of and the reasons for the introduction of routine ant-HCV screening around the world was a mistake.

Synchronisation with anti-HCV testing in the rest of the UK

4.26 Scotland enjoyed administrative devolution over the period with which this topic is concerned. It had a separate health service and a separate blood transfusion system. Health matters in Scotland at a governmental level were dealt with by a department within the Scottish Office. Professor Cash gave evidence to the Penrose Inquiry to the effect that, in early 1985, he was very keen that Scotland institute its own testing system on US anti-HIV kits with a view to Scotland "going it alone" in introducing an HIV testing programme independent of England. He had been prevented from doing so by Dr McIntyre within the SHHD.[1270] Dr McClelland indicated that he had no compunction about recommending NANBH surrogate testing even if the English transfusion directors had no plans to do the same.[1271] The directors had recommended surrogate testing be implemented in Scotland at their meeting on 3 March 1987 with no apparent regard for the English failure to take any real steps in that direction.

4.27 When it came to the introduction of anti-HCV testing, it appears clear that a commitment was made at an early stage to the introduction being synchronised with the rest of the UK. At the government level, the Department of Health "took the lead" on this issue which meant that they made the decisions and the SHHD followed. On the ACVSB, Dr Perry indicated that he had considered it to be "a given" that testing would be introduced throughout the UK at the same time.[1272]

[1270] Penrose Inquiry transcript for 27/09/11 (day 48); 83 (7) to 85 (10) (Professor Cash); [PRSE0006048_0083 to 0085]
[1271] Penrose Inquiry transcript for 15/11/11 (day 63); 132 (6 to 11) (Dr McClelland); [PRSE0006063]
[1272] Penrose Inquiry transcript for 23/11/11 (day 68); 36 (17 to 23) (Dr Perry); [PRSE0006068_0036]

He had the impression that the decision making on this issue all took place within the DoH and was not aware of any involvement on the part of the SHHD in the debate.[1273] Its involvement appeared to be as an observer.[1274]

4.28 Even within SNBTS, it appears clear that Professor Cash had agreed with Dr Gunson at an early stage that Scotland would not introduce routine anti-HCV testing before England. The evidence available to the Inquiry suggests that, by this point in time, Professor Cash was very keen to emphasise that he considered it to be the responsibility of SHHD (and not SNBTS) to make a decision about the introduction of routine anti-HCV testing in Scotland.[1275] His resignation appears to indicate that based on past suggestions that Scotland "go it alone" he had washed his hands of the prospect of anti-HCV testing being done that way. Further, he made it clear in a letter to Dr Gunson on 28 July 1989 that Scotland would not introduce anti-HCV testing unilaterally unless he was instructed to do so by the SHHD and that he had informed Ortho that contracts for the supply of kits to Scotland could not be discussed until he had authorisation from the SHHD to do so.[1276] It was hardly likely, given the fact that the SHHD would not be keen to introduce testing unless and until it had been sanctioned by the Department of Health for England and Wales (which Professor Cash knew well) and/ or recommended by the BTS of which he was the head that such an instruction would be forthcoming. It seems that by this point in time Professor Cash had lost the stomach for the fight and thus had abandoned his advisory role.

4.29 Dr Macdonald gave evidence to the Penrose Inquiry to the effect that the DHHS would have taken the lead on major matters and SHHD would have been required to fit its policy around the DHSS view.[1277] This left Scottish patients without an independent voice to support the case for an urgent introduction of testing to protect their safety, even when this happened in other countries. It left Scottish patients exposed to any problems which might arise which were peculiarly English

---

[1273] Penrose Inquiry transcript for 23/11/11 (day 68); 38 (11 to 25) (Dr Perry); [PRSE0006068_0038]
[1274] Penrose Inquiry transcript for 23/11/11 (day 68); 39 (2 to 8) (Dr Perry); [PRSE0006068_0039]
[1275] See letter from Professor Cash to Dr McIntyre dated 28 July 1989 (SNB.008.2603); [PRSE0002499]
[1276] PRSE0004845
[1277] Penrose Inquiry transcript for 21/11/11 (day 66); 80 (22 to 25) (Dr Macdonald); [PRSE0006066_0080]

in nature and which should not have affected the introduction of testing north of the border. The administrative burden of rolling out a regime across the autonomous regions of England was again dictating the safety of Scottish blood transfusion patients. Whereas Professor Cash and the SNBTS had tried in the past to argue the case for moving quickly on safety measures like testing for anti-HTLV III and surrogate testing, by this point they appear to have given up any such efforts. The position of the government in Scotland that the introduction of routine anti-HCV testing in Scotland would be simultaneous with the introduction in England and Wales was confirmed by Dr McIntyre in his reply to Professor Cash's request for confirmation of the position.[1278] It remained the position that the intention was for a synchronised introduction of routine testing on 22 January 1991 when Dr Gunson wrote to the regional transfusion directors seeking feedback as to when they would be able to start routine testing.[1279] On 15 February 1991, it was declared that 1 July 1991 would be the date for the introduction of routine anti-HCV testing.[1280]

4.30 Whilst this desire for a joint approach and simultaneous introduction may have been considered to have certain advantages, the commitment appeared to be total and it should not have been. It appears clear that on certain important issues progress was made by the Scottish directors which was hampered by a relative lack of progress in England. At the SNBTS directors' meeting on 13 February 1990, the Scottish directors had agreed that counselling would be offered to all positive donors throughout Scotland with the possibility of referral to specialist care. At the same time, the English directors were reported to be split 50/50 on the issue. By this time, Professor Cash had clearly written to the SHHD about the issue of counselling. It was, however, pointed out by Mr Watt that he did not think it appropriate for a response to be expected until the ACVSB had given advice to the DoH on the issue.[1281]

[1278] PRSE0001692 (2 August 1989)
[1279] PRSE0001628
[1280] PRSE0002748_0005
[1281] PRSE0000205_0003

4.31 In England and Wales, Dr Gunson wrote to all RTDs on 22 January 1991 confirming, for the first time, that the DoH had agreed that routine testing for anti-HCV could be "put into operation", and advising the RTDs that he had been "asked to try to ensure that testing starts simultaneously in RTCs in England and Wales and that it is co-ordinated with commencement of testing in Scotland[1282]". He asked RTDs for the 'earliest date' they could commence the testing, whilst noting that financial arrangements were yet to be concluded.

4.32 In a letter written by Professor Cash at the time about the seventh meeting of the ACTTD on 25 May 1991, he pointed out that the delay in England was caused predominantly by financial issues.[1283] A decision had been taken at that meeting that the start date would be delayed until 1 September 1991 due to the desire to evaluate the now available second generation kits.[1284] It had been predictable for some time that these financial issues may arise, on the basis that it had been pointed out at an early stage by the Chairman of the ACVSB that funding for the introduction of anti-HCV testing would require to be found from existing NHS budgets.[1285] Professor Cash made it quite clear in his evidence that the delay between April 1991 and September 1991, allegedly for the evaluation of second generation kits, was actually (to his knowledge at the time) due to problems with funding routine testing in England.[1286] He proposed that this was also known about by the SHHD.[1287] This had the result of the introduction of routine testing in Scotland being delayed as a result of funding issues specific to England, a position which was clearly not in the interests of Scottish patients.

4.33 Correspondence[1288] from Professor Contreras to the public health director of the North West Thames Regional Health Authority on 12 February 1991 demonstrates this issue had been ongoing for some time. She later advised Dr Gunson on 22

[1282] NHBT0000076_006
[1283] PRSE0003692 (letter from Professor Cash to Mr McIntosh dated 27 March 1991)
[1284] PRSE0001223_0002
[1285] PRSE0001477_0004 (fifth meeting of the ACVSB on 17 January 1990)
[1286] Penrose Inquiry transcript for 01/12/11 (day 72); 136 (21) to 137 (6) (Professor Cash); [PRSE0006072_0136 to 0137]
[1287] Penrose Inquiry transcript for 01/12/11 (day 72); 169 (23) to 170 () (Professor Cash); [PRSE0006072_0169 to 0170]
[1288] NHBT0000073_047

February 1991 that "if forced, we would be able to start on 1 July 1991 if the money was available[1289]", and that if the money was not forthcoming, the screening would only be introduced at a later date.

4.34 That Professor Cash was persuaded against his will to go along with the decision to defer testing to September 1991[1290] against this background was a failure in his responsibility to Scottish patients, though it was mitigated (as is indicated above) by means being found to start testing in the west and the south-east early, though unofficially. Promoting the safety of patients had become something to be ashamed of, it would appear.

4.35 An apparently obsessive desire to ensure synchronisation with England, at least at official level, no matter what the reason for any ongoing delay developed. This is demonstrated, in our submission, by Professor Cash's overreaction to the decision of Dr Lloyd in Newcastle to introduce anti-HCV testing there unilaterally before the official start date in April 1991. Further, this episode contradicts any suggestion that Professor Cash even considered making a recommendation to the SHHD that Scotland could do something similar at that time which he claimed was a necessary pre-requisite to testing starting routinely in Scotland. This is also contradicted by the contemporaneous correspondence which makes it clear that Professor Cash understood this to be a decision for SHHD to take alone (referred to above). This obsession with synchrony overtook what should have been the overriding concern of the SNBTS and the SHHD - maximising the safety of blood for Scottish patients. That Professor Cash was able to force this official policy onto the other directors, as was suggested in his Penrose evidence by David McIntosh[1291], was not in the interests of those patients. As he stated, there may have been advantages of a co-ordinated approach but this did not mean that it required to be simultaneous.[1292]

Concerns about (a) confirmatory testing and the (a) accuracy and usability of test kits

---

[1289] NHBT0000191_089 (emphasis in original)
[1290] Penrose Inquiry transcript for 01/12/11 (day 72); 175 (14 to 18) (Professor Cash); [PRSE0006072_0175]
[1291] Penrose Inquiry transcript for 29/11/11 (day 70); 61 (9 to 17) (Mr David McIntosh); [PRSE0006070]
[1292] Penrose Inquiry transcript for 29/11/11 (day 70); 89 (22 to 23) (Mr David McIntosh); [PRSE0006070]

Evaluation of the test kits

4.36 It is clear from the evidence available to the Inquiry that one of the major reasons for the delay in the introduction of routine anti-HCV testing of blood in the UK was concern about the sensitivity and specificity of the available ELISA tests. This led to extensive evaluation of test kits. It appears that this process started early after the isolation of the virus and the release of details of the Chiron prototype ELISA. SNBTS had written to Chiron about the timescale for the availability of tests and had received a reply by July 1988 which indicated that a marketable test might be available by the end of 1989.[1293] The Ortho test (being developed in association with Chiron) was discussed at the SNBTS directors meeting on 27 September 1988.[1294]

4.37 By the time of the first meeting of the ACTTD in February 1989, Dr Gunson had been approached by Ortho about the possibility of trials of the Ortho anti-HCV ELISA in the UK.[1295] Dr McClelland made certain comment about the observation that the Ortho ELISA only had a 50% sensitivity rate made at the meeting of the ACVSB on 22 May 1989. He pointed out to the Penrose Inquiry that he recalled that the actual position at that time was that it was nearer 70 - 80%.[1296] By July 1989, Professor Cash had arranged access to Ortho ELISA test kits for evaluation, an initial evaluation having been completed by staff in the west of Scotland by July 1989.[1297] A report on the Ortho ELISA by the west of Scotland group was available by 5 October 1989.[1298] In this limited study, it was concluded that the Ortho ELISA had an acceptable specificity.[1299] Thus, it was confirmed by Professor Cash in his Penrose evidence that the study showed that the Ortho ELISA was "fantastic and

---

[1293] Penrose Inquiry preliminary report, para 9.93
[1294] PRSE0003565
[1295] PRSE0003507_0004 (24 February 1989)
[1296] Penrose Inquiry transcript for 24/11/11 (day 69); 6 (16 to 21) (Dr McClelland); [PRSE0006069_0006]
[1297] Penrose Inquiry preliminary report, para 9.123
[1298] PRSE0002044
[1299] PRSE0002044_0007

it didn't get much better than that over the years". He described the lengthy evaluation process as "this chase for the holy grail of the perfect test kit - it's an illusion".[1300]

4.38 It appears to be quite clear that concerns about the kits leading to endless further evaluation were unfounded from this point on as far as Scotland and the interests of Scottish patients were concerned. Dr Perry gave evidence to Penrose to the effect that local evaluation was necessary as there required to be consideration of the possibility of there being a difference in local epidemiology.[1301] However, he accepted that that would be deemed to be overkill now and, in any event, such approach that did not then justify an unlimited delay, especially against a background that there was no testing at all and precious little in the donor selection procedures to prevent transmission of a lethal disease. Further, in Scotland it appears that such local evaluation had been undertaken to the satisfaction of the directors at this early stage.

4.39 Professor Cash had advised the SNBTS directors on 3 August 1989 that he thought that it was only a matter of time before testing would be introduced and that it would be likely to happen sometime after April 1990.[1302] There is no suggestion in this statement that such a timescale would cause any problem and the letter seems to suggest that various mechanisms were being out in place to prepare for introduction. He once again reiterated the fact that, as far as he was concerned, this was a UK decision to be made by the UK health departments. There is an air of the science meeting the politics in this statement – things were ready to go but (based on experience) he knew they would not proceed. By 24 August 1989, Dr McClelland had felt the need to write to his staff alerting them to the possibility of the introduction of anti-HCV testing and emphasising its importance.[1303]

4.40 By the time of the Rome meeting in September 1989 (as reported to the fourth meeting of the ACVSB on 30 October 1989) it appears to have had been realised

---

[1300] Penrose Inquiry transcript for 01/12/11 (day 72); 136 (21) to 137 (9) (Professor Cash); [PRSE0006072_0136 to 0137]
[1301] Penrose Inquiry transcript for 23/11/11 (day 68); 119 (7 to 14) (Dr Perry); [PRSE0006068_0119]
[1302] PRSE0001438
[1303] PRSE0003371 and PRSE0002015

internationally of the then available Chiron test (a) that the tests which had been done showed consistent results and (b) that the presence of antibody did mean that the person being tested was positive for NANBH (the test was detecting a marker of NANBH infection). The concern remained the lack of a confirmatory test. [1304] Dr Perry characterised the recommendations in that report as being the basis upon which Dr Gunson was effectively proposing that it should be recommended that the test should be introduced and approved in principle.[1305] Despite Dr Gunson's influential view, it was noted that a more cautious approach was adopted at the meeting than had been expressed by Dr Gunson in his paper to the point that it was not even willing at this stage to recommend anti-HCV testing be adopted in principle.[1306]

4.41 By the time of the fifth meeting of the ACVSB in January 1990, material was available from English evaluations of the test kits which were available which had been carried out at 3 centres (NE Thames, Trent and West Midlands) at each of which 5,000 of the tests had been evaluated in December 1989. [1307] This data demonstrates that the tests were deemed to be easy to perform and that there were no other significant reports from these studies at that time. By the time of the fifth meeting of the ACVSB, Dr Perry recorded that the overriding concern continued to be with false positivity.[1308]

4.42 In his evidence to this Inquiry, Professor Barbara noted that, although he had not considered it at the time, if those donors who tested positive for anti-HCV using the first generation ELISA test had elevated ALTs, "you were approaching the predictive value of real infectivity"[1309]. In other words, there were other methods of seeking to ensure that the tests were sufficiently accurate that were easily available to those involved in the collection of blood, but do not appear to even have been considered at the time.

[1304] NHBT0000041_061_0005
[1305] Penrose Inquiry transcript for 23/11/11 (day 68); 47 (21) to 48 (9) (Dr Perry); [PRSE0006068_0047 to 0048]
[1306] Penrose Inquiry transcript for 23/11/11 (day 68); 49 (15) to 51 (9) (Dr Perry); [PRSE0006068_0049 to 0051]
[1307] PRSE0001414_0015 - 0016
[1308] PRSE0001414_0010
[1309] IBI transcript for 26/01/22: 93 to 94 (Professor John Barbara)

4.43 What requires to be borne in mind is that throughout the period of test evaluation, there was no testing regime in place at all in Scotland to protect the recipients of blood from infection with hepatitis C. It is true to say that in other countries evaluation of the test kits went on as well. In some of them (such as the USA, Germany, France and Italy) such evaluation took place against the background of there being a system of routine surrogate testing which afforded some protection against transmission of PT NANBH. In any event, even with this protection in the background, these countries made the decision to introduce routine anti-HCV testing considerably before it was achieved in Scotland. No doubt these countries faced similar concerns as those faced in the UK about the accuracy of the tests and the possible unnecessary loss of blood to their transfusion systems through false positivity. By the time Dr Mitchell attended the meeting in Rome in September 1989 to discuss the Ortho ELISA, it was being reported that 10% of persons transfused developed NANB hepatitis and that 90% of hepatitis cases were NANB hepatitis. 50% of those infected were thought to progress to chronic phase of the disease.[1310] Those countries, however, appear to have realised the severity of the disease and the need to afford some form of protection against it by way of a specific test.

4.44 By 21 February 1990, Dr Boulton was expressing the clear view to Professor Cash that they should be getting on with routine introduction due to the known chance of infection from blood transfusion and the possibility of severe consequences such as hepatocellular carcinoma.[1311] In March 1990 an article by van der Poel & Ors made a strong recommendation that anti-HCV testing be introduced.[1312]

4.45 By the time of the ACVSB meeting in April 1990 Dr Perry noted that both he and Dr Gunson were of the view that the material available from the US which suggested that the introduction of routine anti-HCV testing would result in a 50% reduction in the incidence of PT NANBH.[1313] Dr Perry indicated in his evidence that by the time of the April 1990 meeting he was of the view that the epidemiological

---

[1310] PRSE0002888_0003
[1311] PRSE0001562
[1312] PRSE0000077 (10 March 1990)
[1313] Dr Gunson appeared to express his view on the US data at the meeting - PRSE0002519_0004 (24 April 1990)

data (relating to the number of infections which would be likely to be prevented by the introduction of routine anti-HCV testing) and the test kit performance data indicated that the time had come for there to be a recommendation that routine testing should be introduced.[1314] He confirmed that this has led to him to "slightly" breach the confidentiality rules of the ACVSB[1315] and communicate his position to Professor Cash, given that the data he had seen by this point suggested that the current testing had the capability to reduce PT NANBH by almost 60%.[1316] Therefore, he and Harold Gunson had advocated a more positive approach.[1317]

4.46 In the meeting notes of the April 1990 meeting themselves, Professor Zuckermann had referred to the US TTV study which had concluded that 77% of those who tested positive for anti-HCV were indeed infected.[1318] The meeting (and it would appear the decision making) was dominated by the academic virologists on the committee.[1319] Dr Gunson had been impressed with the Ortho ELISA from the time of the Ortho conference in Rome in September 1989 and had reported back favourably and reported back favourably to the ACVSB and the ACTTD at that time.[1320] It is interesting to note that Dr Perry described the majority of the committee, who were in favour of deferral of the introduction of testing, as having adopted a "more cautious approach".[1321] As far as patient safety was concerned, we would argue that they were, in fact, adopting a significantly less cautious approach than those, like Dr Perry, who favoured introduction of routine testing based on the available US data at that time. This is reminiscent of the view taken by Dr McClelland in connection with surrogate testing, which had reached the view that the US data was sufficiently persuasive in the absence of any testing regime to protect against transmission of NANBH to recommend that type of testing regime be introduced in March 1987. It is also resonant of the “conclusive proof” approach taken by the government to the risk of AIDS from blood and blood

---

[1314] Penrose Inquiry transcript for 23/11/11 (day 68); 93 (25) to 94 (7) (Dr Perry); [PRSE0006068_0093 to 0094]
[1315] Penrose Inquiry transcript for 23/11/11 (day 68); 100 (25) to 101 (1) (Dr Perry); [PRSE0006068_0100 to 0101]
[1316] Penrose Inquiry transcript for 23/11/11 (day 68); 101 (9 to 11) (Dr Perry); [PRSE0006068_0101]
[1317] Penrose Inquiry transcript for 23/11/11 (day 68); 102 (4 to 7) (Dr Perry); [PRSE0006068_0102]
[1318] PRSE0002519_0003 (24 April 1990)
[1319] PRSE0004633_0003 (30 April 1990)
[1320] PRSE0003333_0010 @ para 11 (judgement of Burton J in A v National Blood Authority)
[1321] PRSE0004633_0003 (30 April 1990)

products and the dilatory approach to the instruction of anti-HIV testing. Once again, patient safety appears to ha been sacrificed to the need for more conclusive evidence of the likely impact of testing in disease prevention before a positive move will be made. It is also very interesting to note that Dr Gunson was in favour of introduction at this stage, given that it was he who later persuaded Professor Cash to accept delaying routine testing to a date 17 months after this point in time.

4.47 In his evidence to the Penrose Inquiry, Mr David McIntosh drew attention to the delays caused by the lack of the proper public health questions being asked at a policy level, by which he must have meant within SHHD. He was of the view that leaving the decision making to "microbiologists talking about whether the test is perfect" was not an answer to the "issue of a public service... to do something that will improve patient care in Scotland".[1322] He was of the view that the desire expressed on committees such as the ACVSB about the need to gather data about the tests could have been satisfied by data being gathered after full implementation of testing.[1323] The lack of urgency to introduce some form of protection by way of testing to prevent infection was not acceptable and certainly not in the best interests of patients. Indeed, given the onward transmission to other patients from those infected with a. potentially fatal but often clinically silent disease, this approach created a major public health risk.

FDA approval

4.48 The Inquiry has heard evidence that the advisory committees (in particular the influential ACVSB) were keen to await FDA approval of US test kits before recommending the routine introduction of testing in the UK. Although the approval of the FDA does not seem objectionable in itself as a pre-requisite to the recommendation of testing in the UK (such approval having come domestically in the US in May 1990), one requires to bear in mind that there were also UK based

[1322] Penrose Inquiry transcript for 29/11/11 (day 70); 31 (14 to 23) (Mr David McIntosh); [PRSE0006070]
[1323] Penrose Inquiry transcript for 29/11/11 (day 70); 47 (4 to 17) (Mr David McIntosh); [PRSE0006070]

evaluations of the kits going on (including the very early and successful Scottish evaluation). In the US routine testing was able to start as soon as the FDA approval was granted. Further, the export licence was granted by the FDA in November 1989, 6 months before the domestic licence was granted.[1324] The UK should have been in a position to move quickly following the granting of FDA approval with the result that routine anti-HCV testing could be brought in line with such a move being taken in the US. As Professor Zuckermann pointed out in a letter to Dr Rejman of the DHSS in around December 1989, the introduction of testing "could not be delayed much beyond FDA approval".[1325] FDA approval had of course been of little influence on decision-making as regards the anti-HIV test kits, when the main difference appears to have been the availability of a possible domestically produced alternative.

Comparative evaluation of the Ortho and Abbott kits

4.49 Further, it was decided by the ACVSB that they would recommend the introduction of routine ant-HCV testing in the UK subject to the ongoing evaluation of the Ortho and Abbot first generation kits which was about to be undertaken in 3 nominated centres.[1326] This decision was taken at the seventh meeting of the group on 2 July 1990. Testing eventually showed that there was not much to choose between the two tests and that it should be left to individual centres to determine which of the tests they would use for routine testing in their regions.[1327] There was no need for this comparative evaluation. It had been a matter for regional centres to choose which of the available test kits they would use in their regions when anti-HIV testing was introduced in the UK in 1985. There was an urgent need for anti-HCV testing to get underway by the middle of 1990 and, that urgent need should have overridden the need for a comparative evaluation to be carried out. This decision

[1324] Penrose Inquiry transcript for 23/11/11 (day 68); 52 (10 to 11) (Dr Perry); [PRSE0006068_0052]
[1325] PRSE0001414_0022
[1326] PRSE0000976_0004
[1327] This was discussed at the eighth meeting of the AVCSB on 21 November 1990 - PRSE0000206

delayed matters sufficiently to push things back to the point where it became necessary to make a decision as to whether to start routine testing with first generation tests at all, as second generation tests were on the horizon. The results of the comparative study were discussed at the eighth meeting of the ACVSB in November 1990, by which time clinical trials of the second generation ELISA were already underway.[1328]

The requirement for there to be an available confirmatory test before the routine introduction of anti-HCV testing

4.50 The evidence available to the Inquiry would also appear to suggest that a further concern which caused a delay in the introduction of routine anti-HCV testing was the absence of a satisfactory confirmatory test. By the middle of 1990, there had been an evaluation within the UK of both the available ELISA test and the RIBA confirmatory test.[1329] At a meeting on 4 January 1990, the absence of a confirmatory test did not, according to Dr Gunson, seem likely to be the cause of any delay in the routine introduction of testing.[1330] Dr Follett received the RIBA for evaluation in February 1990.[1331] A positive report on the first generation confirmatory test from Ortho the "RIBA 1" (by Dr Skidmore in Birmingham) was issued on 2 June 1990.[1332] As was pointed out in a memo written by Dr McIntyre on 6 June 1990, there was a considerable concern about the number of positive donors who would be detected if routine testing were introduced, which would cause an increase in the workload of consultants to whom those patients would require to be referred. [1333] The concept of turning donors into patients is one which is addressed in more detail above. However, Dr Gunson appeared to be of

[1328] Penrose Inquiry preliminary report, para 9.235 (29 October 1990)
[1329] Penrose Inquiry preliminary report, para 9.227
[1330] PRSE0003333_0100 (para 165 of the judgement of Burton J in A v National Blood Authority)
[1331] Penrose Inquiry preliminary report, para 9.186
[1332] Penrose Inquiry preliminary report, para 9.208
[1333] PRSE0003099

the view in April 1990 that the absence of a confirmatory test should not necessarily be a bar to the introduction of routine anti-HCV testing. In other countries, they realised the need to press ahead despite these concerns. A similar attitude should have been adopted in the interests of recipient safety in Scotland.

4.51 In any event, the Ortho RIBA appears to have been launched in May 1990.[1334] Dr Perry indicated in his Penrose evidence that, although the non-availability of a confirmatory test had had a major part to play in the thinking of the ACVSB on the issue of routine anti-HCV testing that "one could [at this point] tick that particular box" as a confirmatory test was now available which had "the broad support of the scientific community".[1335]

Second generation testing

4.52 The decision to delay the introduction of routine anti-HCV testing in order to allow testing to be done on second generation test kits was a mistake. The extent to which the need for such an evaluation was the real reason for further delay at this time (as opposed to funding difficulties in England) is considered above. The Inquiry clear evidence that routine testing could have been instituted using the first generation kits in April 1991 (at the latest) with the evaluation of the second generation kits being run alongside such a programme. Dr McClelland gave evidence at Penrose to the effect that, even before this time, the SNBTS were experienced in the roll out of testing systems.[1336] Dr Perry described the delay to wait for the evaluation of the second generation kits being a case of the best being the enemy of the good.[1337] Professor Leikola made it clear that starting routine

---

[1334] PRSE0003312
[1335] Penrose Inquiry transcript for 23/11/11 (day 68); 109 (23) to 110 (94) (Dr Perry); [PRSE0006068_0109 to 0110]
[1336] Penrose Inquiry transcript for 15/11/11 (day 63); 141 (2 to 12) (Dr McClelland); [PRSE0006063]
[1337] Penrose Inquiry transcript for 23/11/11 (day 68); 136 (1 to 4) (Dr Perry); [PRSE0006068_0136]

testing with one test would not preclude switching to a better one once it became available.[1338]

4.53 The misguided approach of this time is summed up in the evidence given tom the Penrose Inquiry by Dr Mitchell, a member of both the ACVSB and the ACTTD. He explained the decision to delay the introduction of testing until an evaluation of the second generation of kits had been performed on the basis that (a) the first generation kits were useless[1339] (b) there was an overriding concern for falsely positive donors[1340] and (c) getting the top of the range kit was what patients would have wanted.[1341] Meanwhile, the patients had no testing at all to protect them from infection. Other countries had already done so. He then went on to state that all harm diminished him[1342], that the guiding principle was "primum non nocere"[1343] and that blood was a dangerous drug.[1344] These laudable guiding principles could hardly be less consistent with the reasoning given only moments before in his evidence, which is based on (a) an erroneous view that the first generation kits afforded no protection at all (b) concern for the interests of donors rather than those of recipients and (c) a failure to appreciate that what patients would have wanted would be some protection, rather than none. This apparent commitment to the value of evaluating the second generation test kits conflicts with Professor Cash's Penrose evidence to the effect that the decision to undertaken this evaluation was, in fact, a government controlled device (put in place through the ACVSB) to deal with the fact that there were funding problems with the introduction of routine testing in England.[1345]

The rights of donors

[1338] PRSE0001087_0003
[1339] Penrose Inquiry transcript for 24/11/11 (day 69); 188 (24 to 25) (Dr Mitchell); [PRSE0006069_0188]
[1340] Penrose Inquiry transcript for 24/11/11 (day 69); 189 (7 to 13) (Dr Mitchell); [PRSE0006069_0189]
[1341] Penrose Inquiry transcript for 24/11/11 (day 69); 190 (8 to 13) (Dr Mitchell); [PRSE0006069_0190]
[1342] Penrose Inquiry transcript for 24/11/11 (day 69); 191 (4 to 5) (Dr Mitchell); [PRSE0006069_0191]
[1343] Penrose Inquiry transcript for 24/11/11 (day 69); 191 (22) (Dr Mitchell); [PRSE0006069_0191]
[1344] Penrose Inquiry transcript for 24/11/11 (day 69); 191 (24) (Dr Mitchell); [PRSE0006069_0191]
[1345] Penrose Inquiry transcript for 01/12/11 (day 72); 167 (11) to 168 (8) (Professor Cash); [PRSE0006072_0167 to 0168]

4.54 The issue of the requirements to balance the rights and interests of the recipients of blood and blood products and donors is a them which has been discussed before in this submission and played a part, again, in relation to the decision-making around anti-HCV testing. The requirement for the counselling and treatment[1346] of donors who test positive for anti-HCV was a matter which was considered in connection with the question of routine anti-HCV testing, as it had been in connection with surrogate testing. Dr Mitchell sat on both the AVCSB and the ACTTD committees. His attitude on this matter in evidence is alluded to above. At the time he consistently demonstrated a dangerous pre-occupation with the position of donors who had tested positive. At the fifth meeting of the ACVSB he raised the issue of causing alarm to donors.[1347] He reiterated this concern at the sixth meeting on 24 April 1990 where he warned that there may be problems counselling donors on the basis that the true meaning of a positive anti-HCV test was not fully understood.[1348] He also expressed concerns about unnecessary deferral of donors as result of the introduction of anti-HCV screening.[1349]

4.55 Concern for donors appears to be largely the reason why there was concern about having a "proper" confirmatory test.[1350] However, by the time of the fifth meeting of the ACVSB on 17 January 1990, Professor Zuckermann was pointed out in a letter to the DoH that it would be possible to defer donors who tested positive on the ELISA test and to wait for a confirmatory test for up to 12 months.[1351] This would seem to suggest that, in the interests of getting initial testing up and running (whilst still recognising the need to have a confirmatory test for the sake of donors at some point) it would be possible to start routine testing without a confirmatory test system in place. This came from an individual whom Dr Perry described as "a

---

[1346] PRSE0003099
[1347] PRSE0001477_0004
[1348] PRSE0002519_0002 (24 April 1990)
[1349] PRSE0002519_0004 (24 April 1990)
[1350] Penrose Inquiry transcript for 22/11/11 (day 67); 142 (18 to 21) (Dr Dow); [PRSE0006067_0142]
[1351] PRSE0001414_0022

great proponent of the need for a scientifically robust confirmatory assay".[1352] Work was clearly being done on producing such an assay at that time.

4.56 The requirement for there to be a balance between the rights and interests of blood donors and the recipients of their blood and blood products made from it was a necessary part of the decision-making process relating to the introduction of anti-HCV testing. The position of Professor Zuckermann in January 1990 makes it clear that it was an option to introduce routine testing some time before confirmatory testing. This was an option which should have been taken. In any event, at the tenth meeting of the ACVSB on 21 May 1991 it was determined that nothing would be said to donors who tested positive until the AVCSB met to discuss the matter again, though this was the last scheduled meeting before the introduction of routine testing in September 1991.[1353] Given this decision to process without counselling, it can be deduced that the significance attached to counselling was excessive throughout the debate on anti-HCV testing. With appropriate investment, telling donors about the likely implications of a positive test could and should have been a positive public health measure which would have allowed those patients to adapt their lifestyles to deal with their positive status, lessen the risk of infecting others and in time obtain treatment. The position appears to be that it would be better to have no test and have a positive donor live in ignorance. This was a disservice both to donors and recipients of blood.

Funding considerations

4.57 The evidence available to the Inquiry suggests that funding for anti-HCV testing would not have been a problem, had the need of its introduction been deemed to be pressing.[1354] Mr McIntosh agreed in his Penrose evidence that the

[1352] Penrose Inquiry transcript for 23/11/11 (day 67); 61 (7 to 8) (Dr Perry); [PRSE0006068_0061]
[1353] PRSE0001457_0004 (para 16)
[1354] PRSE0002387_0006 (statement of SHHD assistant secretary Mr George Tucker)

arrangements would have been likely to have been sufficiently flexible to accommodate the introduction of testing, had the case for it been pushed.[1355]

4.58 There was an early commitment (both at governmental level and within the SNBTS) to go along with the timing of the introduction of anti-HCV testing in England and Wales. Evidence was heard that the introduction of anti-HCV testing there was delayed by funding problems which was the predominant reason for delay, particularly in 1991.[1356] It does not seem that this was a problem which should have come as a surprise. At the fifth meeting of the ACVSB, Dr Gunson had pointed out that the funding for routine anti-HCV testing in England and Wales would require to be found from existing health allocation there.[1357] Mr David McIntosh took the view that recommendation for more testing in 1991 was a means of dealing with funding problems in England.[1358] The result of the decision to wait for the introduction of anti-HCV testing in England and Wales was that Scottish patients were subjected to English funding delays. This was totally unnecessary.[1359]

4.59 However, in Scotland, the SNBTS did not make a specific application for funding to cover anti-HCV until July 1990[1360], which application was to cover the financial year 1991/92. An application for funding had been made for NANBH surrogate testing in 1986 (for the financial year 1987/88) without there being any indication on the part of SHHD that they were going to introduce surrogate testing. Consistent with the apparently changed attitude of Professor Cash and the directors by the time anti-HCV testing was being considered (see above), no such pressure was applied by way of a funding application. The SNBTS directors should have applied for funding in the year before 1990 to cover anti-HCV testing from April of that year (as they had done in advance for surrogate testing) to force the SHHD to consider

---

[1355] Penrose Inquiry transcript for 29/11/11 (day 70); 29 (23) to 30 (9) (Mr David McIntosh); [PRSE0006070]
[1356] PRSE0003692 (27 March 1991)
[1357] PRSE0001477_0004
[1358] Penrose Inquiry transcript for 29/11/11 (day 70); 46 (23) to 47 (3) and 47 (11 to 17) (Mr David McIntosh); [PRSE0006070]
[1359] Penrose Inquiry transcript for 29/11/11 (day 70); 51 (11 to 23) (Mr David McIntosh); [PRSE0006070]
[1360] PRSE0000597_0015 and Penrose Inquiry preliminary report, para 9.21

it and put some pressure on them to introduce testing in the interests of patients at same time as was the case in other countries in 1990.

4.60 Further, there is no evidence of any attention having been paid to the possibility of potential financial savings in care costs resulting from prevention of infection in the decision-making process. The need to look at the possibility that testing would save money in the long term was clearly alluded to in the July 1987 Lancet letter from the SNBTS directors regarding surrogate testing (see above). This aspect of things should have been considered as part of the public health responsibilities of SHHD and the SNBTS. Once again, the short-sighted approach did not serve the patients of the public purse well.

Ministerial involvement

4.61 The ultimate decision regarding matters relating to public health such as the introduction of routine anti-HCV testing in Scotland lay with the appropriate minister within the SHHD. He relied upon recommendations and advice on such important and technical matters from medical and non-medical civil service staff. In this case, formal authorisation from the minister was given on 26 July 1991 in response to a request from Mr Tucker on 24 July.[1361] Before this, a memo had been sent from Mr Tucker, assistant secretary with responsibility for blood transfusion matters within SHHD, to the then health minister within SHHD, Mr Michael Forsyth on 23 August 1989.[1362] This concerned press interest in the matter at around that time. Mr McIntosh confirmed that the minister must have given his approval to anti-HCV testing in Scotland some time before the beginning of the financial year from April 1991 on the basis that it was part of the approved funding application which he had submitted for that year.[1363]

[1361] PRSE0002671
[1362] PRSE0000558
[1363] Penrose Inquiry transcript for 29/11/11 (day 70); 73 (22) to 74 (4) (Mr David McIntosh); [PRSE0006070]

4.62 The advisory committees, in particular the ACVSB pursued a path of seeking scientific perfection in a test, or "the holy grail" as Professor Cash called it. This approach required to overseen and the advice understood in the correct political context which championed public health in light of the advice. The minister for health within the Scottish Office had ultimate responsibility for this public health issue. The fact that it was brought to his attention only where the press became involved and for ultimate authorisation seems to have deprived him of the opportunity to take that overall control which this process was so clearly lacking. This was the result of a system which only sought ministerial involvement at the point when civil servants had all but made the decision to go ahead with steps like testing. In this case, responsibility was effectively abdicated by the SHHD to the DoH and its advisory committee. Mr Tucker confirmed that the decision making power on this issue had been abdicated to the ACVSB.[1364] He placed considerable importance on the consistency between ministers in England and Scotland and appeared to consider the potential embarrassment of ministers, litigation and matters of presentation before the safety of Scottish patients.[1365] These considerations should at all times have been subsidiary to the interests of Scottish patients, whom they served.

Legal obligations under the Consumer Protection Act 1987

4.63 The introduction of consumer protection legislation in Scotland was addressed as a significant part of the backdrop to the debate about the introduction of surrogate testing. The strict liability provisions of the Consumer Protection Act 1987 came into force on 1 March 1988 and so their introduction closely preceded the discovery of the hepatitis C virus and the debate about anti-HCV testing. The same considerations apply to the relevance of this legislation in connection with

[1364] Penrose Inquiry transcript for 24/11/11 (day 69); 106 (8 to 16) (Mr George Tucker); [PRSE0006069_0106]
[1365] Penrose Inquiry transcript for 24/11/11 (day 69); 106 (20) to 107 (4) (Mr George Tucker); [PRSE0006069_0106 to 0107]

anti-HCV testing as was the case with surrogate testing. Burton J took the view in A v National Blood Authority that the failure to introduce anti-HCV testing in England and Wales was a breach of the defendants' legal obligations under the Act. As is explored below, in Scotland instructions were given that settlements should be sought in similar litigations brought against the Secretary of State for Scotland. It was clearly thought that the same decision would be likely to be reached in Scotland as a uniform defective approach had been taken to anti-HCV testing across the country.

4.64 Professor Cash had been making the argument on numerous occasions that, in his view, the SNBTS would be liable if the provisions of the Act applied to the production of blood and blood products in Scotland (see above). It is clear that the issue of legal liability was not lost on the members of advisory committees. At the very first meeting of the ACVSB, it was suggested that the failure to introduce testing designed to prevent the transmission of NANB hepatitis by blood and blood products (which had been introduced in the USA) may have product liability implications. By the time of the fifth meeting of the ACVSB on 17 January 1990, Professor Zuckermann was pointing out that the non-introduction of testing would be likely to result in "indefensible litigation".[1366] The introduction of the legislation and its more consumer-orientated approach is another factor which should have resulted in routine testing being introduced sooner than it was.

Consequences of the timing of the introduction of routine anti-HCV testing in Scotland

Numbers infected

4.65 Material relating to the total number of infections with HCV from blood transfusions in Scotland is available to the Inquiry. As far as the number of

[1366] PRSE0001414_0022

infections with HCV which could have been prevented, had routine anti-HCV screening been introduced earlier in Scotland, a significant number so infections could have been prevented. Some insight into the numbers of transmissions which could have been which could have been avoided can be achieved on consideration of the Aach & Ors paper of 7 November 1991.[1367] It concluded that although the second-generation tests (93% detection) were more accurate the first-generation tests but that a significant percentage of donors would also have been identified by the first-generation tests (81% detection) and indeed by surrogate testing (73% detection).[1368]

Conclusions

4.66 Routine anti-HCV testing should have been introduced in Scotland by the time that it was introduced in the USA in May 1990. In this regard, it necessary to observe that by this time, it was well known that infections were being transmitted, that hepatitis C could be a very serious disease and that the testing kits available from Ortho could prevent a material number of infections. Satisfactory evaluations had been done in Scotland on the Ortho kits considerably earlier than this. It should have been realised that something needed to be done to prevent the transmission of this virus, a position which had been adopted by contributors at various advisory committee meetings before this point. It should have been realised that improvements to the testing systems could have been considered and incorporated once the testing programme was up and running. Literature from after the introduction of routine testing indicated that the second-generation kits did perform better than the first-generation kits. However, the performance of the first-generation kits eliminated a substantial proportion of infective donations.[1369] In any event, doing nothing was not acceptable.

[1367] PRSE0002386
[1368] PRSE0002386_0004 to 0005
[1369] PRSE0002386_0004 to 0005

4.67 After a thorough assessment of the materials available on this issue by the Penrose Inquiry, Finish expert Professor Leikola could not see a justification for the failure (a) to take a decision to recommend surrogate testing by June/July 1990[1370] (it was not actually recommended until November 1990) or (b) to get testing up and running by October/November 1990.[1371] As noted above, countries with small resources like his achieved routine introduction well before these dates.

4.68 Over the period from 1989 to 1991, there were a number of small delays which were unnecessary, as is set out above. These all led to a significant unnecessary overall delay in the introduction of routine anti-HCV testing. The small delays were all caused, by the absence of a real sense of urgency about getting routine testing underway, a lack of understanding about the fact that some protection was needed, political oversight of the advisory committee and a lack of appreciation that testing, once started, could operate in a fairly flexible fashion (especially given the experience of SNBTS in rolling out such testing programmes in the past). The delay was not in the best interests of the recipients of blood and blood products. By the time of the fifth meeting of the AVCSB, it was thought that the overall incidence of PT NANB in the UK could be as high as 10,000 cases per annum.[1372] It was not acceptable for nothing to be done in light of this situation.

4.69 In his evidence to the Penrose Inquiry, Dr McClelland thought that the reason for the delay was that it was perceived that there was no need for urgency on the basis that NANB hepatitis was perceived as an American problem. This was why he thought that there had been a lack of decisions.[1373] Such an attitude, if it existed, took insufficient account of the safety of patients and the very real threat which this disease posed to them. The responsibility for this lies with those in government and those advising the government over this period. As Dr McClelland said in his evidence nobody appeared to consider the question "what about the patients?".[1374]

[1370] PRSE0001087_0003
[1371] PRSE0001087_0004
[1372] PRSE0001087_0005
[1373] Penrose Inquiry transcript for 24/11/11 (day 69); 67 (21 to 22) (Dr McClelland); [PRSE0006069_0067]
[1374] Penrose Inquiry transcript for 24/11/11 (day 69); 74 (1 to 10) (Dr McClelland); [PRSE0006069_0074]

5. Conclusions regarding the screening of blood

5.1 The delays which were experienced in connection with the screening of blood demonstrated a system which was not fit for purpose and had inadequate focus on the safety of the end user and public health in general. A poorly-defined priority was accorded to the interests of the donor, without realising that a donor may also require the services of a safe transfusion service in the future.

5.2 The overriding need for national co-ordination was the product of a misguided sense that as long as everyone was doing the same thing, nobody could be criticised, via the law or otherwise. This created unnecessary delay and an unsafe system. The whole operation moved at the pace of the slowest runner, to the detriment of everyone in the race. As far as Scotland was concerned, the system undermine the entire purpose of administrative devolution and the separate Scottish health service. The frustrations which this created led to disengagement with the system on the part of those who had the power to alter its course for the better.

5.3 Advisory committees focussed on scientific perfection – the best was clearly the enemy of the good. Membership of government advisory committees relating to blood transfusion policy should include strong representation from clinicians involved in patient care as well as representatives of patient groups in addition with a more laboratory-based expertise. Such committees should be truly independent of the government. Their roles and the limits of their responsibilities require to be defined clearly. There requires to be a clear definition of the responsibilities of the transfusion service and the government towards both donors and the recipients of blood and blood products.

5.4 The delays in connection with screening regimes clearly show the UK blood transfusion service to have been wanting and, viewed in an international context, lagging behind other similar services when it came to patient safety. There require to be clearly defined systems to allow account to be taken of information and

opinions from and actions being taken in other countries for the safety of the recipients of blood and blood products

H. TREATMENT WITH BLOOD PRODUCTS

GENERAL

1. The philosophy behind treatment with blood and blood products – the "voluntary" donor

1.1 The evidence heard by this Inquiry was overwhelmingly to the effect that the UK system was based on the voluntary donation of blood as a basis for the domestic production of red cells and other products derived from blood, such as plasma fractions. The general philosophy which underpinned this policy was that it was generally preferable to procure blood from voluntary donors, as opposed to the system of paid blood donation which operated, in part, as the basis for the system which operated in the US. It was considered to be the case that paying for donations of blood would be likely to act as an incentive for donors to provide donations for financial as opposed to altruistic reasons, with the result that unsuitable, higher risk donors may end up donating blood who would not have done so, had there been no remuneration for the donation being made. Lord Owen had a formative part in the development of this policy which he claimed to have instituted while Minister of State for Health in the mid 1970s Labour government. His evidence was to the effect that he had been influenced strongly in this regard by the approach advocated by Richard Titmuss in his book "The Gift Relationship". This policy decision was the driving philosophy behind the decisions made in the area of blood collection and the production of blood and blood products for the use in the UK.

1.2 Though generally laudable in intent when compared with the clear evidence of dangers created by the system of paid donation elsewhere in this submission, the UK government and NHS's plan to achieve an entirely voluntary system of blood donation and the connected aim of self-sufficiency in blood products was flawed in a number of ways. The result was that blood and blood products produced in the UK were unsafe and caused unnecessary infection. The flaws in the system which had this result were as follows:

1.3 First, there was a false reassurance provided by the fact that blood and blood products came from a voluntary system. This resulted in an attitude that blood and blood products which emanated from this system were safe. In fact, the philosophy is rooted in a comparative analysis with a paid donor system. All that could be confidently guaranteed by a purely voluntary donor system is that the products which came from it were likely to be safer than those which came from a paid system which incentivised unsafe donors to donate blood. Thus the UK system operated under the misapprehension that UK products and the UK system was safe when all that could confidently be said was that it was safer. This results in a kind of blind faith in the UK system which was misplaced.

1.4 Secondly, the Titmuss philosophy which underpinned the was merely that – a set of principles without means or consideration of practical application. In essence, the laudable principle which underpinned the philosophy was really of little worth if it could not be put into practice in a way in which the objectives of such a system – a system of safe blood and blood products built on social responsibility – could be achieved. The first way in which the practical application of the philosophy was in the lack of financial support for its application.

1.5 Self-sufficiency was a myth due to the lack of capital funding – this meant that there was little chance that a voluntary system such as that contemplated by Titmuss could ever have been achieved. In any event, it was never defined. It never had any clear idea of what blood and blood products were going to be covered by the commitment. As such, it was a meaningless concept. It was based on an assumption that the need for blood and blood products would remain the same as it was when the commitment was made by Lord Owen in the mid-1970s. This was an unsafe assumption at the best of times but in the mid-1970s it was even

more so. It took no account of the "effect of the "golden interval" effect described by Dr Mark Winter. It was a time when those treating bleeding disorders generally began to become more convinced (unwisely as it turned out) of (a) the relative safety of concentrate use based on the advent of screening programmes for HBVs and (b) the advantages of greater use of concentrates – home treatment could enable bleeds to be treated more quicky and hopefully effectively and prophylaxis could avoid bleeding episodes. This would result in the aspirations for treatment becoming ever higher and higher and the appetite for concentrates to sky rocket in the ensuing years. The level of usage before the time of the commitment was irrelevant to the likely future demand. As such, the commitment to self-sufficiency was an empty political stunt, soon recognised as such and thus relegated to the status of notional target which nobody was actively seeking to do the work to achieve. It was the "policy" of the government - nothing was being done to define or achieve it. Merely being the policy was of little practical use to the recipients of the products.

1.6 The second way in which this manifested itself was that the UK system as not, in fact, a voluntary system at all but merely one which masqueraded as such as the donors were not paid. It can hardly be said that donations given by a prisoner incentivised by time away from his cell or other non-financial inducements could be said to be voluntary in the sense that Titmuss meant. Given the known risks of insidious viral transmission by blood and blood products (known well before the 1970s as a result of HBV transmission), the particular risk of exposure of the recipients of pooled blood products to those viruses as a consequence of pooling, it seems hard to believe that it was the production of those very products which drove the unsafe elements of the system of blood collection being tolerated or promoted. The Titmuss paradigm had been created in a world before the pressure for plasma had really taken hold. Yet it was the driving force behind the policy pursued by the UK government, without that government ever really having any conception of the realities of its practical application. The need to produce domestic blood and blood products in accordance with the home-grown voluntary principle was the very reason why that principle became so eroded. No-one in government seems to have addressed their mind to the key question of how the

principles could be put into operation without being so eroded. By positively seeking out high risk donors in prisons etc and by not enforcing robust, centrally controlled systems for the exclusion of high risk donors at regular donor sessions (instead allowing regional variation in these practices, as long as collection targets were hit) the system was allowed to become akin to the paid donor system. A system which allowed in high risk donors as they were offered financial inducement was akin to a system which did not do enough to ensure that they were kept out or, in Scotland at least, continued to collect blood deliberately from them. The key to maintaining safety in the inherently dangerous practice of using human blood and plasma was not whether donors were paid or not. The key was whether the system instituted and maintained reasonable measures to ensure that safety was balanced with the need for supply. Not paying donors was a reasonable measure to achieve that aim. It was not a sufficient method, though it was considered to be.

1.7 By way of example to illustrate the point, in his analysis of the extent of the impact of plasma collected from prisons in France is analysed by Douglas Starr in his book "Blood – An Epic History of Medicine and Commerce". He refers to a study undertaken by the French Judicial and Social Affairs Ministries which concluded that, in 1985, though prison blood accounted for only 0.37% of the nation's blood supply, penitentiaries accounted for 25% of the contaminated blood in France.[1375]

1.8 The Titmuss philosophy was forged at a time when the drive for plasma for the production of factor concentrates did not dominate the blood collection system. As will be seen elsewhere in this submission, by the early 1980s, the appetite for factor concentrates and the resultant need for ever greater supplies of plasma were what drove the system. The ever increasing, constantly elusive targets for plasma drove the need to continue to collect blood in Scotland from whatever sources were available. Little actual consideration appears to have been given to whether the collection of blood in prisons and whether the donor selection policies in place at that time results in the voluntary system of altruistic donors upon which Titmuss's philosophy had been based. The illusion that UK blood was

[1375] HSOC0019915 @ page 327

"safe" acted as a basis for a false reassurance about the likely consequences of such a system. The tail (the haemophilia clinicians) was truly wagging the dog (the system of blood collection).

1.9 In any event, in addition to becoming rapidly in need of updated application to the real world of blood and blood products, the Titmuss philosophy was flawed from the start. As was pointed out at the time, it was based on little social science but on social philosophy.[1376] It took no account of the fact that if demand was allowed to continue without control, there would be little room for philosophy. They had pointed to the need for a national strategy for the management of the national resource which was the voluntary blood donation system. As they put it *"the nation cannot afford the Blood Transfusion Service (which ramifies into almost ever corner of the Health Service) to remain the lame duck which it so clearly is)"*.[1377] The failure of the DHSS to heed these calls and to institute such a centrally controlled strategy was clear failure of successive governments. It was predominantly a failure of management, as opposed to a failure of funding.

1.10 Payment of donors was not necessarily an evil which required to be eradicated at all costs. Indeed payment in the right way may have enabled more money to be spent on donor recruitment, more good donors to be attracted to give repeat donations and more to be done to monitor their medical histories.[1378]

1.11 The drive for more and more plasma never resulted in plasmapheresis being introduced in the UK. It was considered. Plasmapheresis was a means by which more plasma could be collected as it enabled donors to donate more frequently and by targeting the plasma and returning the red cells meant that the yield at one donation could be maximised. It enabled fractionators in the US to collect as much plasma as they could to try to keep up with the demand for blood products. The demand was based in part on the treatment regimes of patients with bleeding disorders for ever more products to enable home treatment and eventually

---

[1376] DHSC0100024_126 (1974) – see reference to Cooper and Culyer argument that the total reliance on voluntary blood donation in the UK would be unrealistic, based mainly on the increasing demand for plasma fractions

[1377] DHSC0100024_126 (1974)

[1378] As is noted as having been the experience of certain US blood bankers who paid donors by Starr - HSOC0019915

prophylactic treatment regimes. In the UK, without paid donation and hence without the considerable advantages of plasmapheresis, those treating the bleeding disorder patients promised their patients regimes based on a system with comparably far greater access to the plasma needed to support them. These were unrealistic aspirations. These promises had a domino effect. The lack of consideration for whether there was sufficient UK plasma to resource these treatment regimes put unsustainable pressure on those collecting the plasma. This resulted in the targets going ever up and up. This meant that corners, needed to be cut, risks ignored – in effect it meant that the UK system became unsafe. In other places it meant that the less safe UK products require to be relied upon (analysed in detail below). The relative freedom and control of bleeds, leading to the created by the new treatment regimes created ever more need for products and plasma. This, in turn, created ever greater pressure on the system. Warnings that the system was fit to burst went unheeded. The haematologists were concerned primarily with improving the bleeding conditions which were their principal areas of expertise and responsibility. Viral infection was seen as something which was not their concern. It was not their job to avoid it. If anything, the information which could be gleaned from the inevitable fact of infection amongst the haemophiliac canaries could gain them column inches in reputable medical journals and professional notoriety. They comforted themselves in the knowledge that a system which did not remunerate its donors was "safe", while unrealistically promoting treatment regimes which were having the effect of making them unsafe. Allegations of clinical negligence could always be defended on the basis that we were doing better than others who relied on greater amounts of products which came from paid donors. The voluntary system became like a get out of jail free card for those who used the domestic products preferentially. The system was set up so that there was always someone else to blame if things went wrong – the transfusion doctors for their lack of warnings/ unsafe collection practices, the government for failing to advise them to stop or to provide enough money, the Haemophilia Society for advocating the continued use of the products which appeared to be helping the bleeding. That reality created a false sense of security. The patients themselves were never presented with the full picture. The

lack of safety which resulted from this system was not only for the recipients of the blood products made from the deliberately sought out or carelessly admitted high risk donors but also for the recipients of blood transfusions. The lack of a system of plasmapheresis meant that the red cells collected for them came from the same donors upon whom the system, craving ever more plasma for the support of the bleeding disorder treatment regime, depended. They were also exposed to these high risk donors unnecessarily as a result of the need to maximise the treatments being produced for those with bleeding disorders.

1.12 The clinicians responsible for the care of the end users of blood products, driven by the evidence of better outcomes for the bleeding conditions of their patients, sought to introduce treatment regimes which required amounts of plasma which could only be produced a such a system which had unlimited resources, both in terms of funding and plasma, like the US system which was fuelled by paid donations. By way of example of the way that the system worked, Professor Hann gave evidence to the effect that Dr Willoughby, in introducing a system of prophylaxis might have been right, with hindsight. Whether that is right from the point of view of management of bleeding or not (and even that is controversial, given the amount of joint problems those who survived still have), what is clear is that he did not give adequate consideration to the safety. Innovation in haematological practice was by all means laudable but within the boundaries of safety, which ought to have come first. Of course, in 1983, Professor Hann changed the system towards using only domestic concentrates. During 1983, his changes benefitted from the increased yield which Dr Foster was able to achieve meaning that more concentrate could be made from the same amount of plasma, increasing availability. The fragmented nature of the system in the UK meant that nobody was co-ordinating these various different concerns. Clinical freedom meant that a group of children could be tempted with promises of a better life. Tragically, for many of them those promises led to the end of their lives.

1.13 In conclusion, the Inquiry requires to engage with an assessment of whether in the UK and in Scotland in particular, what the true nature of the "voluntary" donor system was, which requires a clear explanation of what a "voluntary donor" means. "Voluntary" in Scotland at least came to be thought of as being the same

as non-remunerated and so honest. This was thought to be consistent with the principles of the "gift relationship". The "gift relationship" is actually just a relative term. It means that the donors are better if they are unremunerated. It does not mean that the blood or plasma which they donate is safe as many patients were told. It fact, the system just created a general impression that it would produce safer blood than blood which came from other sources where the donors were remunerated and thus the blood was known to be unsafe. In fact that system gave rise to no right to claim safety at all.

1.14 Some donations which were collected were certainly less voluntary than the Titmuss paradigm. Those donating as a result of a feeling of social pressure, donating as part of a group such as at work, donating while in prison or the military, those attracted by the inducement of being involved in the gift relationship and the personal or social benefit which may flow from that are all donating as a result of inducements of sorts, not direct financial inducements but inducement nonetheless. The assumption which was at the root of the system was that voluntary means honest and wholly honest. However, as a result of these inducements and indeed other reasons, such as lack of understanding, lack of attention to the importance of certain matters in someone's past or their past medical history mean that voluntary does not mean honest or wholly honest. The evidence suggests that there was an element of "voluntary" meaning middle class, in the sense of being presumed to be less likely to have been involved in certain unsavoury behaviours, like the "skid row" donors of the US. Dr McClelland certainly accepted that one of the problems in transfusion was that it was not considered that the worthy, volunteer donors would be associated with any risky behaviours.[1379] Again, that is really just a relative consideration of matters. They look less obviously likely to have been engaged in certain behaviours which create risk like IVDU. This was not a valid assumption, in particular when it comes to the transmissibility of HBV and HIV by sex. There was no real reason to assume that the middle class donor has not engaged in homosexual sexual intercourse or intercourse with prostitutes, or for that matter that he had not been engaged in

[1379] IBI transcript for 27/01/22; 124 (Dr McClelland)

IVDU at some point. Yet donor sessions were often run by volunteers who had these assumptions. In any event, many donors were clearly not voluntary in the Titmuss sense. The prisons of Scotland in the 1970s and 1980s, for example, are likely to have looked very much like Scotland's own skid row.

1.15 The result is that the concept of Scotland's system of "voluntary donation" was a sticking plaster to appease the consciences of those who were responsible for the safety of blood and blood products produced and used in Scotland. In fact, it was thought of as a panacea. It was thought of as indicating that blood and blood products were safe. It did not. It just meant at a high level of generality that the system was probably safer than a system which was adopted elsewhere, relied on remunerated donation and was known to be unsafe.

1.16 This reality meant that many of the difficult questions faced by those in the treatment of those who might be given blood or blood products were never addressed or answered. The blood and the product were considered to be "safe", incorrectly. This shows the fallacy of the faith put in the voluntary donor system where (a) inadequate systems were put in place to do what could be done to exclude high risk donors, such as the reliance on self-policed questionnaires and not medical information in the absence the ability to test scientifically (b) certain donors known to come from high risk areas of society and were not volunteers at all (c) despite the faith put in the volunteer system products could be used with impunity in the treatment of certain patients which were known not to from voluntary donors but from paid foreign donors, introducing foreign pathogens into the public health system and (d) all of this despite the fact that the pathogens involved were easily transmissible, in particular the sexually transmissible, potentially fatal HBV and HIV.

2. Medical records

2.1 The Inquiry's investigations have shown that there are significant issues about missing medical records which have been identified amongst patients treated with

blood or blood products in Scotland. The extent of the deficiencies with the system of medical records retention and creation have justifiably given rise to significant concerns about the possibility that decisions must have been made to ensure that records were destroyed or access to them limited so as to minimise the infected and affected community's capacity to find out more about what happened to them. The absence of proper records should, in our submission be viewed in the context of the evidence of the important witness, Diana Walford who said that it was essential when using potentially hazardous substances like blood and blood products that there be good record keeping to be able to understand what products are being and have been administered. [1380] Invariably, the system failed to meet this standard. At an SNBTS regional transfusion directors meeting in March 1983, there was an expressed agreement with Royal College of Pathologists to hold records within SNBTS for "as long as possible" beyond the legal requirement of 6 years.[1381] Holding records for "as long as possible imposed no actual requirement or sanction. The meeting considered the 1982 Royal College of Physicians ruling to hold child and obstetric records for 25 years and other records for 10 years, which was merely noted. There was clearly a dawning realisation that in the field of blood and blood products there was a need to retain records beyond the normal standards. The same, by extension, ought to have applied to the records of the recipients. The normal rules applied across medical practice simply did not provide the necessary basis for monitoring the use of these potentially dangerous materials, as the Inquiry at this remove in time has amply demonstrated.

2.2 Since the start of the HIV litigation process, the medical profession had closed the door to any possibility of transparency with its patients in an effort to achieve self-protection. It is submitted below that from the time of the settlement of the HIV litigation, the governments of the UK had determined that the blood contamination disaster needed to be put to an end. Measures such as the hepatitis waiver were designed to achieve that. A concerted effort to maintain certain

[1380] IBI transcript for 21/07/21; 200 to 201 (Diana Walford)
[1381] PRSE0000193_0004 to _0005 (29 March 1983)

"party lines" about what had happened emerged amongst civil servants which were maintained with ministers and other parliamentarians who sought to raise the issue anew. The Inquiry is urged to examine the relationship between patterns of missing medical records on order to ascertain the extent to which this phenomenon is part of that concerted effort to close and cover up issues relating to the discuss. The possibility of wilful concealment or destruction of records would be consistent with that effort.

2.3 Though the position regarding medical records and their proper management is hard to define, there being a range of diverse and unusual experiences in that regard, certain patterns emerge within the bleeding disorder community which are worthy of note. The Inquiry presentation on the subject of medical records demonstrated that medical records are retained in Scotland for a minimum of six years from the late recorded entry of hospital treatment or three years from the date of death.[1382] The trigger point in relation to the six year time period for children and young adults is the age of 25. Though these entries appear in guidance issues in 1993 (the previous guidance having been issued in 1958) the legal genesis of the rules relating to the retention of medical records is the Public Records (Scotland) Act 1937. Section 12 of that Act allowed for there to be regulations made relating to the retention which are "of insufficient value to justify their preservation". This legal rule allowed the regulations to be made which govern the current system. The rules have been updated over the years to reflect various changes in data protection law but remain broadly the same as they have been over the period since the 1937 Act was passed. In his evidence to the Inquiry, under reference to a letter from 1977 in which he described that records in Liverpool had an annoying habit of going missing, he described the system as chaotic and as a day you day experience in many hospitals throughout country.[1383]

<u>Records relating to the treatment of bleeding disorders</u>

[1382] INQY0000378_0010 and _0011

[1383] IBI transcript for 04/02/22; 69 to 73 (Dr Frank Boulton); HCDO0001093

2.4 As far as medical records relating to the treatment of bleeding disorders in Scotland are concerned, it should be borne in mind that in his evidence to the inquiry, Professor Ludlam intimated that he had had a policy whereby medical records of his patients with bleeding disorders were to be kept indefinitely, due to the advantages for medical care which could be created for future generations of the retention of the information which they contained, as haemophilia and other bleeding disorders were genetic conditions which would be passed down by certain recognised routes through families.[1384] He stated that this has been the recommendation of the Royal College of Pathologists. He also took the view that this should be the case for patients who died to HIV due to the seriousness of the condition.[1385] The Inquiry knows that that did not happen, either for the HIV patients or more generally, from the evidence it has heard. Many patients have no or missing records. Many have no or few records for their loves ones who have died, for example witness Mrs AD. Thus, Professor Ludlam in effect took the view that these records were of sufficient value to justify their preservation to use the language of the 1937 Act (and subsequent legislation), due to their relevance to the diagnosis, treatment and management of future generations. The 1993 guidance (and subsequent versions of the guidance) specifically provided for the need for Health Boards to consider different rules for patients with genetic disorders. The 1993 guidelines also included a 15 year period for records to be retained where they related to clinical trials. The rationale for such an extended rule is presumably due to the fact that adverse reactions from clinical trials can emerge many years after the event. It is argued elsewhere in this submission that the treatment of haemophiliacs was, in essence, one large clinical trial, with the adverse consequences of treatment being monitored and recorded throughout the patients' lives and at time being reported for public health purposes or to the manufacturers of the products being used for treatment. Given these factors, there is a strong basis for the Inquiry to recommend that the records of those who

---

[1384] para 399 of first witness statement of Professor Ludlam (WITN3428001)
[1385] WITN3428001, para 399

have been treated for bleeding disorders (or indeed the recipients of blood transfusions) should be retained indefinitely.

2.5 The Inquiry has a good deal of evidence from patients with bleeding disorders having had various issues with accessing their hospital records. These generally fell into different categories, namely (a) records or part of records simply not having been retained, including evidence of destruction or partial destruction of records (b) and records being available but not being released to the patient on request, including issues relating to records having been held separately from the patient's main medical records causing issues with retention and access. There is evidence available from the Inquiry of patients having managed to access their medical records with entries blacked out. In one such case the patient was told that this had been done "for security reasons" by the RIE.[1386] Things which had been blacked out included the records of the treatments which the patient had received. It is far from clear what the reason for this could be when the records had been issued to the patient himself. Another Edinburgh patient had his records recovered by a lawyer when he had an unusual treatment (a blood transfusion) in 1986. He also found that there was no record of the transfusion and that pages subsequent to the entry relating to the attendance had been blacked out.[1387] One haemophilia patient from Edinburgh provided evidence to the Inquiry of his records having been destroyed, with the result that his ultimate records were much fewer than he had previously seen in the hospital.[1388] Though the evidence which he gave on the subject of medical records was consistent with the possibility that hard copy records were being destroyed for the purposes of electronic storage and retention, the fact that he received no proper warning or explanation for this apparent wholesale destruction of his records and the apparent discrepancy between what he had seen of his physical records and what appears now to have been retained has reasonably given rise to suspicion and uncertainty. Medical records are, of course, designed to provide the opposite of this – clarity

---

[1386] WITN2203001, para 5 (first statement of WITN2203)
[1387] WITN2317001 @ para 7 (first statement of WITN2317)
[1388] WITN2168001 @ para 22 (first statement of Myles Hutchison); IBI transcript for 31/10/2019; 133 to 135 (Myles Hutchison) (INQY1000048)

and certainty as to what has happened and why it did. The case stands as a clear example of the kind of system which the Inquiry encountered frequently in its evidence, namely one which saw the records as belonging to the hospital and nothing to do with the patient. This essential attitude to patient records was related to the fundamental nature of the relationship between doctors and patients which largely excluded patients (or their parents) from decision-making about their care. A system which placed a greater responsibility on hospitals to involve patients more in the compilation of records, accorded patients greater rights to access their records would be one important step towards greater patient engagement in their own health and care.

2.6 More general failures in proper record keeping were evident at the Edinburgh centre. Many of these record keeping failures relate to the patients who were infected with HIV, many of whom subsequently died. The confused and unusual system of record keeping relating to these patients which has become apparent has reasonably contributed to the suspicions relating to how they came to be infected. Certain key records relating to such patients which one would have expected to have been found in patient records were not retained in accordance with normal practice and have subsequently gone missing. These factors have led to suspicion of a cover up about the inadequacies of the way that these infections were handled. A submission is made elsewhere about the meeting held by Dr Ludlam and others relating to AIDS in December 1984. The inadequacies of that meeting have been examined elsewhere. Patients have made robust contentions about the lack of clear messaging and honesty about the serious situation which led to the meeting occurring. However, despite the meeting being connected to medical care, the invitation letter to the meeting does not survive in any known medical records or elsewhere.

2.7 Professor Ludlam accepted in his statement to the Inquiry that it was part of his responsibility to maintain medical records for his patients.[1389] Indeed, he explained that on his appointment he was keen to develop the record keeping

[1389] WITN3428001_0006, para (j)

systems at the unit.[1390] He has clarified that he also introduced a system whereby records were computerised from the mid 1980s when the ward being used for haemophilia care within the hospital moved, which enabled access to records of treatment across the east of Scotland haemophilia centres and permitted sharing of details about product use to with the SNBTS.[1391] He was thus responsible for information retention systems in the hospital and beyond. Despite the attention apparently paid to these systems, important records were kept otherwise than in patient records. At para 400 (c) of his statement, Professor Ludlam talked about there having been short clinical summaries prepared for discussing HIV cases with Dr Brettle.[1392] He said that these were stored in the pocket at the back of the most recent case notes folder and **may** now be in the archive, discussed on more detail below (subject to the caveat referred to above about him knowing nothing about where they have been since his retirement in 2011). These records clearly contained the most sensitive of information about patient care. Subject to the same caveat Professor Ludlam said that there were short notes about what patients wanted to know about their HIV status from early 1985 (following the December 1984 meeting and the January 1985 letter referred to elsewhere in this submission). These were held in a locked confidential file in Ludlam's office. In 2011, he says that some were destroyed and some were filed in the patient notes (none of which appear available now – see below).[1393] It is not clear why. It seems that these should therefore be permanently unavailable or available in case notes, which they appear not to be on the evidence available to the Inquiry.

2.8 In her statement nurse Billie Reynolds stated that during one day handover with Iona Philp, she was shown a treatment book which was used to record all the details of the patients' visits and the blood book, used to record details of blood taken from patients. [1394] She stated that each year, she started a new treatment book and new blood book and that these were stored in her room at the Centre,

---

[1390] WITN3428001_0009, para 26
[1391] WITN3428001, para 41; and PRSE0000669_0012, para 40
[1392] WITN3428001_1048, para 400(c)
[1393] WITN3428001_1048, para 400(d)
[1394] WITN0629001_0003

ie away from the patient's treatment records.[1395] These unusual record keeping practices were allowed to be operate in the Ludlam controlled centre. They should not have been. She also says that Professor Ludlam operated the centre in a very secretive manner and there was an unspoken rule that none of the staff were to write anything about HIV or AIDS in the medical records of the patient or the treatment book. She says that she never saw anything written about/alluding to HIV or AIDS in patient notes or the treatment book.[1396]

2.9 In response to a GMC complaint made against him GRO-A, Professor Ludlam indicated that records relating to the meeting at which that patient was told of his HIV positive status had gone missing as they had been kept in a separate file from the patient's main records and they had never found their way back into his records[1397]. He also confirmed that other records purportedly relating to whether patients wished to know about their HIV status were kept in separate files from their records. Some were apparently returned to the patient files and others were destroyed.[1398] No such records have been seen by the Inquiry from patient medical records. Again, it appears that these essential records have gone missing as they were not retained as part of the normal record keeping systems.

2.10 A dispute exists between another member of the Edinburgh HIV cohort and Professor Ludlam relating to why he was not told about his infection until 1991 – the patient who gave evidence as "Mark" at the Penrose Inquiry.[1399] Professor Ludlam's position is that the patient did not want to know. The patient's position is that he consistently said that he did want to know if there was any bad news – there was, and it was withheld from him for 7 years. In support of his position Professor Ludlam has in the past relied upon another document, purportedly held in his confidential files, which contains a note of a meeting in 1986 where he documented that the patient did not want to know his HIV status. The patient denied the truth of that assertion and the accuracy of that note. It was not copied

---

[1395] WITN0629001_0005
[1396] WITN0629001_0005

[1397] WITN3365031_001
[1398] WITN3428001, para 400(d)
[1399] WITN2232001

to him or even retained in his records. He had no opportunity to seek to correct it as he did not know it existed. It was kept in a confidential locked cabinet and was only added to the patient records shortly before he replied to allegations in connection with this patient at the GMC.[1400] As part of that complaint, Professor Ludlam referred to having recently (in 2004) added information to the patient's medical records which substantiated his position that he had attended meetings at which he had expressed a desire not to know about his HIV status. Thus, these unusual document storage practices, involving keeping records away from a patient's medical records which could be produced. In this regard and others, the production of these records allowed Professor Ludlam to avoid censure at the GMC for his failure to tell this patient about his HIV positive status. It is highly questionable, in our submission (a) that Professor Ludlam should produce a note of this nature and (b) that it should have the effect when produced not from the patient records of leading to an exoneration before the GMC. We seek below to have the Inquiry recommend that patients to have the right to be involved in the compilation of all medical records relating to them to improve accuracy and fairness. The patient in question was not given access to the documentation produced by Professor Ludlam before the GMC, including the records. In his defence, we understand that Dr Ludlam referred to a Scottish policy relating to telling patient of their diagnosis, not physical copy of which ever produced.[1401] The patient has thus been left completely in the dark about his complaints, other than knowing that they were defeated by documents to which he was not allowed access, some of which were medial noted relating to his care which were not kept in his notes until shortly before the GMC complaint, decades after the events in question. We also seek a recommendation to avoid this in future. Both the record keeping practice of Professor Ludlam and the proceedings of the GMC were unacceptable.

[1400] WITN3365029_001_0155 to _0156

[1401] We understand that the inquiry has access to some of the relevant documentation in connection with the witness statement of Charles Massey (WITN3365001)

2.11 Professor Ludlam and his former colleague Dr Dennis gave evidence to the Inquiry about papers having been held separately from patient records and also about records relating directly or indirectly to patients having been held in separate "archives". The evidence in this regard is complex and is redolent of a system which paid little regard to (a) the need for clear demarcation between paperwork relating to patients being held in those patients' medical records and (b) the possibility that patients may require to access medical information relating to their care at any given time, in particular some time after the events to which the records are related. In his evidence to the Inquiry, Professor Ludlam said that he had arranged for certain "administrative files", which contained mostly administrative documents but which may also have included reference to patients or things that had been misfiled in the Lothian Health Board Archive.[1402] This is suggestive of a system which paid little regard to the need to store records which related to patients in a single place to which the patients in question had access. In this regard, it is unclear when this material was put into the administrative files within the LHB archive.

2.12 There is other evidence about "administrative files" which may cast some light on what they contained, as follows, in particular in the statement of Dr Rosemary Dennis, who worked with Professor Ludlam.[1403] In that statement she referred to files which appear to have been kept separately from patient records but did contain important patient information, directly related to infection, as follows:

(a) When she started in 1992, there was a folder in the haemophilia centre containing paper copies of hep C antibody results. She thought there were also some results of full blood counts and these were subsequently filed in the individual case notes.[1404] This was clearly patient related information.

(b) There were administrative files in the haemophilia centre containing copies of letters and information sent out to people as part of the vCJD notification

[1402] IBI transcript for 04/12/20; 118 (Professor Ludlam)
[1403] WITN4030001
[1404] WITN4030001 @ para 221

process.[1405] In his oral evidence, Professor Ludlam said that absolutely everything sent out in the vCJD notification process was stored in the case notes.[1406] At least at some point during the history of the centre, this appears not to have been the case. This was clearly patient related information.

(c) There was a file containing a list of names of people with hepatitis C to "help with patient care" and to make sure that no patient was overlooked when a new treatment or investigation became available.[1407] This was clearly patient related information.

(d) There were administrative files containing patient details that were used to record information relating to treatment, including information sent to the UKHCDO, infusion and home treatment records dating back many years.[1408] This was clearly patient related information. At para 400 (j) of his statement, Professor Ludlam said that annual returns were held in the haemophilia centre but qualified this by saying that when he retired in 2011 and did not know the whereabouts of the records.[1409]

2.13 Therefore, over and above the information held separately from patient medical records, there was also this other body of evidence which showed that there was patient related information contained in these inaccurately entitled "administrative files". These papers appear, to some extent at least, to have ended up in a Lothian Health Board archive.

2.14 Professor Ludlam also gave evidence about another archive of documents in which records directly or indirectly relating to patients were held. He said that he had an extensive archive which he was careful to preserve due to the catastrophic nature of the disaster.[1410] The retention of these "archives" was a phenomenon which

---

[1405] WITN4030001 @ para 222
[1406] IBI transcript for 03/12/20; 10 (6) to (14) (Professor Ludlam)
[1407] WITN4030001 @ para 223
[1408] WITN4030001 @ para 225
[1409] WITN3428001_1048
[1410] IBI transcript for 02/12/20; 96 (3) to (10) (Professor Ludlam)

appeared unique across the country. It was certainly unique that any individual clinicians would have been given such a responsibility for retaining records which belonged to the of control over the operation of the centre which was inappropriate and which demonstrated a need on his part to remain in charge of all aspects of his patients' care. One thing which was clear was that at the time when these archives were designed, neither Professor Ludlam not the health board appear to have paid any regard to the right of patient to access information about their care. These systems appear to have resulted in information directly or indirectly relating to patients' care being placed beyond the reach of those patients.

2.15 He clearly stated that there were two archives, the LHB archive referred to above about the way people worked in the hospital, containing administrative and not patient related files. The evidence analysed above suggested that the LHB archive did contain patient related information in the incorrectly named "administrative files". He said that after the Penrose Inquiry concluded, he boxed up all the information he had about haemophilia matters, including information about the Edinburgh cohort and the information that he and Dr McClelland had looked at to try to assess what had happened to have caused their infections, and it was conveyed to the Edinburgh University archive (which is where part of the Lothian Heath Board archive is) and which contains material held on behalf of the hospital. He said that the Inquiry would need to ask the hospital about the details of this archive. It is not known whether any such further investigation has taken place.[1411]

2.16 He said that the archive was a health board archive which was held in the university library, that it was extensive and that it should contain the material sent to the UKHCDO, ie information relating to patients.[1412] When he gave his evidence in late 2020, he said that he had gone through the archive before the lockdown[1413] and that it appeared to contain a consent form which was to be used for taking of blood for research purposes.[1414] This form was not produced, as far as we are

---

[1411] IBI transcript for 04/12/20; 118 (22) to 121 (11)) (Professor Ludlam)
[1412] IBI transcript for 01/12/20; 46 (4) to (14) (Professor Ludlam)
[1413] IBI transcript for 04/12/20; 51 (9) to (12)) (Professor Ludlam)
[1414] IBI transcript for 04/12/20; 68 (2) to (9) (Professor Ludlam)

aware but documents of this nature clearly would have related to patients. He then went on to say that he was not sure whether the information that he "boxed up" after the Penrose Inquiry is formally part of the Lothian Health Board archive or whether it was held on behalf of the hospital and that it would be necessary to ask the Royal Infirmary of Edinburgh. The system of document retention appears to have been unnecessarily complex. Both archives contained information relating to patient which ought to have been in their records and available to both them and this Inquiry.

2.17 There is other evidence available to the Inquiry about document storage and retention which appear relevant to the issue of where relevant documentary evidence is kept, as follows:

(a) Consent forms for patients going onto treatment or onto home treatment used by both Drs Davies and Ludlam were kept in a separate file and not in the medical records.[1415]

(b) Professor Ludlam had a record of minutes and other documents at some point, either at the time of his evidence or at the time of the Penrose report.[1416]

(c) Subject to his general caveat, Professor Ludlam said that the RIE computer servers held lab results mostly.[1417] These appear to constitute a separate record from the patient medical records. These could reveal important information about testing dates and information about infection.

(d) Subject to the caveat Professor Ludlam said that individual infusion records, including home treatment records were held latterly on computers at the RIE.[1418] These could be relevant to all sorts of issues relating to patient care.

[1415] IBI transcript for 01/12/20; 137 (21) to 139 (8) (Professor Ludlam)
[1416] IBI transcript for 02/12/20; 43 (11 to 17) (Professor Ludlam)
[1417] WITN3428001_1048, para 400(e)
[1418] WITN3428001_1048, para 400(f)

(e) Subject to the caveat, Professor Ludlam said that "family pedigrees" were held in the centre, also relevant to patients and their care.[1419]

(f) Subject to the caveat, Professor Ludlam said that genetic files were held in the department of haematology.[1420] These many relate to research being undertaken on family members which is discussed elsewhere in this submission.

(g) Subject to the caveat, Professor Ludlam said that lab clotting records were held on the department of haematology computers, which are also patient related.[1421]

(h) Subject to the caveat, Professor Ludlam said that social work, clinical psychology and psychiatric records for patients were held in the departments (presumably in the RIE).[1422]

The fact that all of these records appear to have been kept separately from what would be described as the main patient records demonstrates how shambolic the system appears to have been.

2.18 The issue of missing medical records has had clear implications for patients. Aside from simply being information to which they have entitlement, the lack of accurate and complete medical records has made a major contribution to patient and their families not obtaining important answers to their legitimate questions regarding how patients came to be infected. When records are naturally turned to as what should be an accurate and comprehensive record of what happened in connection with medical care (such as for the purposes of accessing support schemes or underpinning the proof of facts requiring to be established to have a successful litigation), the inadequacies of medical records have meant that people have not been able to take these steps which should have been open to them. When the fact or severity of infection has taken time to manifest themselves (as

---

[1419] WITN3428001_1048, para 400(g)
[1420] WITN3428001_1048, para 400(h)
[1421] WITN3428001_1048, para 400(i)
[1422] WITN3428001_1048, paras 400(k) and (l)

with diseases like HCV with which this Inquiry is concerned) the law recognises that limitation rules should properly be extended as the patient could not have known about the loss he or she had suffered. It would be unreasonable to expect patients to make such legal claims when they could not have known about the loss which they had suffered. However, in such situations such legal protections are of little comfort or practical value where the rights accorded by the law are undermined by the fact of missing or inaccurate records. Generally, when patients have looked back to their records to establish the kind of things which might have been necessary to prove their assertions, be they of negligence or other form of culpability, they have found that the retention systems have failed them. The clear consequence of these failings is that the patient testimony of events is the most reliable version of what happened. The absence of comprehensive, accurate medical records should generally not count against them, whether as regard fact finding within this Inquiry, or in other circumstances.

Beyond Edinburgh

2.19 The Inquiry heard evidence of this being a more widespread problem than just in Edinburgh. In fact, medical records appear not to have been retained efficiently for patients with bleeding disorders across Scotland. Many of the witnesses who have oral evidence to the Inquiry about treatment at Yorkhill Hospital had no medical records from the period. This applied to those who were giving evidence on behalf of children who were now deceased and also those who were still alive.[1423] Some records miraculously appeared which gave some details of treatment received by the deceased boys at Yorkhill shortly before their parents gave oral evidence to the Inquiry. It was not clear how this had happened when records had been sought prior to that and none had been found. One patient who was infected with HIV and HCV as a child at Yorkhill (whose case is discussed in

[1423] John McDougall WITN2850001; WITN2245001, para 3 (first statement of WITN2245 – living Yorkhill and GRI patient infected with HCV)

more detail above as a good example of the treatment regime there) later discovered as part of a US litigation that he had been infected with HIV from a US concentrate in 1981. When he obtained his records he found that certain key records with details of his treatment from around that time had been blacked out.[1424] This is likely to have caused a serious impediment to his progression of that litigation and the proof that the infection had been caused by a particular US product, as opposed to other which he received. There would appear to be no good reason for the records being redacted in this way, other than a desire to create such an impediment to finding out the truth. One widow whose husband died of HCV and was treated only as an adult at the GRI sought his records. She was told that they only exited from 1992 (the year after his diagnosis) when he had been a patient there for many years before that.[1425] He had not moved hospitals. The records had not been completely lost or destroyed. There was no explanation provided as to this apparent anomaly which denied her access to any information relevant to his pre-infection treatment, which was of most interest to her. A patient who had been treated at Yorkhill Hospital in Glasgow as a child in the 1970s and 1980s had been unable to recover his records from his treatment there.[1426] The issue with missing medical records was no one which arose only in more recent times. On being tested for development of his HCV infection in 2002, the father of one witness requested information as to when he had become infected. A search undertaken by Dr Lowe at the GRI (where he had always been treated) was hindered by the fact that records of his treatment for haemophilia B did not exist at that time before 1980.[1427] This was despite the fact that he had moved to the adult hospital for treatment there, as was the case with most Glasgow patients. His mother had submitted treatment sheets from home treatments which were no longer available on request.[1428] Another patient who

---

[1424] WITN2149001, para 3 (first statement of WITN2149); WITN2149004

[1425] WITN2122001, para 11 (first statement of Joyce Donnelly)

[1426] WITN2245001, para 4 (first written statement of witness who would subsequently become known as Mr V). Interestingly, his records were available in part, with certain years missing. No explanation was provided as to why.

[1427] **WITN2314002**

[1428] IBI transcript for 08/06/2019; 89 (3-18) (Mr V)

gave oral evidence found that records of treatment which he had received in Dumfries over the years were missing from his records.[1429] In order to take action of any kind about the treatment and its consequences a record of the treatment received would be necessary. This apparent pattern of treatment records being missing or redacted has a material effect for patients who want or wanted to take action of any kind in connection with infections. No explanation has been provided to the Inquiry as to why this has happened. Possible reasons would include accidental or systemic deliberate removal of these records. Redaction does not happen accidentally. Whatever the reason for this, the NHS has deprived patients of important information about their care. It has had the effect of them not being able properly to formulate questions and have their questions answered about how they came to be infected. Given the central importance of this information to questions about how infections happened and possible fault, the absence of this information has reasonably given rise to suspicion about cover-up and fraudulent removal of information to which the patients have a right.

Wishful records

2.20 One witness from Edinburgh who was infected through treatment he had received for his moderate haemophilia (later defined as mild) told the Inquiry that he was informed of his HCV diagnosis in 1993, though his records showed that there had been awareness of his diagnosis within the unit before that. in the note of the meeting he was described as "unconcerned" and said that he had in fact been hysterical. It seems almost inconceivable that the record could be right. His wife was pregnant which must have caused concern. He states that he was actually told very little about the infection, which is not what is recorded in the note. It is an example of how medical records not intimated to the patient and only to his or her GP can be inaccurate and used as a means of a doctor recording what he

[1429] WITN2148001, IBI transcript for 02/07/19: 61 to 63 (Thomas Griffiths)

wished had been the outcome as opposed to what actually happened.[1430] The case is also interesting for the way in which Professor Ludlam has responded to it as it is typical of the response which he tended to give to criticisms made of him. He stated that the patient's blood would have been tested and he would have been told that he would have had hepatitis.[1431] This is inconsistent with the patient's sworn testimony about his reaction to the diagnosis in 1993 and provides a reason for the note to have been falsified. If he had been told of the diagnosis before he may not have been surprised when it was confirmed. It is contended that it simply cannot be true that he was "unconcerned" when told with his pregnant wife. Professor Ludlam's comments about what he or his parents "would have been told" simply cannot be preferred over the clients' clear and understandable testimony about what he recalls. Dr Ludlam's note and his testimony are inaccurate. It is also worthy of note that in his response Dr Ludlam says at paragraph 16 that: "I am sorry that Mr XX's recollection of knowledge about hepatitis and how it was explained has not left him with a good memory." It is unclear what he means by this. It makes little sense. Whatever it means the suggestion that the witness' position about his experiences do not constitute a good memory seems characteristically dismissive of what has clearly been a devastating experience for the witness, compounded by his experience of how his diagnosis was revealed to him by Dr Ludlam. The apology seems completely false.

2.21 Evidence was available from elsewhere to the effect that inaccurate records were produced elsewhere as well. In Dundee, the daughter of a severe haemophilia B patient who is now deceased has provided a detailed analysis of her late father's medical records relating to issues surrounding the delay in her father being informed of his HCV diagnosis, a common theme at the Dundee centre. Her detailed analysis of her father's records, the fact that the delay appeared to have been, the fact that they discussed the position when he was eventually diagnosed in 1996, that he engaged in correspondence about it in 199, that he recounted his experience and discussed it at the time of the Penrose Inquiry and the fact that he

---

[1430] WITN2274001, para 6 (first statement of witness WITN2274)
[1431] WITN3428047, para 8 (response of Professor Ludlam)

came from a family of haemophiliacs who all has and discussed their similar experiences are all factors which render her account more reliable. She is clear that her father and uncles were given little information about their infections in 1996. The records suggests that they were which she rightly disputes.[1432]

3. Ethical and legal rules relevant to treatment

a) Ethical rules about patient autonomy

3.1 The ethics group report spelled out that one of the 4 principles of biomedical ethics was patient autonomy in a text which was written in 1979.[1433] Despite this, the ethics expert group based a lot of their analysis on the rules imposed on medical professionals by the law. It is submitted that this would be an incorrect approach to take to the determination of what ethical principles governed or ought to have governed the practice of medical professionals over the period in which the infections with which the Inquiry is concerned were occurring. The law of negligence is designed to prescribe situations in which money should be payable by way of compensation for loss occasioned due to medical action or inaction. The standard applied is deliberately difficult to establish due to the need to protect doctors who are medically innovative by precluding suit in circumstances where they adopt non-standard procedures which have a rational basis. The law does not recognise the availability of damages on certain situations on a policy basis. This may be due to the fact that the law deems as a result of a policy decision that damages should not be available.[1434] This does not mean that the conduct involved

---

[1432] WITN2087001 @ para 14 (first written statement of WITN2087)

[1433] Ethics expert group report, page 4, under reference to Beauchamp and Childress "Principles of Biomedical Ethics"

[1434] See *Shaw v Kovac and Anr [2017] EWCA Civ 1028 per LJ Davis @ paras 56 to 57 and 58 to 74 (Court of Appeal); and Diamond v Royal Devon & Exeter NHS Foundation Trust [2017] EWHC 1495 (QB) per HHJ Freeman at paras 54 to 60* (damages for breach of autonomy per se as informed consent not properly taken were not available). See the fact that breach of autonomy does not sound in damages per se.

does not fall short of the ethical standards which one would expect and by which doctors are bound. It is submitted that the rules of ethics which governed and govern medical practice are designed to try to maintain principles which guide the doctors towards doing the right thing. This is a different standard. The rules of ethics are not the manifestation of a legal duty but a moral duty, amongst other things to act in the best interests of the patient at all times. The Inquiry ought not to be confused by the standards of the law in seeking to determine whether there have been breaches of those moral duties on the part of the medical profession evident in the blood contamination disaster and by extension on the part of the State. However, as the law also seeks to determine what is right and wrong (with an added policy element determining what policy should apply to who should receive damages), the law is also relevant in the determination of what ethical principles were or ought to have been. The approach of looking at legal authorities which was adopted by the expert ethics group was thus appropriate with the caveat that the former should not just be assumed to be the same as the latter

3.2 The expert ethics group explained in its report that respect for patient autonomy had always been a cornerstone of medical practice, though they stated that though it had been strengthened, has it ever been ethically acceptable to afford patient autonomy no respect.[1435] It must therefore have never been ethically acceptable to afford patient autonomy no respect. They described the attitude to medicine previously as having been "paternalistic". The use of that adjective in this context is, as is submitted elsewhere, not appropriate. In any event, it has tended to be used as a free pass to explain and justify any conduct, as if there were no ethical rules and no protections for patients who wished to have a say in their own treatment and care. This is simply not the case and though the clarify and precision with which rules about autonomy have been expressed in ethical guidance, the moral duty to allow the patient informed involvement in his or her own treatment has always underpinned those precise expressions. BMA guidance from 1980 stated that consent was valid which was freely given if the patient understood the nature and consequences of what is proposed. Importantly in the current context,

[1435] Ethics group expert report, page 2(2)

assumed consent or consent obtained by undue influence was valueless. There are numerous examples of assumed consent in the treatment of haemophilia patients in the evidence heard by the Inquiry. The onus was on the doctor to see that adequate explanations about proposed treatments were given.[1436] In addition, obligations were imposed with regard to storage and access to clinical information, including an obligation to secure kept in secure place. In a research role, a doctor was responsible for limiting disclosure medical information to the extent that consent has been given., pre-supposing that consent had been given to the research. [1437] A doctor had duty to ensure that storage systems were secure and confidential.[1438] Ethical obligations based on the importance of trust and the importance of good communication were also imposed. [1439] The guidance indicated a move towards individual responsibility for health and deciding when to come for treatment should be encouraged but only where the patient is "accurately and responsibly informed".[1440] This had at its the essence the fundamental requirement of patient autonomy.

3.3 The concept that the system of medical ethics requires specific expression in the contexts of blood transfusion and/ or infectious disease is not well founded. The fact that the BMA's "Good Medical Practice" did not exist until 1995[1441] did not mean that there was no system of medical ethics before that time. This is why the ethics expert group urged the Inquiry to judge the actions of the part my moral normal which were known to exist as opposed to by specific rules.[1442] The group also urged the Inquiry that it was important that the development of policy relating to ethics should involve all relevant stakeholders.[1443] It is important to note that patients were not generally involved in the formulation of such rules, though they were the group for whose interests the rules were designed. As such we would agree with the group that the system certainly wronged patients by not

---

[1436] BMA 1980 Guidance (BMAL0000087), para 1.8
[1437] Ibid, para 1.19
[1438] Ibid, para 1.21
[1439] Ibid, paras 2.5 and 2.8
[1440] Ibid, para 5.42
[1441] Ethics expert group report, page 5
[1442] Ethics expert group report, page 7
[1443] Ethics expert group report, page 8

allowing them to be involved in or understand the rules which were designed to protect them, as the result of that was that they could not know (other than by their own inherent moral code) when the rules were being infringed.[1444]

3.4 In any event, guidance available at the time of the infections in the blood contamination disaster makes it clear that the fundamental principles of medical behaviour had remained unaltered. The fundamental principles of medical ethics which have were listed by the ethics expert group in their report thus predated any confiscation in the post HIV period.[1445] The requirement to act in the best interests of the heath of the patient is enshrined in the obligation not to give any deadly medicine which is part of the Hippocratic Oath.[1446] That the health of patient is first consideration of the doctor is part of the Declaration of Geneva.[1447] The requirement to seek the professional opinion of others in the treatment of patients is a part of the International Code of Medical Ethics[1448] as is the need to contact BMA for ethical advice.[1449]

3.5 The World Medical Association Declaration of Lisbon relating to the rights of patients was adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981. It recognised that even if there may be practical, ethical or legal difficulties, a physician should always act according to his/her conscience and always in the best interest of the patient. The centrality of morality and the primary of the patient in medical practice were thus re-emphasised. The Declaration claimed to represent some of the principal rights which the medical profession sought to provide to patients. It provided that whenever legislation or government action denied these rights of the patient, physicians should seek by appropriate means to assure or to restore them. The patient was declared to have the right to accept or to refuse treatment after receiving adequate information. Patients had the right to have things explained in a way they could and understand and have their own views taken into account. In research, the doctor needed to

---

[1444] Ethics expert group report, page 9
[1445] BMA 1970 guidance (BMAL0000085); BMAL0000085_0003
[1446] BMAL0000085_0003
[1447] BMAL0000085_0004
[1448] International Code of Medical Ethics at page 5
[1449] BMAL0000085_0010

be scrupulous about explaining nature of their role to the patient, in particular if he or she also had a therapeutic relationship with the patient.[1450] The importance of communication was stressed.[1451] Telling, explaining and listening was required. The patient was entitled to information about their condition and to be given it unless there are compelling reasons not which would require to be defended, including access to medical records. Also, the importance of communication between doctors was emphasised. It was emphasised that legal obligations are much less than moral or ethical obligations and that what was legal may not be ethical.[1452]

3.6 As regards the possibility of information derived from the patient being passed to third parties, such as for the purposes of medical research, the clear primary of the obligation of confidentiality to the patient was clear. The BMA Guidance of 1980 a recognised a distinction between different types of relationship between doctor and patient, including therapeutic and research. It recognised duty on the doctor to tell the patient in whose interest the doctor was acting. If the doctor normally acted on a therapeutic basis and started acting in a research capacity, the doctor required to explain nature of change of relationship should be carefully explained. Most scrupulous care was required to avoid harm to therapeutic relationship.[1453] A doctor was generally responsible to a patient for security and confidentiality of information in all three types of relationship.[1454] The doctor required to preserve secrecy on all he knew about the patient, with exceptions including (3) overriding duty to society and (4) for medical research approved by the chairman of the BMA Central Ethical Committee or his nominee.[1455] Other sources spelled out the need for attention to be paid to maintaining the primacy of the therapeutic relationship in such circumstances. The requirement for

---

[1450] Page _0017
[1451] Page _0019
[1452] Page _0036
[1453] BMAL0000087, page 9
[1454] Ibid, para 1.5
[1455] Ibid, para 1.6 – the exception would seem to be limited to those situations where the BMA central ethics committee had given approval. Limited local ethics committee approval, the nature of which was often shrouded in secrecy and appears to have been subject to no scrutiny was often used as a pass for any such research

confidentiality and not passing information about patient on to others was clearly spelled out.[1456] The requirements of confidentiality seem to be paramount from this guide - "The Council places the highest possible importance on the maintenance of professional secrecy".

3.7 It has submitted that it has always been the position that patient has had the right to choose for themselves as a matter of law, at least since the 1970s whether to undergo any treatment involving the violation of their physical integrity if they were of sound mind. The law has recognised a right to self- determination against a positive act for a long time. It was and is a right.

3.8 An early manifestation of this was Decision issued by the New York Court of Appeals in 1914, Schloendorff v. Society of New York Hospital, 105 N.E. 92 (N.Y. 1914). Some weeks into the claimant's stay at the hospital in 1908, the house physician diagnosed a fibroid tumour. The physician recommended surgery, which the claimant adamantly declined. She consented to an examination under ether anaesthesia. During the procedure, the doctors performed surgery to remove the tumour. Afterwards, the claimant developed gangrene in the left arm, ultimately leading to the amputation of some fingers. Justice Benjamin Cardozo wrote in the Court's opinion:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."

3.9 Thus, the principle of personal autonomy in medical treatment has even been a cornerstone of civilised legal systems for over a century. Similarly, in *S v S [1972] AC 24,* an issue arose as to whether a blood test should be taken from a child

[1456] Hippocratic Oath at page 4; Declaration of Geneva at page 4; International Code of Medical Ethics at page 5; BMAL0000085_0009

regarding a question of legitimacy. Lord Reid expressed the following view (emphasis added):

"I must now examine the present legal position with regard to blood tests. ***There is no doubt that a person of full age and capacity cannot be ordered to undergo a blood test against his will.*** *In my view, the reason is not that he ought not to be required to furnish evidence which may tell against him. By discovery of documents and in other ways the law often does this.* ***The real reason is that English law goes to great lengths to protect a person of full age and capacity from interference with his personal liberty.*** *We have too often seen freedom disappear in other countries not only by coups d'etat but by gradual erosion: and often it is the first step that counts. So it would be unwise to make even minor concessions. It is true that the matter is regarded differently in the United States. We were referred to a number of state enactments authorising the courts to order adults to submit to blood tests. They may feel that this is safe because of their geographical position, size, power or resources or because they have a written constitution. But here Parliament has dearly endorsed our view by the provision of section 21 (1) of the Act of 1969. But the position is very different with regard to young children.* ***It is a legal wrong to use constraint to an adult beyond what is authorised by statute or ancient common law powers connected with crime and the like****."*[1457]

3.10 Further, *Airedale NHS Trust v Bland [1993] AC 789 (HL)* was a case in which the court was asked to make a declaration that life support could be discontinued for a patient in a permanent vegetative state after injuries suffered at the Hillsborough disaster. Lord Goff said:

"First, it is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect

---

[1457] *S v S [1972] AC 24* @ 43 per Lord Reid

to his wishes, even though they do not consider it to be in his best interests to do so...

I wish to add that, in cases of this kind, there is no question of the patient having committed suicide, nor therefore of the doctor having aided or abetted him in doing so. It is simply that the patient has, as he is entitled to do, declined to consent to treatment which might or would have the effect of prolonging his life, and ***the doctor has, in accordance with his duty, complied with his patient's wishes."***

3.11 Thus, in order to meet with this legal standard, the wishes of patient always need to be ascertained clearly and consistently and the patient has the absolute right to choose whether to undergo treatment, even if the clinician deems the treatment to be beneficial or not.

3.12 In order to achieve similar aims to these legal rules, the expert group opined that there is a requirement for consent to be dynamic and responsive to the patient's health, needs and views.[1458] This means that a doctor cannot take "consent" at the start and assume it applies to everything as interventions and attitudes may differ and change over time. In this context, the Inquiry heard a good deal of evidence about the assumption applied to the care of chronic bleeding disorders that large amount of blood were taken or that treatments were changed without taking the specific consent of the patient. This was based on an assumption that the previous consent would continue to apply, which was not dynamic and hence not ethical. It was also clarified by the group that consent cannot be implied to a new procedure even if is based on what the doctor perceived to be good for the patient.[1459] We submit that in taking valid consent, it must also be an ethical obligation to inform the patient or the parents that a recommended treatment is not the universally recommend by medical professionals. For example, in relation to prophylaxis in the treatment of children in the 1970s or the use of commercial concentrates at Yorkhill Hospital in Glasgow, where other doctors would advocate the use of domestic ones, those responsible for decision making (the children and/ of the

[1458] Ethics expert group report, page 13
[1459] Ethics expert group report, page 14

parents) ought to have been informed that that was the position. As a result, decisions could have been taken on an informed basis. As is submitted elsewhere, in that situation a parents' group existed at which questions of that nature were asked. It is submitted that this created an even more pressing obligation to provide the accurate information about this practice being unusual in response to direct questioning on the subject.

3.13 An important corollary of these requirements (it is submitted) is that there was an ethical obligation on the doctors to provide information directly to the patient or the parent, in the case of children. The Inquiry has heard frequent evidence from medical professionals about their use of organisations such as the Haemophilia Society as a proxy for the fulfilment of their obligations to provide information to patients, either by providing information to the Society and assuming that that would then be transmitted to patients/ parents or simply providing material from the Society to patient/ parents.[1460] This cannot be said to have complied with the clinicians' duties to provide information about risks and benefits to patients, not least based on the fact that such practices were based on an assumption that the recipients were members of the Society (which they were not or the clinicians could not have known) and also involved no tailoring of generic information to individual cases.

3.14 Literature confirming the importance of these ethical principles, irrespective of the legal standard in place has existed since before the time that most of the infections with which the Inquiry is concerned occurred. One such paper is a "Medical Defence Union, Consent to Treatment pamphlet from 1971.[1461] This paper focuses on the ethical requirements relating to consent in surgery but we submit that certain more general ethical principles can be derived from it. The document contemplates that consent for surgery was required and that there were even operations which carried a special risk for which written consent had to be obtained.[1462] Consent is not merely defined in the abstract as it was required that

---

[1460] See for example the reliance placed on these by Professor Lowe - paras 37.3.12 and 37.4.2 of his second statement at WITN3496013

[1461] MDUN0000057

[1462] MDUN0000057_0002

consent be fully and freely give and there was a requirement to explain the procedure in non-technical language, implying that the surgeon requires to ensure that the patient understand the language in which the operation is described for informed consent to be obtained.[1463] Further, there was a requirement that the information be imparted by the medical practitioner.[1464] Thus, relying upon leaflets or consent forms, in particular those produced by other organisations would not have been ethically acceptable, even in 1971. The corollary these rules must be that the patient be given time to digest and assimilate information contained in consent forms or other informative material, including that disseminated to them orally by their doctor as without such rules, the dissemination of essential information would not be effective. All of these specific measures are consistent the ethical duty on a doctor to act in a way which inspire and fosters trust.[1465] Secrecy does not inspire trust.

3.15 It is submitted that there has always been an obligation to identify a patient's values, wishes and preferences, as referred to in the ethics expert group report.[1466] This is at the very heart of any system which respect patient autonomy. An individualised approach is necessary as otherwise a doctor would be assuming what was best for the patient, which would be to negate autonomy. It is submitted that these obligations to inquire as to the patients' treatment preferences must apply *a fortiori* where the patient is being treated for a chronic problem like a bleeding disorder. This is because in such circumstances, the obligation to maintain trust applied to a greater extent based on the chronic nature of the condition. Further, most such patients were expected to play an active role in their treatment. For example, they were expected to present regularly for treatment and review at hospital, give regular blood samples, in some cases to treat themselves at home and keep records of their treatment. Further, the ethics expert group gave a good deal of evidence about the ethical rules which might

---

[1463] Ibid
[1464] Ibid
[1465] See 1980 BMA Handbook of Medical ethics at BMAL0000087_0015 on the importance of trust to the doctor patient relationship and the resistance of outside pressure in the treatment of the patient
[1466] Ethics expert group report, page 50

differ in emergency situations. The chronic care situation differs from this in that there is and was generally time to make decisions about treatment as opposed to being time sensitive. Thus, reflection and advice were usually possible. This also applied to parents of child patients. As a result, patient and parents had and were expected to have a good deal of knowledge about their conditions. The system was designed to be a partnership in which one of the partners was not treated with respect or kept informed. This was clearly destined to failure. In such circumstances, failures in communication on the part of doctors ethical breaches in themselves, contrary to contemporary ethical guidance.[1467]

3.16 As regards testing of patients, contemporary rules suggested that testing without explicit consent should not happen. The Inquiry has heard about the practice of general information was given about the fact that blood taken would be used to test for factor VIII levels but no information being provided about testing for ALT/ AST levels. The normal also appears to have been to test for viral infection without patient knowledge of consent. The literature available to the Inquiry includes a requirement before undertaking screening to be convinced of the reliability of the test and that the patient wishes to know of his status.[1468] This implies the need to have explicit consent as one would have had to have discussed the patient's position about wanting to know the result with the patient before testing. It also implies that the patient would automatically be told the result of a test – that is why the doctor would need to know if the patient would like to be told before testing as if the test were done, the patient would have a right to know. This is also why the doctor would need to be assured as to the reliability of the test as if he was not so convinced, it would be difficult to know what to tell the patient about the meaning of the result. It is questionable whether indirect testing of ALT levels or testing with the original anti-HIV tests (undertaken by Dr Tedder and others) could be said to have been tests which would have inspired confidence in their accuracy. The very fact that it was not known precisely what a positive result

[1467] See 1980 BMA Handbook of Medical ethics at BMAL0000087_0015 to 016 on the importance of good communication in maintaining trust

[1468] See 1980 BMA Handbook of Medical ethics at BMAL0000087_0025 and 0026

meant was prayed in aid as a reason for patients not being told. This was an unethical practice in light of these contemporary rules.

3.17 It should be borne in mind by the Inquiry that the ethics expert group often referred to past practices with regard to patient autonomy. On occasion, it seemed that these might be taken as an endorsement of those practices as opposed to merely a historical account of their occurrence. If they were designed to be an endorsement of practices, they ought not to have been in light of the importance to medical practice of patient autonomy and the texts quoted here which suggested that these are also part of clear contemporary ethical guidance. As regards patient involvement in testing, one passage in the expert report, a paper was relied upon as being a basis for asserting that historically people were not necessarily even told of a cancer diagnosis.[1469] On closer inspection, the paper by a psychotherapist who discourages the practice of not telling patients about their diagnosis. In fact, it embodies common sense, patient orientated thinking in 1982, before the emergence of the full implications of the HIV crisis. It described the worst kind of lying to the patient as being the use the statistical analysis, not refined to the patient's own particular situation, to justify better prognosis.[1470] Not telling a patient about testing or the result of a test is described as really just the doctor projecting his or her own belief system onto the patient.[1471] The paper relays an illustrative anecdote about a patient having had blood test and being told that he had leukaemia, after which he had bad reaction as did not know why he had been tested.[1472] This serves to highlight the importance of keeping a patient (or a parent) informed about all testing so that bad news can be broken in the most compassionate and supportive way. In this regard, we refer the Inquiry to the evidence of the Yorkhill parents being informed at routine clinics or in even more informal settings (such as in a corridor) sons' HIV diagnoses without support, the lack of clarity about the message being conveyed at the Edinburgh December

---

[1469] Ethics expert group report, page 64; The Goldie paper – "The ethics of telling the patient" Journal of medical ethics, 1982, 8, I28-133
[1470] The Goldie paper, page 1
[1471] The Goldie paper, page 3
[1472] The Goldie paper, page 2

1984 meeting and the effects on the Dundee haemophilia patients of not being told about their positive anti-HCV tests or years after they were performed, all of which occurred, in part at least, due to the fact that testing had been carried out without their knowledge or consent. The author points out that the then current medical training method about repetition of what others may have been appropriate for the physical but not for the psychological.[1473]

3.18 It is also important that it be noted clearly by the Inquiry that the duty of the patient comes first and that if there is any suggestion that the harm or the positive test result has occurred due to treatment that that be acknowledged.[1474] This is fundamentally important to the Inquiry's assessment of the way that the State has approach the consequences of the blood contamination disaster. As has been pointed out by the liked of Andy Burnham and Jeremy Hunt, the State has closed ranks around a lie to protect the NHS and the government from exposure to the fact of such widespread infection. This was clearly unethical. This was confirmed by the ethics expert group who had it clear that there was an ethical obligation for recognition of what happened, openness and accountability and an attribution of responsibility when things went wrong in medical care. In this case, there was not only a failure to achieve these ethical requirements (on the part of the medial professional and the State) but a concerted attempt to make sure that these things could not be achieved.[1475] Professor Farsides gave clear evidence on the importance in ethics of being aware that once you have wronged someone, there remains a distinct possibility that you may harmed them in the way that you deal with that situation.[1476]

3.19 The ethics expert group stated in their report that the duty of candour was "less well defined" in the past.[1477] It is submitted that as with the other ethical duties defined above, this does not mean that they did not exist, merely that they were not so precisely and voluminously defined as they might be now in professional

---

[1473] The Goldie paper, page 3
[1474] Ethics expert group report, page 79
[1475] Ethics expert group report, page 9
[1476] IBI transcript for 26/01/21; 56 (Professor Farsides)
[1477] Ibid

guidance. These duties have always existed. Importantly, it is also reported by the ethic group that the poor observance of the duty of candour was based on fears of litigation.[1478] Again, this merely provides a factual explanation as to why the rule was not observed. It does not support the assertion that it did not. Honesty, patient autonomy and the best interests of the patient have always been at the heart of medical ethics.

3.20 In the treatment which was selected for these patients (at least in some cases), in the lack of involvement in decisions about their own treatment, in their testing without knowledge or consent and in their not being informed about their infections or risks or implications, the medical profession generally failed in these duties, as did the State in allowing these things to happen. The extent to which these failures were contributed to by the interest in research being derived from these patients (again without their knowledge or consent) is considered below.

3.21 As regards medical research, the 1980 BMA guidance made it clear that the law on professional negligence and assault was minimum standard and it was not enough that that was complied with.[1479] It was made clear that it was the rules relating to ethics which protected the patients in research and therefore not the law.[1480] Subjects' interests must come first. A doctor required to have consent for controlled clinical trials on value of therapy [1481] and a patient had to have the right must to withdraw.[1482] In addition, it was unethical to carry out research on prisoners if of there was no direct benefit to the individual.[1483] It is submitted because it was known that this could be unlikely to be voluntary.

b) Ethical rules about medical research

[1478] Ibid
[1479] Para 4.1
[1480] Para 4.4
[1481] Para 4.4
[1482] Para 4.5
[1483] Para 4.7

3.22 Rules governing medical research clearly existed before the blood contamination disaster. The suggestion that it was ethical for such research to be carried out without fully-informed patient consent in the 1970s and 1980s is clearly incorrect. That such research took place at that time without that consent being obtained constituted a clear violation of important ethical principles and the respect which required to be given to patient autonomy and dignity.

3.23 It is worthy of note that the tenets of the Nuremberg Code set out clear ethical principles which were designed to cover human experimentation in light of the atrocities of the Nazi regime during WWII. The following provisions, in our view, set clear ethical standards, contrary to what the Penrose Inquiry concluded. In our view, the following provisions of the Code are worthy of note in the context of the provision of blood products to bleeding disorder patients in Scotland:

1. *The voluntary consent of the human subject is absolutely essential.*

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. *The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.*

3. *The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.*

4. *The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.*

5. *No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.*

6. *The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.*

7. *Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.*

8. *The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.*

9. *During the course of the experiment the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state where continuation of the experiment seemed to him to be impossible*

3.24 The Declaration of Helsinki (Recommendations guiding medical doctors in biomedical research involving human subjects) was revised by the 29th World Medical Assembly, Tokyo, Japan, October 1975. The ethical principles within the declaration were therefore in place over much of the period with which the Inquiry is concerned and during which infections occurred. Its original version was signed

in 1964. The document states that in the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.[1484] Nevertheless, both are recognised as research and were and are governed by certain fundamental rules and principles.

3.25 Paragraph 2 provides that "The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance". Paragraph 3 provides that the responsibility for the research lies with the medical practitioners and not the subject "even though the subject has given his or her consent". Consent is therefore at the heart of the ethical rules relating to medical research. The reason for this is clear. The fundamental and predominant responsibility of the medical practitioner is for the patient. It is only if the patient has properly and fully consented to his or her involvement that there can be no room for the research itself to take priority over that fundamental priority. This is why paragraph 5 provides that:

> "Concern for the interests of the subject must always prevail over the interests of science and society".

3.26 Paragraph 6 provides that the right of the subject to preserve his integrity must be respected. In terms of paragraph 8, results of research conducted otherwise than in accordance with the principles in the Declaration should not be accepted for publication. Paragraph 9 again reiterated the need for informed consent of the subject to participation and that the subject must have the right to abstain from involvement and to withdraw. A preference is expressed for the free consent of

---

[1484] 1975 Declaration, page 1

the subject to be obtained in writing. In paragraph 10, there is a clear additional obligation places upon doctors when the subject was in a medically dependent relationship with him (or her) as bleeding disorder patients invariably were. In such cases, consent should be taken by a doctor not involved in the research or in the care. Paragraph 11 provides that consent from guardians should be obtained where the subjects are minors or lack capacity – at least the Edinburgh cohort research (see below) involved 2 children, whose parents were not consulted about consent, as far as evidence available to the Inquiry shows. All of these principles apply to all types of research, whether associated with care or not. The evidence available to the inquiry is clear. Few if any of the requirements of the Declaration were respected in research carried out on subjects in Scotland in the bleeding disorder community. The desire to use these subjects to ascertain information about disease for publication clearly outweighed the interests of the subjects, who were usually in ignorance that they were part of the research, as they were.

3.27 In the evidence provided to the Inquiry the government took the view that ethical matters were for the clinicians and not the government.[1485] This proposition is shown not to be correct, given that the government entered into obligations relating to ethical matters and so was bound by those principles. For example the International Covenant on Civil and Political Rights, adopted by the General Assembly of the United Nations on 19 December 1966, article 7 of which provided that "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." The government was wrong to abrogate its responsibility to the medical profession in this regard. In the pursuit of its statutory duty to protect the interests of patients, the government should have made sure that ethical rules were respected. Their failure to do so, in the accordance with the anarchic concept of "clinical freedom" endangered patient safety.

[1485] Witness statement of Diana Walford (WITN4461001) @ para 63.4(i)

4. Treatment of those with bleeding disorders in Scotland

a) National background – the UKHCDO

4.1 The UKHCDO is an was an unelected organisation of haemophilia doctors. It served as a basis for discussion and for information about haemophilia care being generated and disseminated amongst professionals. It met in general session but also in meeting of its most senior member, the reference centre directors who we its most influential individuals. Its operated somewhat as an unaccountable club of core senior medics, many of whom had trained together. It appears to have had little system for dissent/ discussion beyond the views and priorities of these key senior members. As an organisation, its origins were closely wedded to research and the collation of information about diseases. It was formed by the MRC, a research organisation. Its members were predominantly pathologists, trained in the science of the causes and effects of diseases. As such, it had an existential tension between its two main aims, the treatment of blood related conditions, including haemophilia and the investigation of the nature of disease. Typical members included Professor Ludlam. He had trained under the UKHCDO Chair for most of the material period and key government advisor, Professor Bloom in Cardiff before he became the centre director in Edinburgh. He had been an MRC junior research fellow in the 1970s.[1486] Professor Lee described a new role which she took which combined the laboratory and clinical roles of a consultant and which was akin to the position (as it had always been) in Scotland, as follows:

"And at about that time -- previously, haematology had been within pathology, had been a pathological discipline, but now we were moving to a situation, actually

[1486] Para 441 of first witness statement of Professor Ludlam (WITN3428001)

like Scotland had always had, where the haematologist was a clinician and a laboratory person. And I had to change that hospital laboratory to that."[1487]

4.2 Thus, those who were in the generation above Professor Lee, including Professor Bloom, who had trained her and the like of Dr Ludlam were not patient orientated by training. They were laboratory based, interested primarily in research and investigation.

4.3 The UKHCDO was the basis for the systemic problem about all of the advice being provided to government and those in a position to make decisions being the same people. Though it may have been the case that it appeared that advice was being disseminated from multiple "experts" on treatment regimes, in fact the committees all tended to include the same few people, who also happened to be the people who instituted regimes for the provision of information to patients. This meant that decision makers and patients decision makers and patients did not benefit from a range of informed opinion but in fact were subject the opinion of a self-selected few, with Professor Bloom at its head.

4.4 In any event, the UKHCDO as being the organisation which provided advice to government about the emergence of viral threats was not appropriate. The advice being taken from the UKHCDO was focussed on the importance of maintaining treatment regimes directed at helping the bleeding conditions of the patients. As is argued elsewhere in this submission, this focus on the benefits for the bleeding turned a blind eye to the risks either present or likely to emerge. Insufficient consideration was given to the virological threat from those experts in virology and an epidemiological analysis of how the disease which were known or were suspected to be spread by the diseases transmitted by blood products. See the Mark Winter analysis of the "golden interval" in the treatment of those with bleeding disorders in the period from around the mis 1970s to the emergence of AIDS in the early 1980s. It was during this period that the aggressive treatment regimes were seeded in the treatment of those with bleeding disorders in the UK.

[1487] IBI transcript for 20/10/20; 27 (Professor Lee)

It was at this point that the "concentrate juggernaut" was allowed to start rolling down the hill. That juggernaut was let go without adequate safety regimes. This was because, as Dr Winter set out, it was perceived by those who wished to take advantage of the benefits of factor concentrates in the treatment of patients with bleeding disorders against a perception that the risks had been eliminated. This was a false perception. The main risk of the products which had existed before that time was the risk of the transmission of hepatitis B.[1488] It was erroneously considered by those involved in the treatment of bleeding disorders in the UK that that problem had been eradicated when it had not. The ineffectiveness of screening techniques in the attenuation of hepatitis B is addressed elsewhere in this submission. Further, there was a dangerous lack of consideration of the known unknown risk of disease transmission. The epidemiological history of the use of blood products, in particular industrially produced factor concentrates, in the treatment of those with bleeding disorders was that (a) diseases would emerge in the donor population periodically which may or may not turn out to be serious and (b) diseases which were transmitted by blood (such as hepatitis B) could lead to chronic disease which would not manifest itself until long after the infective event, meaning that information gleaned about the health of the recipient at around the time of the product being administered was unreliable in predicting the long term effect of the product. This latter phenomenon made an approach to the threat posed by potentially transmissible, harmful agents based on tracking the incidence as opposed to the risk of the products all the more inappropriate. Such an approach was always destined to be inaccurate. A more proactive approach was mandated by the history. The concentrate juggernaut was unleashed without adequate safety mechanisms. When those known risks materialised, nothing could be done to stop it.

4.5 This approach to relentless march of concentrate therapy by those in control of the treatment of bleeding disorders in the UK constituted a form of Russian roulette for the patients.

[1488] See the Cash paper on factor IX usage in Edinburgh which refers to the "perennial problem of hepatitis B"

4.6 Little consideration appears to have been given to the potential risks of inherent in the products themselves, irrespective of the risk of disease transmission. The emergence of the threat from (i) antigen overload, the accumulated risk of exposure to huge amounts of protein in itself and (ii) pathogenic overload, even of the pathogens contained in the products were not thought to be harmful per se in a post transfusion situation. What thinking was done about these things before the concentrate juggernaut was unleashed?

4.7 There was little if any proper oversight of the way in which the haemophilia clinicians/ the UKHCDO made decisions about these matters. Perhaps thought that the UKHCDO was a body which oversaw the activities of these clinicians but, in fact, it was just a collective of those clinicians themselves. Haemophilia clinicians and the UKHCDO able to make decisions without oversight by any regulator, other branches of the medica profession and apparently fear of reprisal.

4.8 The UKHCDO was an organisation which was set up to conduct research as an arm of the MRC. Haematologists involved in haemophilia care were pathologists and not physicians. Those who gravitated towards the treatment of those with bleeding disorders were in effect laboratory doctors who were interested predominantly in , many held laboratory positions as well as their responsibilities for clinical care. Many held academic positions. Many were involved in research. In addition to the fact that many had responsibilities beyond the care of haemophilia patients (such as the care of leukaemia patients), the amount of time and effort which the system enabled the physicians, most of whom held strong research and academic interests, to invest in their haemophilia patients was limited.

4.9 The research based origins of the UKHCDO are important. They are consistent with the general attitude held by its members that the treatment regime which had been instituted had given the patients a life or a chance at a life which would otherwise have resulted either in early mortality or a life blighted by serious joint damage. The traditional view haemophilia patients which prevailed was that they were "cripples" who owed their lives to the NHS which has saved them. This context is a key to understanding the attitude which the clinicians took to their patients and the MRC/ UKHCDO had taken to patients with haemophilia from the

outset. Even those clinicians who were more patient orientated and less research focussed operated within that system, a system which undervalued and dehumanised the patients. An outstanding example of the prevailing attitude towards the patients was the way in which the boys at Treloar's were treated. Though the treatment received by the boys at that residential school occurred outside Scotland, it is illustrative of the dehumanised status which patients which was attached to haemophilia patients. The beneficiaries of the miracle treatment which had given them as chance of a life which they would not otherwise have had (and in the case of the Treloar's boys, many more social and educational benefits in addition) the boys at Treloar's and their parents, like other bleeding disorder patient around the country, were not viewed as him and beings with a vested autonomous right to participation in their treatment, but as a group of patients in dent to the system. It was not therefore incumbent upon the NHS (the creditor) to seek to treat them as normal patients had a right to be treated. The reward which they received was life. The price for that reward was to be stripped of their humanity, their right to make decisions about their treatment, the right to make decisions about their participation in research, the right to be kept informed fully and promptly about when they had been exposed to danger. The price they paid was disease. Inherent in the origins of the UKHCDO, as self-appointed and self-policing organisation, was a realisation that a group of patients who were so in debt to the health service could be the source of what the MRC and the laboratory based pathologists who took charge of their care wanted the most – medical information about disease readily available from a compliant and silent group of patients readily willing to put their faith in a group of doctors whose power over them was absolute.

4.10 Thus, factor concentrates were viewed by those doctors as a treatment necessity. This was an inaccurate characterisation of their value. As is explored elsewhere in this submission, that the doctors by and large did not question the necessity of the treatment regimes upon which they (and not the patients or their parents) decided was a fundamental flaw in their approach. It meant that the doctors (illegitimately) felt that they were justified in turning a blind eye to the risks which they clearly ought to have known were inherent in every product which they

administered, whether produced domestically or abroad. It meant that they did not feel bound by ethical considerations such a patient autonomy. After all, how could a patient have a right to take an alternative view of his treatment when the treatment was so necessary for the sustenance of life itself? It meant that attention was not paid to the emerging information about the risks, either of NANB hepatitis or of AIDS. It meant that a blind eye was turned to the threats. It meant that a culture emerged based on the faith placed in the all-healing power of the concentrates was unquestioned and ever more mild patients were exposed, patients for whom, on a proper assessment of the risks and benefits ought never to have been exposed to them at all but whose exposure provided the collateral benefit of unique research information about the disease which they would inevitably transmit. See Edinburgh as being an example of a place where that was challenged and mostly cryoprecipitate was used until the arrival of Professor Ludlam in late 1979/ early 1980. Elsewhere, the unquestioned adherence to the necessity of concentrates was the norm.

4.11 The systematic nature of this treatment regime based on total adherence to the principle that factor concentrates were necessary led to the need for the emergence of national "lines to take" for example with patients. The domino effect of having to continue the line. Once you do not tell a patient about the risk in the products which you administer to him, in particular in cases where a patient, perhaps from a long line of haemophiliacs is well versed in the science related to his condition and the past risks of treatment, it becomes near impossible to tell him about the fact that the risk has materialised. It becomes impossible to tell him about the fact that you have (without his knowledge) in fact also been aware of the risks and have been monitoring him for the manifestation of those risks. It becomes necessary to keep that patient under your control in order to make sure that he is not exposed to some outside influence which might expose the system for what it is. Where the nature of the failures has been systemic, as is the case here, it becomes necessary for the system to devise *ex post facto* justifications to protect itself against criticism. It becomes necessary for the profession to protect the system against the threat of being exposed. Thus the "lines to take" were developed in the face of litigation which threatened to expose the system for what

it was. Thus, one sees that the need to allow the patient to be fully informed about the risks he is taking in deciding upon a particular course of treatment is not some lofty ethical principle to be discussed in academia but the very essence of the doctor/ patient relationship. Much has been said in this Inquiry by witnesses about the "gift relationship" between the blood donor and the system to which he or she altruistically donated his blood. A similar relationship should have existed between patients and their physicians. The permission to intrude upon the body of another is predicated upon the need for the physician not to do so unless the intrusion and its risks and benefits have been properly explained, explored, understood and accepted by the patient. To do otherwise is to risk setting in motion the intractable series of events about which this Inquiry has heard so much evidence.

4.12 The emergence of threat and the need to supress information about it – the Cardiff infection Ludlam even now, attempting to portray that as a suspect case when it clearly was not (the Inquiry presentation on the Cardiff AIDS case). The 1988 meeting about the litigation.

b) The treatment regimes in Scotland and resultant infections – general themes/ issues

4.13 In this section, we will deal with the evidence which the Inquiry has heard about the general factors which influenced the treatment of those with bleeding disorders in Scotland, in particular with regard to the minimisation of the risk of pathogenic exposure. The steps taken to minimise the risk of patients with bleeding disorders suffering from infection from NANB hepatitis as a result of treatment in the period between December 1984 and April 1987 is addressed separately below.

Self-sufficiency

Decision-making around self-sufficiency in Scotland

4.14 The Inquiry has heard a great deal of evidence relating to the commitment to national self-sufficiency by David Owen in 1975. However, this was not a new policy. In Scotland, at least there had been a commitment to the achievement of national self-sufficiency which had been made at the time of the commissioning of the Protein Fractionation Centre. Despite this, at a joint meeting of the SNBTS and haemophilia centre directors on 30 January 1981, attended also by representatives from the SHHD, it was "agreed" that self-sufficiency must be the aim for Scotland.[1489] This agreement seems to indicate that it was within the power of these bodies, in meeting together, to make such a decision. However, it does appear that little attention is given to the way in which the bodies would operate to achieve that mutually agreed aim. It also appears odd that such an agreement would be reached at that time, given the historic commitment to self-sufficiency which was the driving force behind the investment in the PFC many years before. The 1981 declaration demonstrates the lack of any real system having been in in place to secure the aim of self-sufficiency being met during the 1970s.

4.15 Such a declaration, whether made in 1981 or earlier, was, in any event, of little consequence, in reality. No consideration appears to have been given in the 1981 meeting to the possibility of what would require to be done to stop haemophilia directors continuing to use imported products. Despite the recognition for the need for "good planning" to achieve this aim, little by way of planning seems to be put in place as to how the aim would be achieved, nor whose responsibility the achievement of the aim would be. The principle was and had been of little value, given the practical reality that by 1981 and before imported products had taken a foothold in the Scottish system and the lack of a clearly defined plan as to how to eradicate that.

4.16 From the perspective of the haemophilia clinicians, in his Penrose evidence Professor Forbes resisted any suggestion that there had been any steer given by

---

[1489] PRSE0000181_0002, para 6

the SHHD towards implementing a policy of self-sufficiency in Scotland.[1490] When asked at Penrose, Dr McClelland had no idea from whom any stated policy regarding self-sufficiency would have emanated.[1491] He also anticipated that a formal direction from the government in the form of a letter from the Chief Medical Officer to this effect would have been taken seriously but that there was no tradition of such formal directions being given.[1492] Dr McClelland was also of the view that to the extent that any concerns were raised by the government about the use of commercial products, these concerns were mostly to do with funding, rather than to do with safety.[1493] There was a concern that, given the investment in the PFC, purchasing commercial material was, in effect, "paying twice". Dr Perry could not identify any definitive moment at which the SHHD had declared that self-sufficiency was to be the rule until the late 1980s.[1494] He stated that any notion of self-sufficiency was always subordinate to the concept of clinical freedom of the clinicians to prescribe what product they wanted, apparently without restriction.[1495] This was precisely the issue – notional declarations of commitment towards the principle were of little value without a clear plan as to how to achieve it. Even though the financial ramifications of having invested in PFC and still continuing to pay for commercial imports were realised within government, it appears that nothing was done. It was not that the government was paying twice. They appear to have failed to realise that they were paying for more than was necessary. The PFC had been funded to support national self-sufficiency. That concept had been allowed to evolve such that the system's capacity could no longer support what was being demanded. There was a failure to act and a failure of any clear structure as to who required to take the lead. Meanwhile, infections with fatal disease (including AIDS in 1981) were happening

---

[1490] Penrose Inquiry transcript for 28/04/11 (day 17); 82 (20 to 23) (Professor Forbes); [PRSE0006017_0082]
[1491] Penrose Inquiry transcript for 06/05/11 (day 21);104 (20) (Dr McClelland); [PRSE0006021_0104]
[1492] Penrose Inquiry transcript for 06/05/11 (day 21); 114 (8 to 21) (Dr McClelland); [PRSE0006021_0114]
[1493] Penrose Inquiry transcript for 06/05/11 (day 21); 103 (7 to 10) and 115 (6 to 11) (Dr McClelland); [PRSE0006021_0103 and 0115]
[1494] Penrose Inquiry transcript for 13/05/11 (day 25); 10 (1 to 16) (Dr Perry); [PRSE0006025_0010]
[1495] Penrose Inquiry transcript for 13/05/11 (day 25); 1 (22) to 2 (2) (Dr Perry); [PRSE0006025_0001 to 0002]

in Scotland. As the figures show, the demand was at that very moment running out of control.

4.17 These issues continued throughout the first half of the decade, with fatal consequences. In the minutes of the SNBTS directors meeting on 8 December 1983, it was noted that Professor Cash would include the issue of Yorkhill being the only hospital in Scotland which appeared to continue to use substantial quantities of commercial products in a report he was compiling on planning for self-sufficiency. This would seem to suggest that he had some responsibility in this area, though there is no detail of the purpose or the addressee of the report. That planning for self-sufficiency was still going on by this point was the very problem – it should and could have been achieved many years before. Professor Cash had no jurisdiction over the haemophilia directors. Only government action in the form of a CMO letter or clear government policy (such as that contemplated by Dr McClelland) could have altered their course. Given that it was being planned for, it does not seem that it had been achieved by that point. It was noted that Yorkhill appeared to be the only hospital in Scotland still using significant amounts of commercial material at that time.[1496]

4.18 At the joint meeting on 2 February 1984, Dr Bell of the SHHD pointed out that self-sufficiency for Scotland was the national policy but that the SHHD would not intervene in what was prescribed. He urged that it was not "sensible" for commercial material to be purchased when domestically produced material was available.[1497] This suggests that the clinicians were free to prescribe what they wanted and that despite the policy, there was not mechanism to enforce it. In circumstances where doctors were accorded this freedom and no decision was taken by the government to impose self sufficiency, it seems hardly surprising that commercial products continued to be used. In our submission, there was little point in the government adopting such a national policy in light of the lack of measures taken to ensure that the policy goal was achieved. As is clear from the minute, Professor Ludlam (unlike Dr Macdonald in the west) took the view that

[1496] PRSE0002899_0003
[1497] PRSE0001556_0003

the higher purity commercial material was needed for certain of his patients. Dr McClelland confirmed in his evidence at Penrose that Professor Ludlam was responsible for the purchase of commercial products in Edinburgh.[1498] Dr Macdonald had indicated that he was happy with the purity and quality of the SNBTS products in 1983 but Professor Ludlam had been purchasing more commercial product at that time as well.[1499] Professor Ludlam told that Inquiry that one of patients was on home treatment with commercial concentrates as "he [Professor Ludlam] was lent on quite heavily" by the patient whose brother was also a haemophiliac and was on commercial home treatment.[1500] Such clinical and financial freedom was accorded to the consultants with the result that government's stated commitment to self-sufficiency was merely notional.

4.19 In his evidence to the Penrose Inquiry, Dr Perry was of the view that, despite its notional support for the concept of self-sufficiency in Scotland and the fact that it was always far more likely to have been achieved in Scotland than in England, the SHHD had no real power to make a unilateral declaration restricting use to domestic concentrates. In his view, this was because this would have been a licensing issue which would have had to have been decided on a UK basis, given that licensing of pharmaceutical products was a matter which was dealt with at Westminster, essentially being a 'reserved' matter in the era of administrative devolution.[1501] Even if theoretically possible he did not think that SHHD would ever have taken a different view on such a matter to the DHSS.[1502]

4.20 This exchange demonstrates the fallacy of administrative devolution. Products were licensed on a UK basis and so were available north of the border – in fact, they could have been prescribed on a named patient basis even if they were not licensed. As is submitted in other areas in this submission, the SHHD was in control of matters pertaining to health throughout this period so was free, in the interests of public safety and in light of the achievability of self-sufficiency, to direct the

---

[1498] Penrose Inquiry transcript for 06/05/11 (day 21); 98 (6 to 15) (Dr McClelland); [PRSE0006021_0098]
[1499] PRSE0001736_0002 to 0003
[1500] Penrose Inquiry transcript for 04/05/11 (day 19); 88 (Professor Ludlam); [PRSE0006019_0088]
[1501] Penrose Inquiry transcript for 13/05/11 (day 25); 12 (13 to 17) (Dr Perry); [PRSE0006025_0012]
[1502] Penrose Inquiry transcript for 13/05/11 (day 25); 13 (25) to 14 (3) (Dr Perry); [PRSE0006025_0013 to 0014]

practice of using commercial products would cease in accordance with the policy. However, to do so would have been to have taken a different position to the DHSS (part of the same government) whose stated policy had been to support self-sufficiency throughout this period, in circumstances where the goal was far less achievable in the rest of the UK. It is submitted that this paradox is the explanation for the SHHD's lack of enthusiasm to take a more proactive approach to the achievement of national self-sufficiency in Scotland. Doing so would have allowed or at least promoted the policy to have been achieved in Scotland. However, doing so would have meant highlighting the inadequacy of the position in the rets of the UK and the failure of government to achieve the policy aim there. Either the SHHD was shackled by this failure, for fear that it would create a postcode lottery (which already existed to an extent) or it failed to take positive action to achieve the implementation of the policy which it could have done, given the separate production and blood transfusion system which operated in Scotland, its greater proximity to self-sufficiency in blood products and the ability of the SHHD to take steps to implement this policy in the interests of public health. This failure undermined the purpose of having such a separate system.

Efforts made towards the achievement of self-sufficiency

4.21 Scotland was never self-sufficient in factor VIII concentrate until after the majority of the infections of those with bleeding disorders in Scotland had occurred. The fact that Scotland was near to achieving self-sufficiency in these products makes infections in Scotland all the more culpable. A well formulated plan for self-sufficiency could practically have resulted in all blood products used in Scotland being (a) being produced from voluntary donors in Scotland (b) and only from properly vetted, safe donors.

4.22 The main issue with the concept of self-sufficiency is the fact that it was never defined. This meant that it was an illusion from the start, based on an ephemeral concept arising from lofty notions of the superiority of products derived from the

plasma of voluntary donors. Those notions were relative and not any guarantee of safety, as is discussed in detail above. The fact that a clear definition of self-sufficiency was never put in place in the 1960s when Scotland committed to self-sufficiency meant:

(a) That it was known in the 1960s that imported blood products were dangerous and should be avoided in the most basic interests of patient safety; and

(b) That, given the fact that it was known that the amount of plasma required for all blood products to be made domestically would be challenging to the blood transfusion service's ability to collect plasma, it was known that clear limits had to be set to what treatment needs could be met by domestically sourced plasma (Cash and Spencely). That was an error which created an ever unachievable target.

4.23 We are aware of relatively little (if any) evidence available to the Inquiry on the subject of any national co-ordination or management of the likely projected amounts of blood products which would be required for the treatment of patients with bleeding disorders in any given year over this period. In our submission, it was essential to (a) monitoring of the amounts of concentrates being administered to patients in light of international guidance that exposures should be limited to the minimum amount necessary and (b) the achievement of national self-sufficiency in blood products for there to be a central system where usage was controlled and projections made accordingly to meet future demand. Such a system would have required at least the possibility of a central body interfering with unmitigated clinical freedom, a concept which was never even contemplated. It should have been. Early predications in Scotland of the possibility that unchecked demand may cause problems was predicted in an article co-authored by Professor Cash.[1503] These early warnings about the possibility that the system may reach a saturation point for factor VIII production appear not to have been heeded. Clinical freedom was allowed to run free.

[1503] PRSE0001255 - Spencely & Cash, 'Factor VIII replacement in the treatment of haemophilia A – a simple illustration of a need-supply-demand spiral', British Journal of Preventative Medicine, 1974

4.24 The principal problem with the approach taken to the formulation of the treatment plans of those with bleeding disorders in Scotland was that these plans were formulated on the basis of what those who formulated these plans considered to be the most aggressive and modern treatment for those suffering from the bleeding disorders and this took no account and did not stem from the informed consent of the patients or their parents. This approach created two significant problems for the safety of the system:

a) It created a need for the system to continue to rely on imported factor VIII concentrates which were know or certainly ought to have been known be unsafe; and

b) The fact that the system worked consistently at breaking point, constantly under pressure to continue to collect more and more plasma in order to meet the ever-increasing treatment demands of the haemophilia clinicians (whose demand for plasma drove the policies adopted by the transfusion directors) meant that the system continued to rely on unsafe collection practices. A more precautionary approach would have been safer but in a system so consistently at its limits would not have met the targets for plasma which were consistently and relentlessly required.

This resulted in a system which claimed to be committed to self-sufficiency actually turning its back on its achievability. To create a treatment regime which could only be satisfied by the techniques avowed to be unsafe by the Scottish system (such as the increased use of paid, skid row donors, the collection of plasma by plasmapheresis which was based on a paid donor system where donors would tolerate being bled regularly as they were remunerated) was in fact a commitment to that treatment only being achievable by safe means.

4.25 It is important to note that the clear evidence heard by the Inquiry was that patients or their parents (where appropriate) were not involved in decisions about their treatment. The evidence heard by the Inquiry in this regard is analysed in more detail below but for present purposes it is important to note that the

clinicians who gave evidence to the Inquiry consistently claimed that the main driver for the ever-increasing need for plasma was the constant demands of patients (and indeed patient organisations such as the Haemophilia Society) for ever more products to support these treatment demands. This is an illegitimate presentation of the facts. Patients were correctly told that home treatment and prophylaxis would be good for their bleeding disorders. They were keen to enjoy the benefits which would be offered by these regimes. They were not, however, told about the risks which the adoption of these regimes necessitated. It is correct to say that the patients wished to enjoy the benefits which these regimes offered. It is incorrect to say that this was an informed choice. If the Inquiry feels the need for the reasons for this state of affairs to be explained, the following appears to constitute a fair analysis of how this approach to the treatment regimes of those with bleeding disorders in Scotland came about:

(a) Those who made the decisions were haematologists predominantly trained in and concerned with the bleeding disorder element of the patient's health and not the risks of diseases. They prioritised the need to make advances in the treatment of the bleeding disorders to the detriment of the requirement only to do so safely;

(b) As is explored elsewhere in this submission, haemophilia clinicians inappropriately underestimated the risks of severe disease which they ought to have known were associated with the products;

(c) Haemophilia clinicians adopted an attitude to treatment which subverted the right of patients to be fully informed about the risks and benefits of the treatment which they were being given (an attitude incorrectly characterised as "paternalistic" by the medical profession). This resulted in the formulation of treatment plans which took no account of the likely consequences of needing to secure the patients' informed consent and allowed clinicians focussed only on bleeding to ignore the risks of achieving the best haematological outcome;

(d) The NHS in Scotland achieved significant practical benefits from the encouragement of patients into treatment regimes which minimised the ned for them to receive hospital based care, which of course required funding for hospital staff, space and equipment. Home treatment was sold to patients on

the basis of its benefits to the patients for their autonomy and the possibility that early treatment of bleeds would have a better haematological. It also crested a significant financial benefit to hospitals, all of which were pushed for space and staff for the treatment of patients with bleeding disorders in Scotland in the 1970s and 1980s; and

(e) There was no cohesive plan for what was in the best interests of patients in Scotland. The paradoxical attitude of the Scottish NHS as regards the policies for the treatment of those with bleeding disorders in Scotland is demonstrated by the fact that the system in general supp the concept of self-sufficiency but all of those who were seeking to achieve it relied (until the arrival of Professor Hann in 1983) on the fact that one centre used predominantly commercial products in the treatment of haemophilia A patients, namely Yorkhill.

4.26 For example, the aggressive treatments strategies which were adopted by the haemophilia clinicians in Scotland who championed domestic products were based on no consideration of the real limitations on the transfusion services safely to collect plasma within a system based on voluntary donations. It may well have been possible based on the aggressive, remunerated plasmapheresis programmes in the USA for new treatment methodologies which were perceived to have brought practical and haematological benefit to the patients to be achieved. In such systems, it was possible to collect enough plasma to satisfy the increased quantities of factor concentrates needed to support home treatment and prophylactic treatment regimes.

4.27 In addition, the system contained no proper economic assessment of the pros and cons of a safe system as opposed to a system based on the use of imported concentrates. The achievement of self-sufficiency was, in part, due to financial considerations - a claimed lack of funding for the equipment and staff needed to fractionate plasma, to collect sufficient plasma and the development of technology for the safe fractionation of plasma (including the development of viral attenuation techniques like heat treatment). A proper analysis of the economics of the actual arrangements would have made it clear that the money being spend on expensive commercial concentrates which were being imported to fill the gap could have been offset by the savings which could have been made if the money

had instead been used to invest properly in the domestic system. A proper economic analysis of the relative costs which would be required to achieve a "safe" system satisfied by domestically produced products against the savings which could be made in the resultant lack of need to buy imported concentrates was a mistake which resulted in the system being flawed.

4.28 There is a certain myth which surrounds self-sufficiency, namely that the infections which were caused by blood and blood products would have been eradicated, had there been an ability completely to rely on domestically produced blood products for the treatment of patient with bleeding disorders. That treatment of patients with blood products which were derived from local blood and plasma was, of course, a laudable aim which was advocated by many organisations which existed in order to promote both efficacy and safety in the treatment of bleeding disorders, not least the WHO. The avoidance of the use of imported products had the laudable objectives of (a) seeking to avoid the use pf products which came from foreign areas which may least to the introduction of foreign pathogens into the UK community and (b) seeking to avoid the use of products not produced in accordance with safe practices where the method of production were either not know or known not to be safe (as in the US). However, this myth that simply relying on domestically sourced products was the answer can be dispelled by reference to the experience in Scotland where many patients who were treated with domestically produced products, The Oxford research by Fletcher, Craske & Ors (referred to in more detail above) was published in the British Medical Journal under the title "NANB hepatitis after transfusion of factor VIII in infrequently treated patients" 10 December 1983.[1504] This was taken by the medical community to mean that by that point (or, more likely significantly before) the advantage previously enjoyed by domestically produced factor VIII over imported factor VIII in terms of its infectivity had been lost. In fact the infection of the 7 seven patient from NHS concentrates had been reported by Dr Craske on 23 September 1982[1505]. This had been reported to the UKHCDO annual meting by Dr

[1504] PRSE0002154
[1505] HCDO0000135_015_0001

Craske earlier that month.[1506] The actual prevalence of NANB hepatitis in the UK donor population and the lack of measures taken to prevent its transmission by pooled products had result in both imported and domestic factor VIII being highly likely to transmit the virus on first infusion.

4.29 The evidence heard by the inquiry from various witnesses, not least Lord Owen, perpetuated several myths about the concept of self-sufficiency. The origin of the principle, on Lord Owen's evidence, at least in is mind was his study of "The Gift Relationship". One of the essential flaws about the way in which the Gift relationship philosophy was understood and hence taken forward as a social philosophy worthy of political action was that it appears not to have been fully understood. Its basic ethos – that voluntary blood is generally better than blood which comes from paid donors, especially foreign paid donors based on its analysis of the relative UK and US systems – appears to have been the only message which was taken from it. Other messages appear to have been lost, however, in its political adoption. Not least amongst these is the danger of blood which underlies the unique nature of the social contract which arises in the gift relationship. The basic assessment as understood by Lord Owen appears to be a bipartite one, a relationship between State and donor which honours the voluntary nature of the donor's gift and thus respects the rights of the donors in the process, based on an altruistic though essentially relative notion of safety (relative in the sense not of the resultant product being 'safe' but being essentially 'safer' then that deriving from another system based on paid donors). Inherent in the analysis presented by Professor Titmuss and apparently lost on the authors of the political action based on his philosophy was the fact that the inherent dangers involved in the use of human blood meant that the resultant social relationships arising out of its use were complex and involved multiple parties. Inherent in the philosophy which his treatise expounded was the need not only for respect for the donor as the giver of the gift (a concept well understood and central to the UK blood transfusion system) but also for the essential need for truthfulness between the State and with end user about the dangers involved in the "gift" which they were being given. The

[1506] PRSE0000185_0003 and _0004

text generally appears to adopt a now outdated approach to informed consent (based on the fact that the patient simply needs to trust the giver). There is an inherent tension between this general reflection of ultimate reality, that ultimately the patient (as in all medicine) must take a leap of faith, and the importance with Titmuss places on the contract arising out of the use of blood requiring as truthful an approach with the patient (at the time the text was written limited to the recipient of a transfusion in the crudest sense) as possible in order that the multi-party social contract is fulfilled.[1507] That element of the contract was never recognised or implemented by government. No steps appear to have be taken to ensure that that part of the social contract was implemented. The overwhelming evidence heard by the Inquiry and assessed elsewhere in this submission that the essential truthfulness between the State (or the actors of the state in the form of the clinicians) was not respected. The almost mythical status accorded to the text as expounding the fundamental philosophy of the blood transfusion service in the UK was not fully understood or implemented.

4.30 The analysis presented by Titmuss was conducted against a background where hepatitis (in his case understood to mean serum hepatitis) was, according to the quotes Journal of the American Medical Association a therapeutic measure which "causes death in approximately one of every 150 transfusions in persons over 40 years of age".[1508] In this context, it is submitted that the Titmuss philosophy is not just about the relationship between the State and the donor but also, given the inherent dangers of blood transfusion (not just related to viral transmission and possible death but also other dangers such as errors in blood grouping, cross-matching, labelling, patient identification and many procedures at all stages) as well as clinical misjudgements and medication error[1509]) the social contract involved in its use requires (a) fundamental precaution in its use and (b) absolute truthfulness with the recipients about the risks of his or her involvement in the

---

[1507] See HSOC0019917 – "The Gift Relationship" at page 144 – "this is one social right the patient has; the right to truthfulness. Essentially, this is because he can exercise no preferences, and because one man's truthfulness can reduce another man's welfare."
[1508] HSOC0019917 – "The Gift Relationship" at page 145
[1509] Ibid.

process. That these aspects of the social contract were not insisted upon/ enforced represent a significant departure from the social contract between the State and the recipients of blood and blood products in the UK. It is not a defence to this assessment, it is submitted, that the failures in this regard resulted from the exercise by transfusion and haematology doctors of their "clinical freedom", given that the moral obligations owed in this regard stemming from the social contract upon which the system was based lie with the State and, on this analysis, these doctors were acting as the agents of the State. Any breach of these obligations stems from the abdication of such responsibility by the State to those medical professionals. The State must ultimately be deemed responsible for it. Instead of talking account of the need for a unique form of social contract, which arises from the altruistic nature of the donation but also from the inherently dangerous nature of the gift, the altruism of the donors appears to have been used as a proxy for safety – blood and blood products were all too often seen to be safe because blood were given by altruistic, voluntary donors. This again neglects two important ingredients of the social analysis undertaken by Titmuss, namely (a) that the blood which is collected via such as system is inherently dangerous material, whether given by voluntary donors or not and (b) the analysis is at best relative – it examines the means by which the UK system might be made **safer** than the inherently hazardous US one – it not an analysis which could form the basis of an assumption that the blood collected from voluntary donors should be assumed to be **safe**.

Particular considerations relating to haemophilia B

4.31 Less alternative treatments were available for haemophilia B patients. There was no cryoprecipitate or DDAVP equivalent. They were also treated with domestic concentrates as sought plasma was collected for Scotland to be self-sufficient in factor IX, but not in factor VIII as there were many more haemophilia A than haemophilia B patients. However, these patients could and should also have had

less factor IX concentrate due to the known high risks of viral transmission and their viral load reduced. Milder patients could also have avoided concentrates, as per the same principles set out above with greater use of FFP or lifestyle advice to avoid bleeds. This could have avoided exposure to the risk of HIV infection and also the effects of exposure to such a large viral load, especially in children. Like transfusion patients they were the victims of the fact that the system was driven by the need to collect every drop of plasma for the production of factor VIII, they were the victims of the end to provide so much product for others. Factor IX was made from the supernatant from the same blood collected and used in the production of factor VIII. The need to go to exposed haemophilia B patients to the same risky donors who in a more conservative system of treatment could have been excluded. Further, virally safe tranexamic could be used in the treatment of haemophilia B.[1510] This appears to have been underused to spare infections.

The Haemophilia Society

4.32 The role of the Haemophilia Society as a charitable organisation throughout the period with which the Inquiry is concerned which consulted with government and the medical profession on behalf of its members in an effort to further its aims, namely the promotion of the interests of those with bleeding disorders in the UK. The Inquiry is charged with an investigation of the actions of the Society in connection with the blood contamination disaster. The following have emerged as the conclusions to be reached about the actions of the Society over the Inquiry's period of reference:

4.33 The Society, like the patients on whose behalf it operated was limited by the medical advice which it received about the risks of disease and the relative benefits of treatment as well as the practicality of alternatives as well as their relative risks and benefits. The Society was consistently treated as if it constituted an expert body of medical opinion separate from the corporate views of the

[1510] WITN3174003_0005, Dr Mitchell

UKHCDO. It was not. The same people were advising the patients as were advising the government. False reassurance provided by the clinicians to the Society and the patients/ their parents was the same false reassurance provided to government.

4.34 The Society was, both at the time and subsequently, been used by the government and the medical profession as a proxy for patient consent. This was and remains an entirely inappropriate and unreasonable approach. In fact, it represents an example of an *ex post facto* line adopted and maintained by the medical profession to justify its shortcomings in connection with the disaster. To say that the treatment which caused the infections was insisted upon by the patients when the evidence clearly shows that their insistence was based on an inadequate understanding of the risks for which the medical profession is responsible is not an adequate defence. For example, the evidence shows that not all patients were members of the Society and so it could not be assumed that the advice given to the Society was advice which was available to all patients. In any event, such advice was general. The apparently prevalent attitude that leaving a Haemophilia Society Bulletin in the waiting room of the surgery could, by the general advice which it contained which may or may not have been seen or understood by any given patient is redolent of the general unwillingness or inability of haemophilia clinicians to provide proper individualised advice and obtain proper informed consent from their patients over the material period. Much has been said in evidence given to this inquiry about the paramount importance of clinical freedom (which is addressed in more detail elsewhere in this submission). In fact, the reliance placed by haemophilia clinicians on the generalised advice given by the medical advisory committee of the UKHCDO in accordance with its slavish adherence to the philosophy that concentrates and ever more concentrates were absolutely necessary demonstrates that the clinical freedom of many individual haemophilia clinicians was abrogated to the general position of the UKHCDO, as expressed through the medical advisory committee of the Haemophilia Society.

4.35 Criticisms of the Society which have been voiced by patients would generally be answered by the legitimate limitations of knowledge based on incomplete or inaccurate medical advice.

4.36 Possible exploration of some minor areas in which the Society may be deemed to have fallen short of acting in the best interests of the patients?

c) Policy about treatment regimes in Scotland

4.37 Separate consideration of the structures in place within Scotland for decision making about the way in which those with bleeding disorders in Scotland would be used. Microcosm of the UKHCDO, regular meetings between the Scottish haemophilia directors and also with the SNBTS regional directors/ Professor Cash.

4.38 The relationship between those who were in a position to assess the risks in the donor population (those in charge of transfusion within the SNBTS) and those responsible for the treatment of the end users (the haemophilia clinicians) was inadequate. Dr McClelland's office was on the same corridor as Dr Ludlam. The former was of the view that "there was little shadow of doubt [by at least September 1983 at the latest that that this [AIDS] was a disease transmissible by blood and blood products".[1511] This appears not to have been communicated and was certainly not acted upon.

4.39 No evidence of any particular consideration of the practices of blood collection/ screening or the variability of the approach. See the fact that Northern Irish plasma was also collected and pooled for the production of concentrates in Scotland. Wilful blindness to the risks, though information about them freely available.

4.40 The relationship between the haemophilia directors and SNBTS/ PFC being much closer than in the parts of the UK (England and Wales) supplied by BP, which was seen there as just another supplier akin to the other commercial suppliers of concentrates. Inherent within the Scottish system that the patients were (without their knowledge or consent) used as a means for providing information

4.41 Analysis of the constant demand for domestic products – eg Boulton and Ludlam, living on the edge of supply

---

[1511] IBI transcript for 28 January 2022; 21 (Dr Brian McClelland)

4.42 The anomaly of disagreeing with the treatment philosophy at Yorkhill but the entire system of supplying domestic products to the centres depending on Yorkhill adopting a widely discredited attitude. Tension between the need for decisions about supply which necessarily involved decisions and efficacy and safety and clinical freedom of the directors to make their own decisions as a manifestation of "clinical freedom".

d) Mortality and morbidity

4.43 Analysis of the argument put forward by the clinicians, underpinning the attitude of government to the way in which treatment regimes were offered in Scotland was that the concentrate were necessary on the apparent basis:

(a) That without them the life expectancy of haemophiliacs would have been significantly limited;
(b) That without them the morbidity associated with the haemophilia would have been significantly worse than it otherwise would have been; and
(c) That the treatment alternatives were woefully inadequate in comparison.

4.44 The main thrust of the arguments for the like expectancy advantages was advanced in the evidence of Professor Charles Hay. He made the assertion in his statement that there was a "pre-treatment life expectancy of 10 - 15 years" and that the life expectancy had increased to near normal.[1512] He did not claim that this was all down to concentrates. In support of this extraordinary contention, Professor Hay cited two papers. One was a 1983 report on the treatment of haemophiliacs over the period 1976 to 1980.[1513] This paper compared the ages of

[1512] Witness statement of Dr Charles Hay (WITN3289039), para 29.1
[1513] WITN3289047

death in that period of haemophilia A and B patients who died in the period between 1969 and 1974. This showed a small increase in the average age of death in those who died over this period compared to the previous period. This cannot possibly have been solely attributable to concentrates, which the paper claimed had been increased in their usage over the period since 1976. The increases are likely to have been due to the totality of treatment received, including cryoprecipitate. The figure to which Professor Hay was referring was a projection of median life expectancy which also appears on page 2 of the report. This appears to be little more than a guess. The paper indicated surprise at the figure and made clear that they needed to be treated with caution based on the limited numbers whose details had been put into the life table calculation. This paper is not a basis for the claim made by Professor Hay. The most common cause of death remained cerebral haemorrhage. It was clearly indicated on page 5 that whether this estimate would be accurate remained to be seen. He also referred to another paper, this time from 2006.[1514] The results of this study could, of course, not have been known about at the time when infections were occurring. By this time, most of any advantage from the use of factor concentrates could have been achieved safely with the advent of heat treated concentrates. On page 1, the common impression of haemophilia treaters about life expectancy are set out, namely that life expectancy has increased due to the advent of concentrates and the advent of comprehensive care. The latter would have been possible with or without concentrates. In any event, the article refers to a Dutch study which shows no actual increase in life expectancy in haemophilia patients, compared with the pre concentrate era. The figures were of course hard to interpret due to the mortality from AIDS and HCV. This, of course, shows the fallacy of the approach taken by the haemophilia clinicians at the time when their treatment was being increase with factor concentrates so much in the late 1970s and early 1980s. the focus was solely on estimated advantages (little more than guesses) for life expectancy and morbidity from the point of view of bleeding alone. Life expectancy or morbidity advantages from a bleeding perspective were of no value to those who were

[1514] WITN3289052

infected with other fatal or life limiting diseases. It is also clear from page 1 of the report that Professor Hay's life expectancy figures of 10 to 15 years appear to stem from the middle of the 19th century. Clearly, healthcare was not the same then as it would have been in the second half of the 20th century of treatment had remained on cryoprecipitate. Clearly the advantages of comprehensive care, incusing physiotherapy orthopaedics etc, were also considered to play a role, which could have been offered anyway. The Swedish paper at reference 8 suggested that mean death age in severe haemophiliacs was in fact 50 in 1980 (at a time when concentrates would not have had the chance to influence mortality greatly), with 36% of deaths being non-bleeding related and 16.7% having inhibitory antibodies (for whom treatment was not relevant anyway). It is of interest that at Professor Hay's experience that prophylaxis was not introduced until at the earliest 1987, when factor concentrates had started to be virally attenuated.[1515] In his oral evidence Professor Hay appeared, in any event, to accept that it had been the use of cryoprecipitate that had caused the considerable advantages in life expectancy and that a reversion to that treatment would only have made a minimal difference to the life expectancy outcome.[1516] It is submitted that, in fact, reversion would have made little of any such difference as it would only have been required for a short period before heat treatment was discovered. That this was, at that time, little more than a guess about life expectancy was reflected in the fact that Professor Hay accepted that the perceived advantages would not "flower" until the period after 1980.[1517] The large increase in life expectancy was shown on comparison of the Rizza paper with the preceding Biggs paper to have been as a result of cryoprecipitate and not factor concentrates.[1518]

4.45 Even as an advocate for the estimated advantages of factor concentrates, he would not have expected patients to have been on prophylaxis until they were made safe. It is hard to decern any scientific reasoning why the huge increases in

---

[1515] Witness statement of Dr Charles Hay (WITN3289039), answer 21
[1516] IBI transcript for 04/11/20; 60 to 62 (Professor Hay)
[1517] IBI transcript for 05/11/20; 101 to 103 (Professor Hay)
[1518] PRSE0004645 (1974)

the use of factor concentrates described in the paper relied upon and the extra which would be needed for prophylaxis would be deemed to be a bridge too far in safety terms. Actual practice was Insafe based on the estimated life expectancy advantage balanced against the known risk of viral infection. Prophylaxis would simply have been an even more unacceptable balance. Prophylaxis had of course been used at Yorkhill Hospital in Glasgow from the late 1970s.

4.46 Dr Mark Winter also advanced an argument in favour of such advantages of concentrates. He advanced such arguments by comparing the situation with time he spent looking after haemophiliacs in Islamabad, which he set up as a means of knowing what the position for haemophiliacs would have been, but for the treatment which he gave them, mainly with factor concentrates in the UK.[1519] In our submission, this was an unscientific comparison which was not comparing like with like. Is this not an accurate control group as without treatment under modern healthcare in a civilised country from circa 1970 onwards a haemophiliac could be expected to have lived considerably longer than one might have expected to in Islamabad, with the advantages of a modern, Western healthcare system, comprehensive care and treatment with cryoprecipitate. The comparison between the two papers showed, contrary to the assertions made by Professor Hay that the difference in the main cause of death, intracranial bleeding, did not increase significantly between the cryo treatment era and the concentrate treatment era.[1520] In any event, Dr Winter suggested that in the US, even by the 1930s, the average life expectancy was 21 or 22 with no treatment[1521], not the gloomier predictions based on the Hay evidence which was from the 19th century. Dr Walford expressed the view on her evidence that before cryoprecipitate was introduced in around 1964, the median life expectancy was 37, suggesting that it and not factor concentrates created the major jump in improved life expectancy.[1522] She provided no evidence, when asked, for the assertion that it had been concentrates which caused that jump. When asked about the life

---

[1519] IBI transcript for 01/10/20; 133 to 134 (Dr Winter)
[1520] IBI transcript for 05/11/20; 109 to 111 (Professor Hay)
[1521] IBI transcript for 01/10/20; 133 (Dr Winter)
[1522] IBI transcript for 21/07/21; 22 to 28 (Dr Walford)

expectancy impacts of a temporary reversion to cryoprecipitate to dela with the AIDS threat, she merely based her position on issues of supply, not issues of the impact that such a reversion might have had on mortality or morbidity for that matter.

4.47 It is submitted that the evidence about the mortality and morbidity advantages offers by treatment do not demonstrate that these advantages were associated solely with concentrates, as opposed to the virally safer cryoprecipitate. The factor VIII content of that product was the great breakthrough in treatment from its advent due to the advances made by Dr Judith Pool. The attribution of these advantages to factor concentrates is a construct which has been imposed on the narrative of the disaster by the haemophilia clinicians. To the extent that there were any mortality advantages offered by the use of factor concentrates, they were advantages which are likely to have been realised in the long term. Therefore, they are not, in any event, advantages which could not have been sacrificed in the interests of safety in the short term. Even of they offered ling term morbidity and mortality advantages over cryoprecipitate, these advantages could have been safely enjoyed once the fractionation technology allowed the products to be heat treated. In any event, any mortality and morbidity advantages associated with factor concentrates would only have applied to severe haemophilia patients due to the effect which they may have had on reducing the risk of spontaneous cerebral haemorrhage and the long terms effects of bleeding into joints. Thus, any assertion treatment with factor concentrates offered particular morbidity or mortality advantages for all patients, including mild and moderate patients, is not accurate.

4.48 The proposition that the mortality advantages of treatment were predominantly associated with the advent of cryoprecipitate was supported by the fractionation expert group. In their report, they offered the expert view that in the late 1950s, half of the patients with haemophilia would die by the age of 19 years, whereas the median life expectancy reached approximately 50 years in the western world in the early 1980s. More specifically, for the time period that cryoprecipitate was the main treatment for people with haemophilia, a life expectancy of 57 years from birth was reported for the 1960s and 1970s in Sweden, 63 years from birth

from 1973 to 1985 in the Netherlands, and 61 years from age 1 year from 1971 to 1980 in the United States. This opinion shows that the data relied upon to vouch the proposition made by Professor Hay, in fact, showed the mortality advantages not of concentrates but of cryoprecipitate.[1523] The Darby article looked at a large number of haemophiliacs (of which Dr Hay was a co-author) not infected with HIV showed that all cause mortality in severe haemophiliacs did not differ between 1977 and 1999. It found that despite the advances in treatment in the last two decades of the 20th century mortality from intra-cranial haemorrhage in the absence of inhibitors did to alter greatly over that time period. Life expectancy in severe haemophilia remained 15 years lower than in the general population. Little life expectancy advantage had been gained by the advent of factor concentrates. Of course, those who had died from HIV were not part of the study.[1524]

4.49 The evidence of the Edinburgh haemophilia patients and the impact of their particular treatment regimes is put in an important context by the evidence of one particular witness, the daughter of a severe Edinburgh haemophiliac. In her clearly and obviously thoroughly researched statement about her father, the witness sets out to the Inquiry that he was born in 1926 and died in 1995, aged 69.[1525] Due to the fact that had an inhibitor, he was unable to receive normal treatment which were received by others in the centre. He was clearly aware of such treatment as his two brothers was also treated in the Edinburgh centre (and became infected with HCV and HIV) as were his two nephews (who also became infected with HCV and HIV) and the two sons of one of them, who were infected with HCV.[1526] The witness' father deliberately avoided treatment and going to the hospital as he thought there was little that could be done for him and he would end up sting there for no real advantage. When he did receive treatment, it was with FEIBA or porcine factor VIII. He did receive factor VIII concentrate from abroad but only from 1985, when the product would have been heat treated.[1527] The Inquiry is

---

[1523] EXPG0000044_0059; Darby article at PRSE0001629
[1524] PRSE0001629_0010
[1525] WITN3477001 @ para 1 (first statement of Carolyn McGimpsey)
[1526] WITN3477001 @ para 2 (first statement of Carolyn McGimpsey)
[1527] WITN3477001 @ paras 6 to 8 (first statement of Carolyn McGimpsey)

aware that Dr Ludlam's treatment philosophy was to avoid the use of commercial factor VIII, which is likely to be the reason why this patient did not receive commercial products before that date, despite his inhibitor to the PFC concentrate. Despite this limited treatment regime, the witness' father lived until the age of 69. He was able to maintain employment as a civil servant within the DHSS and only suffered joint problems in later life.[1528] He was able to have a normal life expectancy despite not having had the benefit of concentrates. Due to his inhibitor and the lack of any locally available imported treatment, he often avoided treatment and managed his bleeds himself. The lack of a concentrate regime did not result in him having an early death, as many of the clinicians predicted would have happened in such a case. Within the NHS in existence since the 1920s when this man was born, he was able to life until the age of 69 and maintain employment. His case is an unusual (perhaps unique) control case which demonstrates that the evidence about the likelihood that haemophiliacs is simply not accurate. Insofar as the gloomy life expectancy predictions of these clinicians factored into their thinking (and it is submitted elsewhere that this was an example of the *ex post facto* rationale for the treatment regimes which emerged in the aftermath of the disaster) this case shows they are inaccurate. It is of course also demonstrative of the effects of concentrate use in Edinburgh. As this man had an inhibitor he "dodged the bullet" (as he put it himself) of HIV, a fate which was not avoided by his two brothers, now sadly deceased and two nephews.[1529] A similar story was given by a patient who has treated as a child in Edinburgh. He resisted treatment for religious reasons and concerns about infection but also had an inhibitor. He was treated with a combination of therapies including factor VII, factor VIII, factor IX and FEIBA.[1530] Though he contracted HCV he was not infected with HIV, like many others.[1531] One factor which the 1985 Ludlam research (considered elsewhere) showed was associated with seroconversion to HIV was the amount of treatment received. This patient's inhibitor status and his

---

[1528] WITN3477001 @ para 4 (first statement of Carolyn McGimpsey)
[1529] WITN3477001 @ para 9 (first statement of Carolyn McGimpsey)
[1530] WITN2233001, para 4 (first statement of Steven Newby)
[1531] WITN2233001, para 36 (first statement of Steven Newby)

objections to treatment limited the amount he received, which meant he avoided HIV. He has actually managed to secure and maintain employment and has a settled family life, despite the limitations of his treatment.[1532] In fact, GRO-C ; GRO-C GRO-C without which it was claimed by Dr Ludlam that he would never walk again.[1533] These cases show that less treatment would not have had the consequences which the clinicians have suggested it would.

4.50 The 1988 article relating to the progression of HIV caused disease in the Edinburgh cohort patients has a table in it which the years of birth of the 18 infected patients are set out.[1534] The inclusion in the paper of this information is criticised elsewhere in this submission. However, what can be said from this table (though it contains a random sample) is that 9 of the 18 patients listed were born in the 1940s, 3 were born in the 1950s and 5 on the 1960s and one in 1970. Given that we know that the Edinburgh treatment regime was mostly with cryoprecipitate until around the time of Professor Ludlam's arrival at the centre, the fact that half of these patients were in the 1980s in or around their 40s could not be attributable to the benefits of concentrates with which they had only been treated for a small part of their lives. The Edinburgh patients are an unusual group in that their exposure to concentrates before 1980 was limited. They had the benefit of being treated in a modern, Western healthcare system. Their mortality is contemporaneous to the period with which the assertion by Dr Hay and others has been made. The fact that these patients lived at least to this point contradicts this central theory of the haemophilia doctors' position as regards the advantages of concentrates.

BLOOD PRODUCTS

[1532] WITN2233001, para 1 (first statement of Steven Newby)
[1533] WITN2233001, para 5 (first statement of Steven Newby)
[1534] PRSE0004673_0002

e) Procurement and selection of blood products used in the treatment of bleeding disorders in Scotland

4.51 The systems for the selection and procurement of blood products used in the treatment of patients with bleeding disorders in Scotland merits some attention as it is relevant to the question of patients came to be infected and the options available to those responsible for treatment which might have avoided infections occurring or mitigated their effects. A system whereby the SNBTS provided haemophilia centres with PFC factor concentrates and relevant Health Board bought commercial factor VIII appears to have been in operation throughout this period.[1535] The narrative included in this 1981 memo seems to suggest, as was apparent over the relevant period, that there was a drive towards self-sufficiency in blood products in Scotland which was at that time hampered by a lack of availability of plasma. That the shortfall of PFC factor VIII concentrate might have to result in commercial factor VIII being purchased by the Health Board and an increased risk of liver disease being created was recognised by Dr Ludlam. It is interesting to note that there is no suggestion at that time that there was any apparent limitation on the availability of funds for the purchase of commercial material, should that have proven necessary. The evidence heard by the Inquiry, in particular from government witnesses, often resorted to the excuse that there was a lack of funding available to take what might be considered to have been safer options with regard to the production and procurement of blood products. The exchange between Dr Ludlam and Dr McClelland in this memo is illustrative of an apparent systemic failing with regard to the finding of the blood product system. Funds appear to have been available within health boards to purchase expensive commercial concentrates. The cost to the NHS of the production of the safer NHS concentrates was comparatively much less. There seems to have been little consideration or exploration of the possibility of investing the extra money

[1535] PRSE0004847 (14 January 1981)

used in the purchase of commercial products to fund a system of greater plasm procurement (by way, for example, of greater donor recruitment, holding more donor sessions, greater investment in plasmapheresis equipment and facilities) which would have avoided the need for the commercial factor VIII concentrates to be purchased in the first place. Any suggestion that poverty may have been the reason for the way that blood products were procured and used seems to be misplaced.

4.52 Thinking along these lines was apparent at the time on a local level. Early in his tenure as the haemophilia director in Edinburgh (at around this time) Dr Ludlam argued that the need for extra funding from the Lothian Health Board budget for a nursing position within the haemophilia centre could be avoided as the nurse would be able to educate patients in the more efficient use of products, reducing the need for so much products (in particular commercial products) to be purchased and thus resulting in the position in effect becoming self-funding.[1536] Such thinking did not appear to have taken place at more strategic level within SNBSTS or the CSA which would have enabled self-sufficiency to have been achieved through more careful investment of the same funds from the NHS budget.

4.53 Such limited strategic thinking also appears to have been a feature of the SNBTS/ NHS's attitude toward the risk of hepatitis transmission, mentioned as an increased risk of the more expensive commercial products by Dr Ludlam in the 1981 memo. Short term targeted investment in producing more and safer products (by introducing greater plasma collection regimes along with mor rigorous donor exclusion measures) would not only have avoided the need to expend greater sums on commercial products in the short term but also avoided the cost of treatment for those infected with hepatitis on the long term, not only in the recipients of blood products but also in those infected by blood transfusion.

4.54 In his evidence to the Penrose Inquiry, Professor Forbes pointed out that he required to use whatever product was available to him as his department in

---

[1536] LOTH0000216 (12 December 1982)

Glasgow did not have any spare money to pick and choose products.[1537] He opined that fate had determined the rate of HIV infection in Glasgow. His view was that as they were not using huge amounts of concentrate (by implication based on these funding restrictions) not as high a percentage of his patients were infected with HIV.[1538] It is interesting to note that the funding restrictions resulted in (a) less ability to get hold of the more expensive commercial concentrates and (b) less ability to expose patients to large amounts of concentrates, for example for home treatment and/or prophylactic regimes. This, in turn, resulted in lower rates of infection with HIV. We would submit that the avoidance of infection should have happened by design, rather than in the fortunate way described by Professor Forbes. The safer course (exposing patients to less products) was also the cheaper one. Cheaper still would have been to have relied on the PFC concentrates, produced free of charge to the Health Boards in Scotland. It would also have been cheaper to have restricted the number of different products available to the centre as more usage from a single supplier could have resulted in better terms being negotiated with that supplier based on the law of supply and demand, which would also have been safer as it would have restricted the number of varied donor panels to which the patients would have been exposed. It is argued below that the variety of the products used in Glasgow offset any incidental safety advantage gained by the financial limits and thus lesser product use.

Selection of products

4.55 As far as the selection of products was concerned, evidence available to the Inquiry was generally to the effect that the haemophilia centre director was able to pick and choose what products they wanted, without apparent restriction as to cost. This is apparent, for example, in the divergent approached taken by Dr Ludlam in Edinburgh and Dr Willoughby at Yorkhill, as examined in more detail below. It is

[1537] Penrose Inquiry transcript for 28/04/11 (day 17); 23 (24 to 25) (Professor Forbes); [PRSE0006017_0023]
[1538] Penrose Inquiry transcript for 28/04/11 (day 17); 118 (4 to 8) (Professor Forbes); [PRSE0006017_0118]

therefore important to realise that the directors had both therapeutic and financial freedom and thus must personally bear responsibility for the consequences of their choices, invariably taken without the involvement of patients or their parents.

4.56 By way of contrast, Professor Forbes gave evidence to the Penrose Inquiry to the effect that he, as the haemophilia centre director at the GRI in Glasgow, would have had no responsibility for the selection of which products would have been available in the hospital.[1539] He suggested that the SNBTS would be responsible for the determination of whether commercial or NHS material would be available and he would only become aware of what product there was when he came to administer it. Factor concentrates were a prescription medicine and it seems quite remarkable that such a senior haemophilia clinician as Professor Forbes would appear to have been so comfortable with the concept that product selection was left to others in this way. The inquiry has heard evidence about batch dedication, system whereby the risk to individual recipient of blood products was minimised by limiting the number of batches of product and hence the number of potentially infective donors to which an individual could become exposed. The material available to the Inquiry shows that a variety of different commercial products as well as domestic products were used at the GRI, in contrast to any other centre in Scotland. The lack of any clinical control over which product, never mind which batch of which product an individual patient received had the result of unnecessarily exposing that patient to a large number of donors which a more dedicated product selection and batch allocation policy would have avoided. That undoubtedly increased the risk of infection.

f) Increases in the amount of factor concentrates used in treatment

[1539] Penrose Inquiry transcript for 28/04/11 (day 17); 130 (25) to 131 (7) (Professor Forbes); [PRSE0006017_0130 to 0131]

4.57 Insofar as the statistical material available to the Penrose Inquiry from the UKHCDO can be deemed reliable, it is clear that the patterns of factor concentrate use, in particular amongst haemophilia A patients merits some further attention. Increases in the use of factor concentrates grew hugely internationally over the period – usage grew approximately 16.625 times between 1971 and 1984 and 3.325 times between 1976 and 1984 and 1.94 times between 1979 and 1984.[1540] The usage of products in Scotland is analysed in the statistics section above.

4.58 Haemophilia treaters were responsible generally for decision making around the amount of concentrates being used over the material period when infections were occurring. As is discussed elsewhere in this submission, decisions were made by the heads of the centres, often without regard to the wishes or views of the patients. The evidence shows that these decisions were taken not just in a way which excluded the patients but in a way which excluded the views of other clinicians or medical professional who may have a relevant view on the amount of product being used. The medical profession required to carry out a balancing exercise between the use of products for the prevention of bleeds against the risks of viral transmission, in particular (a) the likelihood of the products used transmitting viral hepatitis (b) the likelihood of the products used transmitting HIV (c) the likelihood of contracting AIDS as a result and (d) the severity of the consequences of AIDS, alone or in combination with viral hepatitis. The evidence heard by the Inquiry demonstrated that little consideration appears to have been given, in increasing hugely the amount of concentrate being used in Scotland in the first half of the 1980s, little attention appears to have been paid to the increased risk which extra exposure to pooled products may entail. Little evidence of the consideration the cumulative risks of increased exposure to hepatitis and possible exposure to the agent causing AIDS has been heard. These conditions appear to have been considered in the main as separate risks, despite the fact that the known immuno-suppressant characteristics of AIDS would inevitably diminish the patient's ability to fight the attack on the liver from the viral hepatitis. In

[1540] See EXPG0000044_0059 (Inquiry expert group report on fractionation); and reference 236, article by Johnson et al (1984)

addition, little if consideration appears to have been given to the possible effects of the increased exposure to the hepatitis viruses per se which increased concentrate use would inevitably involve. Repeated exposure made the likelihood of natural clearance of the disease less. Increased exposure should have involved consideration of the possible need for other lifestyle changes, such as alcohol reduction or adopting a healthier diet to reduce other insults to the liver. In particular, the almost inevitable effects of increased exposure to the livers of growing children who were receiving treatment for haemophilia appears not to have entered into the thinking of the relevant clinicians at all. Any of these things should have been at the forefront of the minds of those who were making recommendations about the treatment of bleeding disorders. They appear not to have featured at all. There was a relentless rise on the amount of concentrates being used, apparently without any cost or practical restriction on the total clinical freedom of the haemophilia clinicians. When this relentless rise started, there was no clear thought about the risks of hepatitis. When the risk of HIV emerged, there was no clear assessment of the risk which it posed *per se* or the cumulative risk of this and all other known or suspected pathogenic risks. These practices were dangerous and by the time of the emergence of HTLV III, out of control.

4.59 The amount of factor concentrates being used seems, in the first half of the 1980s, to have been solely within the control of the local haemophilia director. Despite representations made by Dr Boulton to Professor Ludlam in 1982 and 1983 about the amounts of SNBTS factor VIII being used in Edinburgh exceeding supply, this continued to be a matter over which the local transfusion service had little control. Predominantly for reasons of supply, Dr McClelland suggested in his evidence to the Penrose Inquiry that a more co-ordinated national system involving peer review by haemophilia directors of and guidance relating to the products used by their colleagues be introduced.[1541] Dr Boulton (formerly a haemophilia director himself) had found it necessary to apologise for his impertinence in making a treatment suggestion to Professor Ludlam in the past.[1542] There were certain

[1541] PRSE0003653 (2 February 1983)
[1542] PRSE0001269 (29 December 1982)

professional tensions between Professor Ludlam and Dr Boulton regarding the consumption of factor concentrates in the south east region.[1543] The following correspondence indites the nature and extent of the problems and their causes:

(a) See PRSE0000492 – there was an immediate start in February 1980 of the Ludlam home treatment programme. He indicated he was likely to want to expand the programme considerably in next year meaning much more concentrate and less cryo.

(b) See PRSE0003044 – 10 May 1982 – Dr Boulton wrote to Dr Ludlam warning about the issue of amount of F8 being used for home treatment patients. He was borrowing from other centres and needed to use cryo programme to the max.

(c) See PRSE0003294 – 8 August 1982 – Dr Boulton wrote to Ludlam regarding his concerns about the F8 supply

(d) See PRSE0001840 – 23 August 1982 – In this note by Dr Boulton of a meeting with Dr Ludlam, he set out the current system of getting back PFC factor VIII from PFC based on amount of blood collected in the region. There were thus limits to what could be provided and in order to provide for the demand Dr Ludlam wanted, the SEBTS needed to collect every drop of plasma it could get and supply it to the PFC. At this point, usage far outweighing the supply. Dr Ludlam had suggested getting some of the PFC allocation for Glasgow in exchange for commercial product. This would mean NHS Lothian paying for commercial product to get PFC allocation from the GRI. Dr Ludlam appeared to wish to re-invent the system, rather than survive within the allocation. Dr Boulton stated that there would be a need to buy more commercial concentrate if current usage continued. The situation was desperate.

(e) See PRSE0003959 – 3 September 1982 – In a letter from Dr Boulton to Dr Ludlam, he set out the anticipated availability of F8 from PFC and told him he

[1543] PRSE0001840 (23 August, year unclear but possibly 1982 or 1983 - the PFC supply was 84,000 units, dropping to 73,000 units but the usage was between 95,000 and 130,000 units per month)

was using too much. The letter refers to Dr Ludlam possibly looking into getting plasma fractionated elsewhere. Again, he wished to re-invent the system.

(f) See PRSE0003269 – 29 December 1982 – Dr Boulton intimated to Ludlam that he was about to run out of F8 due to usage for 2 boys.

(g) See PRSE0003653 – a latter of 2 February 1983 regarding the supply issues raised by Ludlam for Edinburgh. Dr McClelland raised with Dr Cash the need for "peer review" of reasonable consumption by haemophilia directors. This was the madness of clinical freedom in action.

(h) See PRSE0002081 – 10 May 1983 – this is a letter to Dr McClelland about Dr Ludlam needing more PFC F8 despite a recent increase from 300+ to 570 vials. 3 patients had needed to be treated with commercial product, despite Dr Ludlam's apparent commitment to the safety of domestic product.

(i) See PRSE0004678 – this is a December 1983 letter from Dr McClelland where he says he does not know why the exchange arrangement with Belfast is still going on. In PRSE0003085, the exchange of commercial for NHS material from Belfast in January 1984 is referred to. Having been frustrated in his bid to make a swap arrangement with Glasgow, Dr Ludlam had entered into one (in secret) one with Dr Mayne in Belfast. Oddly at this time, Dr Ludlam was treating at least two boys (subsequently infected with HIV) on home treatment with factor VIII concentrate. This was despite the fact that at a 2 February 1984 meeting he acknowledged that the guidance was to treat children with cryoprecipitate. He was prepared, in effect, to get the Health Board to pay for commercial material from Dr Mayne in order to keep these boys on concentrate, contrary to this guidance.[1544] Dr Ludlam's own colleague, Dr Boulton suggested that he was used to not moving boys onto concentrate from cryo until they were teenagers, precisely when between 13 and 17 depending on their size. This was just how normal approach, not just to do with the AIDS risk.[1545] This puts into sharp context the treatment regime at Yorkhill and the decision of Dr Ludlam to keep

---

[1544] PRSE0001556_0002 (2 February 1984)

[1545] IBI transcript for 04/02/22; 169 (Dr Frank Boulton)

these boys on concentrates in 1984. Both regimes were not standard. Both caused HIV infections in children.

4.60 This evidence demonstrates that Dr Boulton, previously a haemophilia director in England but employed then by the transfusion services in Edinburgh, had misgivings about the amounts of concentrate which were being used on patients there. These concerns clearly arise in part out of considerations of supply but also in part, it would appear when one considers this correspondence along with that sent to Professor Bloom, out of his fears for the safety of patients who are exposed to so much concentrate and the methods of plasma collection which required to be employed to satisfy it. In his oral evidence to the Inquiry, Dr Brian McClelland said that as a transfusion doctor, you "must respect" the clinicians' view on need and that the philosophy of the treating clinician was a factor driving the plasma collection targets.[1546] Dr Ludlam's treatment philosophy was clearly dangerously out of control. It was unsafe. In Dr McClelland's statement, he said that the duty of care of the haemophilia clinicians was to provide the best treatment which could **safely** be provided within the limitations of the system. That was the reason for example why Professor Ludlam did not just buy and prescribe lots of commercial concentrate.[1547] However, what was clear from this correspondence was that the unfettered prescription of products was also rendering the system unsafe, thus breaching Dr Ludlam's duty of care. It was doing so by forcing collection targets which meant that every drop of plasma was needed. This was not a safe way of collecting blood. It would also be wrong to think that this problem of out of control clinical freedom was a solely Edinburgh phenomenon. Dr McClelland said that the same problem existed in Glasgow which was the biggest region in terms of numbers of haemophiliacs.[1548] The strain on the system was intolerable and unsafe. He said that the risks were certainly pointed out but that the clinicians worked with the "hope and expectation" that the local donor system would mean it would be okay. This was a blind faith in light of the evidence

[1546] IBI transcript for 27/01/22; 65 (Brian McClelland)
[1547] Paras 103 and 119 of witness statement of Dr Brian McClelland
[1548] IBI transcript for 27/01/22; 77 to 79 (Dr McClelland)

of the risk.[1549] This pressure led to what Dr McClelland described as still a "wartime" approach to donation, even in the AIDS era of having to overlook "legitimate concerns" like whether donation in. the workplace was truly voluntary in order to meet targets.[1550] The system which resulted meant that even in his relatively safety conscious area, it turned out that they had donors who had used IV drugs who donated and were HCV positive.[1551] National donor guidelines to disqualify for a history of drug abuse only came in in 1984 anyway.[1552] The reference to "drug abuse" did not result in the exclusion of positive donors.

4.61 A co-ordinated approach to the use of products would necessarily have combined questions of efficacy, safety and supply and would have meant that a more consistent, considered and safe approach to the use of concentrates could have been achieved throughout Scotland. The ever-rising demand for concentrates meant that the transfusion service required in the early years of the 1980s to continue to source as much plasma as it could to satisfy the apparently relentless demand. This must have had an impact on the safety of the plasma collection practices. By the time new risks emerged, the collection system was already used to straining every sinew to gather every last drop of plasma. It was a system ripe for penetration by any new pathogen, such as HTLV III. As is submitted elsewhere in this submission, by the time 1983 came along new plasma processing techniques developed by Dr Foster had increased yield at the PFC such that less strain existed on the plasma supply. However, collection practices had not been changed in light of this and the plasma which had been collected had still been harvested from the previous system where plasma was in short supply. This resulted in a surplus of sticked of factor VIII concentrate which had been made under the strained system. In effect, the riskiest collection practices had been allowed to continue (including collection from prisons) although the system (driven not by red cell requirement but by plasma needs) no longer required them to. The effect of this was that there was plasma and indeed red cells for transfusion

---

[1549] IBI transcript for 27/01/22; 79 (Dr McClelland)
[1550] IBI transcript for 27/01/22; 97 (Dr McClelland)
[1551] IBI transcript for 27/01/22; 111 (Dr McClelland)
[1552] NHBT0053225

which had unnecessarily been collected from risky sources. Thereby, AIDS had been allowed to penetrate the Scottish system, with fatal consequences both for those with bleeding disorders who whose lifestyles were by this dependent on heavy factor concentrate therapy regimes and, by dint of the collection regimes designed to fuel them with plasma, recipients of red cell or other blood component transfusions as well. By the time of the WHO conference in Geneva in November 1983, the possibilities were considered of (a) concentrate use being limited to essential situations only[1553] and (b) reducing the number of donors to which a patient was exposed[1554] in light of the AIDS threat. The ongoing commitment to the use of factor concentrates in Scotland paid no heed to these timely warnings. A limitation on the relentless use of concentrates could still have prevented the majority of the domestically caused infections which did not occur until 1984. That these possibilities were being considered makes it clear that the use of concentrate in the amounts being consumed in Scotland was not clinically necessary at all.

4.62 Though the rise in factor concentrate usage was most marked in the Edinburgh centre as a result of the arrival of Dr Ludlam, the relentless march of concentrate usage was also apparent in other centres in the period from the late 1970s into the first half of the 1980s. In a statement made to the Penrose Inquiry, Professor CRM Prentice (who was partly responsible for the treatment of haemophilia patients at the GRI until February 1983, when he left to work in Leeds)[1555] described the advances in the treatment of haemophiliacs, in particular the development of cryoprecipitate and factor VIII concentrates. He stated that factor VIII concentrate was mandatory in the treatment of haemophiliacs and that there was no alternative.[1556] This attitude is illustrative of the "concentrates first, questions later" attitude prevalent at the time amongst haemophilia clinicians. In particular, on the very same page, Professor Prentice extols the virtues and advantages afforded by cryoprecipitate. It represented at least one alternative to

[1553] PRSE0004401_0018
[1554] PRSE0004401_0017
[1555] PRSE0002263
[1556] PRSE0002263_0003

factor VIII concentrate therapy, as is explored in more detail elsewhere in this submission.

Batch dedication

4.63 The Inquiry heard evidence that system of batch dedication was used to try to minimise viral transmission risks. Such a system was introduced in Edinburgh.[1557] The existence of such a system was designed in principle to minimise the batch exposures of individual patients. Batches were given to specified groups of patients based alphabetically on their surnames. The existence of this system indicates a clear knowledge of the risk of HIV transmission from batches of factor VIII concentrate (almost exclusively of SNBTS origin). However, there is no evidence of measures being taken to reduce exposure to the volume of concentrate and, in this regard, the system represents a failure to minimise the risk appropriately. Further, given that haemophilia is a hereditary disease affecting almost exclusively males, patients from the same family who lived in the same area received treatment at the same centre. The allocation of batches to individuals based on surname would also maximise the chances that, if there were an infected batch, members of the same family would all be exposed to that infected batch.

4.64 In any event, Professor Ludlam told the Penrose Inquiry that this system came in both Edinburgh and Glasgow, it would appear from about 1984.[1558] When pushed, he suggested that it was probably in late 1984 or early 1985.[1559] This ws confirmed in the evidence of Dr Boulton.[1560] Given that most, if not all, of the patients who became infected with HIV in Scotland were infected by this time and the fact that successfully heat treated SNBTS factor VIII concentrate became available from

[1557] Penrose Inquiry transcript for 04/05/11 (day 19); 114 (11 to 15) (Professor Ludlam); [PRSE0006019_0114]
[1558] Penrose Inquiry transcript for 03/05/2011 (day 18); 95 (2 to 21) (Professor Ludlam); [PRSE0006018_0095]
[1559] Penrose Inquiry transcript for 04/05/11 (day 19); 114 (11 to 15) (Professor Ludlam); [PRSE0006019_0114]
[1560] Para 204 of Dr Boulton witness statement @ WITN3456002

December 1984, this measure came too late in any event to have any impact. In any event, Dr Boulton confirmed in his Penrose evidence that the system did not work very well in practice.[1561] The evidence about measures indicated that what was done was too little, too late.

g) Home treatment

General

4.65 One of the main reasons for the large increase in the use of concentrates in Scotland in the late 170s and into the early 1980s was the increased use of home treatment in haemophilia therapy. There was a known, inevitable connection between home therapy and increased exposure to a larger number of donors and therefore a greater risk of infection. In his Penrose evidence, Dr Winter was asked about an article he had written on how one would cope if the supply of factor VIII concentrate were to be interrupted. He explained that the article had been based on a real event where there was a transient shortage in his centre of concentrates. His response was (a) to postpone non-essential surgery (b) look at treatment regimes and (c) moderate the amounts used by patients on home treatment.[1562] More concentrate than was strictly necessary was being used by his patients, in part as a result of home treatment. It was possible by these methods to reduce the amounts of concentrates being used. Home treatment was an unnecessary and unsafe therapy. Further, Dr Boulton appears to have suggested to Professor Bloom in May 1983 that the deferral of home treatment programmes would be a method whereby reliance on commercial concentrates in England might be

---

[1561] Penrose Inquiry transcript for 12/05/11 (day 24); 30 (16) to 31 (3) (Dr Boulton); [PRSE0006024_0030 to 0031]

[1562] Penrose Inquiry transcript for 26/04/11 (day 15); 53 (22) to 54 (7) (Dr Winter); [PRSE0006015_0053 to 0054]

reduced.[1563] This also seems to mean home treatment used up more concentrate than treatment in the hospital would and thereby increased the risk, in particular of HIV. In the editorial in the New England Journal of Medicine in January 1983, it was pointed out that the emerging threat of AIDS required a different attitude to be taken towards the dependence on concentrates and a reversion to cryoprecipitate therapy and a revision of home treatment programmes.[1564] In light of the emerging evidence in the first part of 1983, this would have been the most cautious and therefore the preferable option in Scotland as well. Again, as patients had not been appraised of the risks, the idea of withdrawing the convenience of home treatment, though necessary in the interests of safety, had been rendered practically impossible by the way these regimes had been introduced by the clinicians.

4.66 Evidence is available to the Inquiry that cryoprecipitate could have been (and was) used for home treatment throughout the UK. It is also worthy of note that the view that cryoprecipitate could not be used for home treatment was not unanimously held by the haemophilia clinicians who gave evidence. Professor Forbes in his evidence to Penrose made it clear that certain of his patients used cryoprecipitate at home.[1565] This possibility was not adequately explored in Scotland, in particular the possibility of home treatment being provided using the lyophilised cryoprecipitate which could be manufactured at Law Hospital. Therefore, the factual reality was that home treatment usually involved the use of concentrates and not cryoprecipitate in Scotland.

4.67 There may have been certain advantages in home treatment for patients who lived a long way from a haemophilia centre. However, it should have been assessed along with patients based on a fully informed basis as to the risks when balanced against the apparent convenience. The theoretical commitment of the centres remained to offer treatment there. Professor Forbes described there being an

---

[1563] That this line was taken is indicated in the reply from Professor Bloom which is PRSE0003701 (23 May 1983)
[1564] PRSE0002410_0002 (13 January 1983)
[1565] Penrose Inquiry transcript for 28/04/11 (day 17); 83 (8 to 16) and 101 (42 to 17) (Professor Forbes); [PRSE0006017_0083]

"open access policy" at the GRI. Professor Ludlam operated a system in Edinburgh whereby patients could be brought to the centre at the RIE by ambulance (sometimes from far away)[1566] and the centre was available 24 hours.[1567]

4.68 One key aspect of the home treatment programmes which were instituted in Scotland over this period is that a full assessment of the risks and benefits was rarely, if ever, presented to the patients or their parents. Clearly, patient and their parents would have been attracted by the apparent convenience and consequent emancipation which home treatment with factor concentrates would have involved. However, it was essential (and indeed their right) to be fully appraised of the risks that the new system involved as well. However, it would have been difficult for the risks inherent in increased concentrate exposure to have been discussed when the risks inherent in product use, whether in the hospital or at home had (on the evidence of most of the Scottish patients from whom the Inquiry heard) never been discussed with them at all, or at least not sufficiently. If a patient was unaware of the risk that the products posed, it would not seem that using safe products at home, in larger quantities would have any downside. The failure on the part of haemophilia clinicians to discuss the risks on the first place had started a kind of domino effect which was becoming relentless. By failing to discuss the risks in the first place, it became difficult to discuss the increased risk of home treatment where the patient would use the products when they wanted, with little if any limitation. The fact that patients were treated at home meant that they adapted their lifestyles accordingly. When new risks such as HTLV III emerged, it would have been difficult to have convinced the patients to go back to their old regimes. However, the key point is that this was all done without a clear explanation of the risks at each stage. The failure of the doctors to discuss the risks and how they increased with increased convenience was the root cause of the relentless increase in the use of factor concentrates and the relentless increase in the risk. Professor Charles Forbes gave evidence to the Penrose Inquiry, under

---

[1566] Penrose Inquiry transcript for 03/05/2011 (day 18); 66 (9) to 67 (13) (Professor Ludlam); [PRSE0006018_0066 to 0067]

[1567] Penrose Inquiry transcript for 03/05/2011 (day 18); 67 (18 to 19) (Professor Ludlam); [PRSE0006018_0067]

reference to a document from 11 October 1974. [1568]At that time, it appeared to be the rationale behind the beginnings of home treatment that it would result in a reduction of the number of patients crippled and an improvement the quality of life.[1569] It appears that the thinking in that area was in very general terms and appears to have had no consideration of the risks which might be associated with home treatment programmes. The vagueness of the thinking and the lack of consideration of the downsides appear to be reasons why these matters which required to be discussed in detail with patients or parents. Patients had a right to choose for themselves and the advantages in terms of the improvement for bleeding which quicker, non-hospital based treatment might entail needed to be understood and decisions reached on an informed basis by the patients themselves.

4.69 In addition, the extension of the home treatment programmes had a clear benefit to the system of not having to provide facilities within the hospital. Capital and staff costs could therefore be reduced. In his evidence to the Penrose Inquiry, Professor Ludlam confirmed that home treatment relieved pressure on nursing staff, ambulance staff and doctors who no longer needed to see in-patients every morning.[1570] This must have played a part in the decision making around driving patients away from the hospital, in particular in hospitals (such as Yorkhill) where the evidence shows that the facilities available within the hospital were really wholly unsuitable for inpatient treatment.

Edinburgh

4.70 In Edinburgh, limited home treatment programmes were started in Edinburgh under the regime of Dr Davies from the 1970s.[1571] One of the main reasons why demand for concentrate in Edinburgh rose sharply was that after 1980 as Professor

[1568] PRSE0004626
[1569] Penrose Inquiry transcript for 28/04/11 (day 17); 37 (8 to 13) (Professor Forbes); [PRSE0006017_0037]
[1570] Penrose Inquiry transcript for 04/05/11 (day 19); 126 (12 to 20) (Professor Ludlam); [PRSE0006019_0126]
[1571] PRSE0002323

Ludlam wanted more to be able to treat people on home therapy.[1572] The link between concentrates and home therapy is exemplified by the fact that, in his evidence at the Penrose Inquiry, Professor Ludlam, generally an advocate of domestically produced products, stated that he would have sought more commercial concentrates from his local health authority in order to get more patients onto home therapy, had it not been for the fact that he had inherited a group of patients who had never been exposed to commercial concentrates under his predecessor, Dr Davies.[1573] His desire to get patients onto home treatment was such that he would, in theory, have been prepared to expose his patients to treatment with commercial products, known to carry higher risks of hepatitis due to the blood donation system from which they had been created. What this meant was that the domestic system was put under even more pressure. Instead of asking himself whether the domestic system could tolerate home treatment safely, Dr Ludlam approached the questions the wrong way round. He decided that he would expand home therapy and use domestic products to do it. That produced a pressure on the system of domestic production with which it could not cope, or at least with which it could not cope safely.

Glasgow

4.71 The claimed advantages of home treatment included (a) convenience for patients and (b) lesser pressure on hospitals to provide facilities and staff for administering treatment and (c) the likelihood that a patient, recognising the sensation that a bleed was starting, would be able to administer treatment to stop the bleed more quickly than would be the case if hospital attendance were required. It was hoped that early treatment, in children in particular, would have a long term advantage for the condition of their joints.[1574] It appeared to be the case from the evidence

[1572] Penrose Inquiry transcript for 03/05/2011 (day 18); 68 (13 to 15) (Professor Ludlam); [PRSE0006018_0068]
[1573] Penrose Inquiry transcript for 03/05/11 (day 18); 72 (7 to 17) (Professor Ludlam); [PRSE0006018_0072]
[1574] Penrose Inquiry transcript for 05/05/11 (day 20); 15 (22) to 16 (2) (Dr Pettigrew); [PRSE0006020_0015 to 0016]

of Professor Forbes to the Penrose Inquiry, that large number of patients in Scotland and in Glasgow, in particular, had been put onto home treatment in the latter half of the 1970s during the so-called "golden age" after introduction/ licensing of concentrates and before the viral contamination problems associated with NANBH and later HIV.[1575] He made it clear that home treatment (and prophylaxis for that matter, though to a more limited extent) was started against a background of there being few concerns about the safety of the concentrates or large exposure to them.[1576] The key issue with that approach was that there was no mechanism for review of the regimes once evidence of the greater risks associated with them became more apparent. Thus, no proper risk assessment of the regimes was ever undertaken.

4.72 In the early 1980s it was generally deemed inappropriate for patients to be able to use cryoprecipitate if on home treatment programmes. It is, therefore, perhaps not surprising that the advent of home treatment in centres like Edinburgh and Glasgow resulted in patients (a) being committed to concentrate as the mainstay of their therapy rather than cryoprecipitate treatment and (b) self-administering unregulated and hence unnecessarily large amounts of concentrate at home. Though offering certain therapeutic advantages (the timing aspect as recognised above), it is submitted that the rise of home treatment programmes was based on expediency rather than a proper long term assessment of cost and benefit to the patients. As far as cost is concerned, for example, it seems that the cost savings in the hospital may have been outweighed by the increased usage and expense of the concentrates required by patients on home treatment. Dr Winter gave some evidence to the Penrose Inquiry regarding the cost of clinical care as against the cost of concentrate therapy per patient. The latter expense he said "could be extremely high".[1577]

[1575] Penrose Inquiry transcript for 28/04/11 (day 17); 58 (Dr Forbes); [PRSE0006017_0058]
[1576] Penrose Inquiry transcript for 28/04/11 (day 17); 61 (14 to 19) (Dr Forbes); [PRSE0006017_0061]
[1577] Penrose Inquiry transcript for 26/04/11 (day 15); 65 (1 to 6) (Dr Winter); [PRSE0006015_0065]

4.73 In Yorkhill, patients were not regularly seen in the hospital at all under the directorship of Dr Willoughby, according to Dr Pettigrew in her evidence to the Penrose Inquiry.[1578] Home treatment was a major part of the treatment programme. In her Penrose evidence and despite the apparent reliance on home treatment as the mainstay of the treatment regimes of the boys with haemophilia, Dr Pettigrew had no recollection of discussing the risks associated with home treatment with Dr Willoughby.[1579] She was unable to give a detailed account about her knowledge of the risks (in particular of whether the risks were of hepatitis B or NANB hepatitis) and the extent to which these were discussed with the parents when asked about this at Penrose. The main reasons why home treatment appears to have featured so prominently in the Yorkhill treatment regimes appears to relate to the accommodation and manpower issues which affected the delivery of haemophilia treatment at that hospital over the key relevant period. This is discussed on more detail below. The inability to have standing staff at the hospital or indeed adequate accommodation played a part, in our view, of the way that the treatment regimes developed, to the detriment of patient safety. In addition, the apparent lack of dialogue with parents about home treatment regimes has a particular significance for Yorkhill. The practical advantages for parents of children and the children themselves were clearly likely to the attractive to the Yorkhill families. As such, it was all the more incumbent for the doctors there to be clear with the families about the associated risks and indeed to continue to monitor the risk/ benefit analysis as things went on. This is discussed more fully in the context of prophylaxis below.

h) Prophylaxis

[1578] Penrose Inquiry transcript for 05/05/11 (day 20); 4 (17 to 20) and 21 (2 to 10) (Dr Pettigrew); [PRSE0006020_0004 and 0021]
[1579] Penrose Inquiry transcript for 05/05/11 (day 20); 20 (1 to 4) (Dr Pettigrew); [PRSE0006020_0020]

4.74 The evidence available to the inquiry suggests that prophylactic treatment can be understood in two ways, namely the use of short-term extra treatment in connection with the risk of emergence of a specific bleed, for example into a specific joint or the more widespread, permanent use of prophylaxis to try to prevent bleeds happening at all or keep them to a minimum, effectively attempting as far as possible to prevent the effect of the bleeding disorder from occurring. Both of these types of prophylaxis can be contrasted with what the evidence would suggest was the more normal "on demand" type of treatment for bleeding disorders where treatment was only administered when necessary in response to abled occurring, either at home or in the hospital. The specific issue of the use of prophylactic treatment at Yorkhill Hospital in Glasgow in the late 1980s and early 1980s is addressed in more detail below.

4.75 Overall, we would characterise the latter type of prophylactic treatment as being far too risky in the late 1970s to mi 1980s as it resulted in patients being exposed to much more treatment, invariably in the form of concentrate therapy than would otherwise be necessary. Use of concentrate in such large quantities was simply unsafe in light of the risks of the factor concentrates available at that time. Such regimes ought not to have been embarked upon until they could be done safely, at least into the period when virally inactivated concentrates became available.

4.76 The evidence would tend to suggest that prophylactic treatment with factor concentrates was instituted on the basis of the perception that it would prevent spontaneous cerebral bleeding and death amongst patients with bleeding disorders. Further, it was hoped that a reduction in the number of spontaneous bleeds in severe patients would be good for the long term prospects of joint, in particular in children's joints.[1580] In his evidence to the Penrose Inquiry, Dr Mark Winter explained that it aimed to prevent spontaneous bleeding in severely affected patients by raising their factor levels to the point where, though

[1580] Penrose Inquiry transcript for 05/05/11 (day 20); 15 (6 to 12) (Dr Pettigrew); [PRSE0006020_0015]

susceptible to traumatic bleeds, their susceptibility to dangerous spontaneous bleeding might be reduced to the level of a more moderate patient with some natural factor occurring in the blood. This evidence would tend to suggest that treatment in moderate patients could have been avoided, or certainly reduced, possibly minimised had patients been counselled properly as to how to avoid traumatic bleeding by making appropriate lifestyle choices.

4.77 Dr Winter also pointed out that (a) to achieve this regular treatment with concentrates was necessary and (b) that prophylaxis was a European treatment regime which had not until very recently (at the time of his evidence to Penrose in 2011) been widely practised in the US. [1581] He said prophylactic regimes (based on the Swedish model) did not really get underway until the 1980s.[1582] They were clearly contemplated before then as there was some discussion of them (and some reluctance expressed about them) at a meeting of the UKHCDO on 13 January 1977.[1583] Professor Forbes (in his Penrose evidence) noted that the reluctance to embark upon them at that time stemmed from the "huge amount of exposure to plasma products" that the programmes would entail.[1584] Professor Hann (in his Penrose evidence) suggested that prophylactic therapy required around three times as much concentrate than on demand therapy.[1585] Thus, even amongst haemophilia treaters who were generally keen on the use of factor concentrates, there was a clear knowledge that generalised prophylaxis created an unnecessary risk for patients, given the huge increase in the amounts of factor concentrates to which a patient would require to be exposed, compared to the alternative on demand treatment regime. Despite this, the then current reverence for the mantra of clinical freedom allowed individuals clinicians to embark upon which programmes, apparently without professional or financial restriction.

[1581] Penrose Inquiry transcript for 26/04/11 (day 15); 74 (1 to 18) (Dr Winter); [PRSE0006015_0074]
[1582] Penrose Inquiry transcript for 26/04/11 (day 15); 74 (25) to 75 (4) (Dr Winter); [PRSE0006015_0074 to 0075]
[1583] PRSE0002268_0010
[1584] Penrose Inquiry transcript for 26/04/11 (day 15); 57 (1 to 2) (Dr Winter); [PRSE0006015_0057]
[1585] Penrose Inquiry transcript for 06/05/11 (day 21); 11 (22) to 12 (6) (Professor Hann); [PRSE0006021_0011 to 0012]

4.78 A study by Rizza and Spooner studied the treatment of patients with bleeding disorders predominantly in the period 1976 to 1980. The authors noted that there had been an increase in use of factor VIII concentrates over this period.[1586] They concluded that there was a near normal median expectation of life in severe haemophiliacs and a greater than average mean life expectancy in mild haemophiliacs, though bleeding (and in particular cerebral bleeding) represented the main cause of death in the haemophiliac population. There is no mention in the article of widespread use of prophylactic treatment in the UK by 1980 and, indeed, in projecting future trends, the authors refer to the possibility of an even further increased requirement for factor concentrates in the future in the event of "the widespread use of prophylactic treatment".[1587] In his evidence to the Penrose Inquiry, Professor Ludlam pointed out that deaths from haemorrhage diminished significantly in patients with bleeding disorders with the introduction of fresh frozen plasma and, in particular, cryoprecipitate. The introduction of concentrates resulted in a small additional life expectancy.[1588] The overall assessment of the impact of various products in life expectancy is discussed elsewhere in this submission. For present purposes, it seems that on any view (without widespread prophylaxis) mortality risk had been minimised anyway. Given that the main advantage of prophylaxis (as analysed by Dr Winter) was reducing the mortality risk posed by , given that this appeared to be a small risk anyway, it does not seem feasible to argue that this perceived benefit of such regimes could be deemed to have been great, which balanced with the known risks. At the levels at which factor concentrates were being used in the treatment of patients with bleeding disorders by 1980, at which time there was no widespread prophylaxis, meant that life expectancy, even for severe patients, had reached near normal levels. Indeed, in his Penrose evidence, Dr Winter attributed the fact that cerebral bleeds are now very much less common than they used to be to (a) better education and (b) the availability of earlier treatment.[1589] He did not mention prophylaxis as the reason,

---

[1586] PRSE0000795
[1587] PRSE0000795_0005
[1588] Penrose Inquiry transcript for 04/05/11 (day 19); 123 (13 to 22) (Professor Ludlam); [PRSE0006019_0123]
[1589] Penrose Inquiry transcript for 26/04/11 (day 15); 77 (12 to 13) (Dr Winter); [PRSE0006015_0077]

despite making these comments directly after this evidence on the evolution of prophylactic treatment.

4.79 Prophylactic treatment regimes should never have been started in Scotland on the basis of a proper balance between the value of such treatment and the potential risk of viral transmission from such massive use of concentrates which was well known by the time they were instituted, not to mention the known risks of antigenic overload caused even by on demand treatment regimes with factor concentrates. Further, any prophylaxis should have been stopped by around 1980 based on (a) the apparently limited information that it was actually benefitting the patients and (b) the existing knowledge at that time that there was a risk from NANB hepatitis which could only logically be increased by vastly greater exposure. Minimising exposure to factor concentrates in severe patients to them would have constituted a better balance between the risks and benefits of concentrate therapy. It would have meant that far less concentrate was required and would ultimately have materially decreased the risk of patients being exposed to AIDS in the early years of the 1980s.

i) Cryoprecipitate

4.80 Cryoprecipitate was able to be produced from plasma in a form which brought off the factor VIII and fibrinogen content of the plasma, leaving behind a supernatant which contained the rest of the contests of the plasma, including factor IX.[1590] This alternative treatment option for the treatment of patients with haemophilia A was largely disregarded. As it derived from single donations, even with multiple donations being required in certain clinical circumstances the recipient would be exposed to far fewer donations and so exposure to less donors and so was far safer as far as the risk of transmission of viruses was concerned. Though this alternative was available only to patients who suffered from haemophilia A as opposed to

[1590] PRSE0002052_0014 (1977)

haemophilia B, the evidence heard by the Inquiry was (a) that they were far more numerous and (b) that they were the ones whose exposure to factor concentrates exposed them to the risk of AIDS which materialised in Scotland almost exclusively in the haemophilia A as opposed to the haemophilia B community (with some important exceptions, discussed below). Thus, an examination of the potential for cryoprecipitate to have been used more in Scotland is an important part of examining how and whether fatal infections ought to have been prevented.

4.81 Advantages of cryoprecipitate were in evidence from the early years of its use in the 1960s. The UK experience of its lower risks was clear in Dr Harold Gunson's report to the European Health Committee of the Council of Europe on 25 June 1982. He reported that there appeared to be a low contamination rate of NANB Hepatitis in the UK in patients receiving cryoprecipitate but a high rate following transfusion of Factor VIII concentrates prepared from large pools.[1591] He suggested that avoiding the use of large-pool fractions for those with mild coagulation defects was a practical way of reducing the incidence of post-transfusion NANB Hepatitis. This was clearly an issue at that time but it was also pointed out that there were no plans to introduce ALT testing and there was an urgent need for a specific test. The even higher risk of hepatitis transmission from commercial concentrates was also spelt out. On the eve of the HIV crisis, it was thus admitted by the government advisor in transfusion medicine that there was a greater risk from concentrates than cryoprecipitate in NANBH transmission and also that there was an urgent need for protection. He also suggested at that time that cryoprecipitate should be used in the treatment of milder patients. The reason for this must logically have been that such patients did not need to encounter the risk of disease transmission which concentrate use would have entailed due to the fact that they would need treatment less frequently and hence could get away with never been exposed to concentrates at all. There is no suggestion that cryoprecipitate would not have been a perfectly adequate means of treating bleeds in these patients. It is notable that he was not advising the use

[1591] PRSE0001575

of DDAVP in such patients, which he ought to have done, as this would have avoided risk of hepatitis completely.

4.82 The disadvantages of it as a product were continually listed as a mantra by many of the haemophilia clinicians who gave evidence to the Inquiry. However, its advantages as a product were also well known from the early years and throughout the 1970s. In 1977, Dr John Wallace commented on its ease of preparation – it could be prepared within a matter of hours of the plasma being collected whereas at that time the fractionation of the then alternative intermediate factor VIII concentrate would take two to three months from the date of collection of the plasma from which it was derived.[1592] Large amount of cryoprecipitate were still in use in Glasgow at the time of Dr Wallace's test in 1977. It appears that 50,000 donations (around 40% of the annual number of donations being collected in Glasgow of 120,000) was having its plasma processed into cryoprecipitate, 90% of which was being used in the treatment of around 60 severe and moderate haemophiliacs there, the rest being used in the treatment of the remainder of the 270 local haemophiliacs.[1593]

4.83 The heavy reliance on the use of concentrates materially increased the risk for patients of the likelihood of them being infected with disease. The epidemiology suggests that they were exposed to a risk of HIV which they would not have had and the risk of HCV was eventually rendered inevitable on first exposure (see above).

Patient involvement in decision making about cryoprecipitate use

4.84 The duty of the doctor, or any professional, must at some point be to recommend that the patient do something which may appear unpopular but which is in his patient's interests. Under reference to the 1975 World in Action programme, Dr Winter spoke in his evidence to the Penrose Inquiry of the reluctance which

[1592] PRSE0002052_0015 (1977)
[1593] PRSE0002052_0014 to _0015 (1977)

patients would have had to stopping treatment with concentrates in light of variable information and variable opinions from doctors (he was referring at that stage to the hepatitis risk from concentrates, which he had placed at 100%[1594]) given the lifestyle advantages which they had enjoyed as a result of concentrate therapy.[1595] This was all the more likely given his evidence on the potential drawbacks of alternative treatments like cryoprecipitate which included possible reactions, the need to go to hospital and the inaccuracy of the factor VIII dose (the legitimacy of his characterisation of these drawbacks are discussed elsewhere in this section).[1596] He did, however, accept that if patients had starker, clearer information they might have modified their use of factor VIII, at least in the home setting.[1597] The likely reluctance on the part of the patient who saw and understood only the immediate advantages of concentrate therapy was inevitable. The fact that bad news about concentrate therapy was likely to be received unwillingly imposed an even greater burden on the doctor to be full and frank with their patients about the emerging threat of AIDS when it became known. Furthermore, the difference between the approach adopted by the likes of Dr Winter in 1975 nd the position in Scotland as regard the possible "reversion" to cryoprecipitate is important. In his analysis, Dr Winter's patients would have needs some persuasion to revert to cryoprecipitate at that time. It is inevitable that that dilemma must have played a part in his thinking as regards what he said to his patients. This was a dilemma faced by many clinicians in England whose patients had seen the perceived practical advantages which had been made available to them by the licensing of US factor VIII concentrates since 1973. In Scotland, no such dilemma existed. The usage of factor concentrates imported from abroad was very much less. As is widely accepted, in Edinburgh the mainstay of treatment around 175 and for the rest of the decade remained cryoprecipitate.

[1594] Penrose Inquiry transcript for 26/04/11 (day 15); 84 (2 to 17) and 92 (4 to 9) (Dr Winter); [PRSE0006015_0084 and 0092]
[1595] Penrose Inquiry transcript for 26/04/11 (day 15); 94 (22) to 96 (1) (Dr Winter); [PRSE0006015_0094 to 0096]
[1596] Penrose Inquiry transcript for 26/04/11 (day 15); 78 to 81 (Dr Winter); [PRSE0006015_0078 to 0081]
[1597] Penrose Inquiry transcript for 27/04/11 (day 16); 145 (24) to 146 (3) (Dr Mark Winter); [PRSE0006016_0145 to 0146]

Thus, there was a far lesser dilemma to be faced. The proposed "reversion" to cryoprecipitate in light of the evidence of the risks associated with concentrates in Scotland was would have been a much lesser step or indeed no step at all. Furthermore, the significance of these cultural differences must be understood so that the relevant of national guidance emanating from the UKHCDO to Scotland can be fully appreciated. Guidance was being formulated there, including at times as regards whet patients should be told or advised about product use, in a context which had (since the time of the World in Action documentary at least) been dominated by the dilemma which Dr Winter described. Discussion, decision-making and policy all [proceeded on that basis. Given that that basis was not for the most part applicable to or in the best interests of the patients in Scotland, the discussions, the decisions and the guidance were not either.

4.85 In his evidence to the Penrose Inquiry, in the context of a discussion about a possible reversion to cryoprecipitate in 1983 in light of the AIDS crisis, Professor Ludlam commented on efforts made by Dr Oscar Ratnoff in the USA to switch his patients from concentrate therapy back to cryoprecipitate. He pointed to the significance of the fact that only 5 out of the 90 patients offered this option by Dr Ratnoff accepted the proposal.[1598] This was a characteristic attempt on the part of Professor Ludlam to focus on evidence which exonerated his own inaction. The data is of no relevance other than to indicate that a renowned haemophilia clinician saw fit to make this switch and also to offer the option to his patients. The decisions taken by the American patients, in light of considerations pertaining to them and their treatment are of no relevance to the likely response to such a similar suggestion made by a clinician in Scotland, far less to their right to be allowed to make their own decisions about their own healthcare. In any event, the precise nature of the information/ advice given to the patients by Dr Ratnoff as to why the switch would be advantageous is unknown and so the outcome is meaningless for our purposes. Further, the Inquiry has access to plenty of evidence

[1598] Penrose Inquiry transcript for 04/05/11 (day 19); 29 (15) to 30 (10) (Professor Ludlam); [PRSE0006019_0029 to 0030]

to the contrary – ie that Edinburgh patients would have changed treatment regimes, of they had been offered the properly informed option to do so.

The practical considerations surrounding the use of cryoprecipitate

4.86 Generally, cryoprecipitate could have been made the mainstay of treatment on a practical level, in particular in response to the emerging risks of AIDS in around 1983. Cryoprecipitate was made everywhere in Scotland.[1599] In his evidence to the Penrose Inquiry, Professor Forbes explained in his evidence that cryoprecipitate fell out of favour (from around 1980) due to the "volume, the number of donations needed, the method of making it up, the time involved and so on".[1600] Nevertheless, he suggested that he could get access to it in Glasgow when he wanted as his department had a good relationship with the local blood transfusion service.[1601] Professor Prentice, in his statement to the Penrose Inquiry did not see that there was such a stark difference between cryoprecipitate and the available intermediate purity SNBTS concentrate, as might otherwise be imagined. He was clear that the main breakthrough which had revolutionised treatment had been the development of cryoprecipitate by the Pool group (as is examined in more detail elsewhere in this submission, with regard to the morbidity and mortality benefits of cryoprecipitate, often incorrectly associated with factor concentrates). He described cryoprecipitate as "the first high potency concentrate of factor VIII concentrate which could be prepared quickly and easily".[1602] Professor Lowe agreed with this assessment of the concentrate as he identified the Scottish concentrates as having issues with (a) solubility (b) variability in the amount of factor VIII as marked on the bottle and in reality and (c) purity.[1603]

[1599] Penrose Inquiry transcript for 10/05/11 (day 22); 77 (9 to 10) (Dr Foster) [PRSE0006022_0077]
[1600] Penrose Inquiry transcript for 28/04/11 (day 17); 78 (12 to 15) (Professor Forbes); [PRSE0006017_0078]
[1601] Penrose Inquiry transcript for 28/04/11 (day 17); 78 (17 to 20) (Professor Forbes); [PRSE0006017_0078]
[1602] PRSE0002263_0003 (statement by Professor Prentice to the Penrose Inquiry)
[1603] STHB0000828 _ 0004

4.87 The advantages of SNBTS factor VIII concentrate claimed in evidence by certain clinicians were, in fact, marginal. The Inquiry should be careful when assessing the claimed limitations of cryoprecipitate as a therapy not to assume that the then available concentrates in Scotland (produced at the PFC) did not have significant practical issues which were well-recognised by clinicians as well. In the 1970s and 80s, the then available SNBTS concentrate was of intermediate purity took around half an hour to dissolve.[1604] In his oral evidence to the Inquiry, Dr Brian McClelland said that SNBTS factor VIII was not always the clinicians' first choice, mentioning the inconvenience of the time taken to dissolve.[1605] Dr Boulton referred to the continued bleeding problems experienced with the PFC product due to its impurity based on the fibrinogen content.[1606] The claimed advantage of this concentrate over cryoprecipitate, as far as practicality was concerned, was not significant. Cryoprecipitate fell out of favour primarily for perceived reasons of practicality and convenience, primarily for clinicians. Little attention was paid to its safety advantages which had been part of the thinking of Dr Howard Davies who had favoured its use in Edinburgh before the arrival of Dr Ludlam. It was still available but not favoured for reasons of practical convenience, which were on the evidence, limited. Allergic reactions were also claims as a reason why cryoprecipitate fell out favour. Again, the evidence on this consideration seemed to overplay the significance of this element. Such reactions were not unknown but were also apparent in the use of SNBTS intermediate concentrates due to their purity issues. This the issue was not whether cryoprecipitate had such problems as the factor VIII concentrate had them too.

4.88 Further, as Professor Ludlam described in his evidence at the Penrose Inquiry, the rise in the preference for home treatment made cryoprecipitate less attractive due to problems with storage, preparation for use and possible reactions in a home environment[1607] (thought use of cryoprecipitate at home was not impossible, as

---

[1604] Penrose Inquiry transcript for 05/05/11 (day 20); 17 (5 to 6) (Dr Pettigrew); [PRSE0006020_0017]
[1605] IBI transcript for 27/01/22; 74 (Dr Brian McClelland)
[1606] para 341 of Dr Boulton witness statement @ WITN3456002
[1607] Penrose Inquiry transcript for 03/05/2011 (day 18); 34 (2) to 38 (10) (Professor Ludlam); [PRSE0006018_0034 to 0038]

described by Professor Forbes and as accepted by Professor Ludlam in their Penrose evidence[1608]). This move came despite warnings to the contrary from Professor Cash who had said at a joint meeting in January 1981 that clinicians should bear in mind the role which cryoprecipitate had to play in the treatment of haemophiliacs.[1609] In his oral evidence to Penrose he expanded upon this by saying that from a supply perspective, the shift from cryoprecipitate to concentrates meant that a lot more plasma needed to be sourced effectively to "stand still", pushing the goal of self-sufficiency even further away and adding to the need to continue to rely on risky donors to source the required plasma.[1610] The response from the clinicians to his suggestion that there may be implications of the shift from cryoprecipitate to factor VIII concentrate as the mainstay of treatment was, in Professor Cash's own words, that it "went down like a load of lead".[1611]

4.89 In January 1983 an editorial in the prestigious New England Journal of Medicine suggested that cryoprecipitate should be used in preference to factor concentrates. This was despite the fact that the concentrate therapy had proved to be very successful and "even though we may not have enough evidence to demand such a radical change".[1612] In response to questions asked about this editorial, Dr Winter pointed out at the Penrose Inquiry that when a move back to cryoprecipitate was contemplated, there were problems of supply and it was unrealistic to expect that it could be used at home.[1613] These supply issues did not exist in Scotland (see below). In any event, this casual attitude taken to the emergence of AIDS in later 1982 until the spring of 1983 when cases started to emerge in the UK meant that no proper risk assessment was performed in relation to the short term advantages of concentrate use against the longer term infection risks associated with concentrates on which there was near total reliance. As Dr McClelland confirmed in his Penrose evidence, it would have been possible to

---

[1608] Penrose Inquiry transcript for 03/05/2011 (day 18); 38 (8 to 10) (Professor Ludlam); [PRSE0006018_0038]
[1609] PRSE0000144_0002 (30 January 1981)
[1610] Penrose Inquiry transcript for 13/05/11 (day 25); 113 (16) to 114 (4) (Professor Cash); [PRSE0006025_0113 to 0114]
[1611] Penrose Inquiry transcript for 13/05/11 (day 25); 112 (20 to 23) (Professor Cash); [PRSE0006025_0112]
[1612] PRSE0002410_0002 (13 January 1983)
[1613] Penrose Inquiry transcript for 27/04/11 (day 16); 25 (18) to 26 (10) (Dr Winter); [PRSE0006016_0025 to 0026]

revert to cryoprecipitate completely had there been a clinical demand for that move but it would have taken some time to achieve. Dr McClelland pointed out that in Edinburgh the main treatment had been with cryoprecipitate under the Dr Howard Davies regime prior to 1980.[1614] He accepted that it would have been feasible to revert to a cryoprecipitate based treatment regime of there had been a clinical demand for it at any time in the early 1980s. This would have required new facilities from the CSA but he accepted that this would have required only "a fairly modest investment".[1615] The clinical demand never came. Had it come, it could have been met.

4.90 Given the inevitable exposure of those using high quantities of pooled products to any new pathogen, when a potentially fatal one emerged, there was a need for the system to be nimble and reactive. No consideration had been given to the likely need for the contingency of switching to the safer cryoprecipitate, even gradually, at an early enough a stage to enable the switch to be made. When "moving back to cryoprecipitate" was contemplated in England, they were told that there was not enough. What was necessary was a realisation (a) that AIDS could be transmitted through blood and blood products (b) that evidence of AIDS in the UK had been available from late 1981 (c) that little could be and was being done in the blood collection system in the UK to minimise the risk of a positive donor donating and (d) that the system had become geared towards and dependent on the use of concentrates (and large amounts of it at that) to the extent that a switch back to cryoprecipitate could not happen instantaneously. As the NJEM editorial points out what was needed was a decision that the switch was required even in the absence of irrefutable evidence that a total switch was necessary. A clinical need for cryoprecipitate and a change of treatment philosophy could and should have been identified and supported by the early part of 1983.

4.91 In the east of Scotland, cryoprecipitate had been the product used in the treatment of the majority of patients when Professor Ludlam arrived in 1980, with

---

[1614] Penrose Inquiry transcript for 06/05/11 (day 21); 153 (11 to 14) (Dr McClelland); [PRSE0006021_0153]
[1615] Penrose Inquiry transcript for 06/05/11 (day 21); 158 (7 to 11) and 158 (24) to 159 (4) (Dr McClelland); [PRSE0006021_0158 to 0159]

a few patients only on home treatment with concentrates[1616]. This fell out of favour due to Professor Ludlam's preference for concentrate therapy and his view that cryoprecipitate was unsuitable for home treatment[1617], a programme onto which more patients had been put as the decade progressed. By 2 February 1984, it appears that a policy had emerged in Scotland that less cryoprecipitate would be used in the treatment of haemophilia A patients, with a proposal being put forward at a joint meeting that the production could be reduced. Professor Ludlam and Dr Hann pointed out at that time that cryoprecipitate was the preferred treatment for children in light of the emerging AIDS risk.[1618] On the basis of the information outlined above about the risks of AIDS to haemophiliacs, the wrong attitude was being adopted to the use of cryoprecipitate in 1983/84. It was deemed to be an appropriate product for the treatment of children to protect them from the risk of AIDS, given the clear possibility that they could be treated without concentrates for long enough that a solution to the AIDS problems could be found. The same approach, in our submission, could and should have been applied to the treatment of all haemophilia A patients, for whom a temporary suspension of factor VIII concentrate therapy should have been at least discussed with them as an option.

4.92 The reasons why cryoprecipitate was really only being used in the treatment of children with haemophilia A over this period would appear to be (a) the limitations on the amount of cryoprecipitate available and hence the requirement to restrict its use to one defined group and (b) the pre-existing commitment to concentrates, including the existence of home treatment regimes.

4.93 The various issues linked to the use of cryoprecipitate which have been emphasised by clinicians as being the reasons why it was not used as the mainstay of treatment. In any event, these considerations could and should have been avoided by better investment in the development of safer and more practical freeze-dried products, which were developed in the west of Scotland (as considered elsewhere in this submission). These are generally all actually relatively

---

[1616] Penrose Inquiry transcript for 03/05/2011 (day 18); 44 (17 to 21) (Professor Ludlam); [PRSE0006018_0044]
[1617] Penrose Inquiry transcript for 03/05/2011 (day 18); 37 (20 to 22) (Professor Ludlam); [PRSE0006018_0037]
[1618] PRSE0001556_0002

minor considerations, the significance of which in the analysis has been deliberately overstated as part of the argument formulated *ex post facto* by the medical profession/ the NHS. In essence, the evidence shows that these were not considerations of such widespread weight or application to merit the wholesale move away from cryo which was dictated by the system as part of the "concentrate juggernaut". The individual considerations:

- Hard to make up, takes time – not material.
- The possibility of allergic reactions to cryoprecipitate based on their impurity was mentioned in evidence by those who sought to undermine the usefulness of the product. not common and not material. Dr Wallace commented in 1977 that adverse reactions are less common from cryoprecipitate than from FFP and that its use had not been associated with inhibitor formation in haemophilia A patients.[1619] The uncertainty in 1977 as to whether intermediate concentrates could offer real, the advantages for minor bleeding episode and the lower risk of viral hepatitis (for which reason it was also administered for its fibrinogen content), the simplicity and speed with which it could be prepared and the anticipated limitations of supply led Dr Wallace to opine that cryoprecipitate would remain the mainstay of therapy at the time of his text in 1977.[1620] That is did not remains a matter of interest and concern for those who received treatment for haemophilia A, in particular in Scotland where (as analysed in detail elsewhere) cryoprecipitate had not been replaced by factor concentrates in the late 1970s and remained a mainstay of their treatment until the end of that decade.
- The lack of suitability for home treatment/ reliance on hospital treatment, need for freezer. Not material and not borne out by the evidence. See eg Edinburgh where this was the mainstay of treatment until 1980. The Wallace analysis of the use of concentrates or cryoprecipitate pointed out that the former could be delivered in smaller volumes and this advantages over cryoprecipitate

[1619] PRSE0002052_0016 (1977)
[1620] PRSE0002052_0016 (1977)

"particularly for home treatment" but its use in the home was not ruled out. The Inquiry has herd ample evidence that the desire of patients to administer their therapy at home would not have prohibited the use of cryoprecipitate in that setting. Dr Dormandy. In essence, the debate was a question of practicality and convenience. There was certain advantages to the use of factor concentrates at home for haemophilia A patients, including the ability to travel. However, a more nuanced approach again appears not to have been considered. The reduction in the amount of factor concentrates used in the treatment of patients would have reduced the risk of HIV as well as the immune reactions which were noted to extreme exposures to concentrates. A binary position appears to have been adopted and no consideration appears to have been given to a more gradual move away from cryoprecipitate, perhaps involving concentrate use on a more modest scale for travel. The problem with that was the fact that large scale investment had been made in the PFC at a time when little consideration appears to have been given to the safety implications of that investment. Inevitably, it would become necessary to use the PFC to its capacity. The die had been cast for bleeding disorder patients in Scotland at the time it was commissioned, without account being taken for the need for investment in the inevitable safety implications which such an investment and inevitable move towards concentrate therapy would involve.

- The inconsistency of the amount of factor VIII in the bag. The reasons for this were explained in Dr Wallace's 1977 text on transfusion.[1621] He stated there that the main reason for this was the inconsistency in the factor VIII level of the donor and that this drawback could be offset by the use of a number of packs of cryoprecipitate as the inconsistency in the factor VIII levels in each donor would be neutralised by the production of what was, in effect a small pool. This was said to have been the practice in Edinburgh anyway, given that more than a single infusion of cryoprecipitate would be necessary for the treatment of a bleed. In any event, impurity, allergic reaction and inconsistency of factor VIII levels were also problems which were experienced with common with relatively

[1621] PRSE0002052_0015 (1977)

impure intermediate factor VIII concentrates in use in Scotland in the 1970s and early 1980s anyway. In a 1983 article, those at the PFC listed certain of the drawbacks of its then available intermediate purity factor VIII concentrate as including fibrinogen overload, inconvenient injection volume and longer reconstitution time than higher purity concentrates, over which the available concentrate was favoured due to its better factor VIII yield.[1622] These drawbacks of cryoprecipitate were, therefore, more of a neutral consideration in product choice than consideration of cryoprecipitate in isolation may make them appear.

4.94 Given that patients in Scotland have consistently told the Inquiry under oath that they or their children were not offered the option to choose to be treated with cryoprecipitate at any time after the concentrate juggernaut was unleashed, the NHS in effect offers to prove that these considerations were so all consuming as to make this not a reasonable treatment alternative which therefore did not require to be offered as an option. That is not only inaccurate but in fact the materiality of the arguments against cryoprecipitate paled into insignificance when honestly weighed against the safety advantages which it would have offered. At the very least, patients/their parents had the right to be offered the informed choice.

4.95 See the use of cryo in children as being evidence that it was not only known to be safe but also that it could have been used more extensively – that was based on a knowledge that it was safer and a hope that children (not exposed in the past to treatment as they were not yet *in vivo*) may never require to be exposed to the inevitable infection associated with concentrates.

<u>The increased use of cryoprecipitate in response to the emerging threat of AIDS</u>

[1622] PRSE0003674 – "Journal of Thrombosis and Haemostasis, "Zinc fractionation of cryoprecipitate", by Foster, P. E. et al., 1983."

4.96 The Inquiry heard evidence about the possibility, even against a background of the reliance on concentrates having increased dramatically in Scotland in the late 1970s and in particular the early 1980s of a return to greater reliance on cryoprecipitate in the treatment of patients with bleeding disorders as part of the

4.97 When questions on this possibility, Dr Diana Walford explained that not sending the plasma (or more particularly the supernatant) to the fractionation centres and using it in the transfusion centres to make cryoprecipitate as opposed to factor VIII concentrate would have impacted on the production of factor IX. This would have been problematic on her assessment as there was no cryoprecipitate equivalent for haemophilia B patients who would otherwise have had to be treated with plasma. That this was a fallacious argument was made clear in the evidence of Dr peter Foster of the PFC. He made clear that as the number of haemophilia B patients were so much fewer, it would only have been necessary to send around 10% of the collected plasma to the PFC for fractionation of the supernatant into factor IX to maintain the required supply.[1623] That would have allowed an extra 38,150kg of plasma actually used in the production of factor VIII to be used in the production of cryoprecipitate, a 15 fold increase in the amount which was actually being produced in 1983. Actually an accurate measure of the total, using also the plasma already collected for cryo would have meant a 16.15 fold increase of the amount of cryo produced.

4.98 It was consistently suggested that patients would not have tolerated a return to a system of treatment which was associated with the old days. It should be noted that this is an assumption, as patients were not given the option. In his evidence to the Inquiry, Dr Peter Foster recalled this possibility having been raised at a meeting on 2 February 1984 by Professor Cash and that it was refused by the haemophilia directors.[1624] It might be said that this offer came later than it should have done and the minute records only that an offer of cryo production was only for a minimum amount for emergencies, not even the inspecific "increase in supplies" which Dr Foster appears almost 40 years later to have recalled having

[1623] WITN6914001_0127, para (ix)
[1624] WITN6914001_0127, para (viii); PRSE0001556

been offered. In this regard, it should also be borne in mind that, in Edinburgh in particular, this would not have been a return to a treatment regime of the distant past as it might have been in areas of England where concentrates had been the mainstay of treatment for many years. Dr Davies had favoured the use of cryoprecipitate until he left and Dr Ludlam arrived at the centre in around 1980.

4.99 NB – other features of the system which could have been changed. The possibility of changing the treatment to deal with the emerging threat of AIDS was deliberately misrepresented by many of the haemophilia clinicians who gave evidence to the inquiry. They presented the dilemma as being a permanent change which gave rise to a need to consider their perception of the advantages of lifelong treatment with concentrates. This was a false dilemma. It was quite clear from other evidence that there was good reason to think that any change would only be a temporary one. Dr Peter Foster was clear that this was his appreciation of the position – a technological solution would be found which it was in Scotland by December 1984 in the form of heat treatment at 68 degrees for 2 hours. Dr Brian McClelland also had faith that the technology would solve the threat of AIDS to haemophiliacs in the UK, which of course did happen. This was also the position of Dr Gabra as to why his freeze dried cryoprecipitate project was abandoned (see below).

j) Small pool concentrates

4.100 In Scotland, a production facility in the west of Scotland (at Law Hospital, the headquarters of the west of Scotland BTS) presented a missed opportunity at least to asst towards balancing the risks of large pool factor VIII concentrate with the issues which the clinicians had with cryoprecipitate (argued elsewhere in this submission to have been overblown). Active consideration of the need to find ways of preventing or limiting disease transmission from SNBTS produced blood products began in around 1981, with the Factor VIII Study group. Though these issues could and should have been part of the thinking of the development

towards self-sufficiency much earlier, this group look at various scientific possibilities to address this clearly serious problem. That group considered the developing scientific thought processes related to heat treatment of concentrates and also looked at the possibility of greater investment in the freeze-dried cryoprecipitate product which was developed at Law Hospital.

4.101 The possible production of freeze-dried cryoprecipitate for the treatment of haemophilia A patients appears to have been in contemplation at the time of a joint meeting on 4 March 1981. Professor Cash had been asked to look into this as a possible project and represented to the meeting that such a product could be used for home treatment was used extensively in Belgium.[1625] By the time of a further joint meeting on 21 January 1983, the project had been abandoned given the fact that the plasma freeze drying plant Law Hospital had been closed.[1626] The future of FDC was uncertain due to the aim of developing a concentrate with a reduced risk of hepatitis at that time. In his evidence to the Penrose Inquiry, Dr Peter Foster, however. He confirmed that in the west of Scotland the entire process of producing cryoprecipitate was carried out at Law Hospital.[1627] The freeze dried product had undergone a successful clinical trial in the west of Scotland, it was an effective product with potential for being scaled up.[1628] Dr Foster pointed out that the cost associated with Law Hospital contributed to the decision to close it but it was also due to issues which the Medicines Inspectorate had with the product. However, he was of the view that if there had been a demand from the haemophilia clinicians for the freeze-dried product, then the Inspectorate would have reviewed these requirements.[1629] However, by this time, there was no such clinical interest in anything other than concentrates, the demand for which went up and up.[1630] This is despite the fact that the issue of heat treatment technology was being discussed in parallel with the freeze dried cryoprecipitate option. It is worthy of note that Professor Ludlam gave evidence

---

[1625] PRSE0000181_0002 to 0003
[1626] PRSE0001736_0003 to 0004
[1627] Penrose Inquiry transcript for 10/05/11 (day 22); 22 (25) to 23 (1) (Dr Peter Foster)
[1628] PRSE0002263_0003 (Professor Prentice statement)
[1629] Penrose Inquiry transcript for 10/05/11 (day 22); 65 (10) to 66 (1) (Dr Peter Foster)
[1630] Penrose Inquiry transcript for 10/05/11 (day 22); 43 (22) to 44 (4) (Dr Peter Foster)

to the Penrose Inquiry to the effect that despite a high rate of HIV in the general Belgian community (and hence a likelihood of there being a high prevalence of the disease in the donor population) there were relatively few HIV infections in patients with bleeding disorders there.[1631] This shows that a similar approach to the development of FDC in Scotland would have been likely to have had the same effect on HIV transmission.

4.102 The evidence which is available is indicative of the general commitment to factor concentrates which was almost total by 1983. This commitment did not balance sufficiently the risk of viral transmission against the claimed therapeutic and social advantages of the factor concentrates. There was no contingency plan which allowed for a switch to lower risk products in the event of the emergence of a predictable outbreak of virus associated with blood products. Despite the technologies being considered together, no option appears to have been considered involving the temporary use of FD cryoprecipitate pending the development of successful heat treatment technology. This represented substandard planning.

4.103 In the heat of the emerging AIDS crisis, the availability of small pool concentrates in other countries was seen in the UK as a sign of backward treatment regimes, in particular in the aftermath of the Council or Europe recommendation. The response by the clinical advisor on transfusion, Dr Gunson to the recommendation was a clear indication that the concentrate juggernaut in the UK had resulted in a state of affairs (in England and Wales at least) where safety could not be prioritised in the UK by a use of small pool concentrates (ie cryoprecipitate), when it was advised that that course be taken in the rest of Europe. It is argued elsewhere in. this submission that a reversion to frozen cryoprecipitate could and should have been implemented in Scotland. However, it is also clear that the abandonment of investment in freeze dried cryoprecipitate was a mistake. The availability of such a product would and could at least have assisted with the temporary reversion to a safer smaller pool product in those years. This is discussed in more detail below.

[1631] Penrose Inquiry transcript for 04/05/11 (day 19); 63 (2 to 17) (Professor Ludlam); [PRSE0006019_0063]

k) DDAVP

4.104 DDAVP was a synthetic alterative to plasma based products which was available from the late 1970s. It raised an existing factor VIII level by a number of times and so worked for non-severe patients who had a resting factor VIII level of their own. It had an application to major procedures as well as minor ones from the 1970s.[1632] It was effective in most patients and available. Available for use in mild and moderate patients, this product created no risk of infection at all. It should at least have been the first port of call and its greater use would have avoided infections.

4.105 Again a "party line" emerged in the aftermath of the infections that this caused allergic reactions and did not work in all cases is an attempt to mislead the Inquiry on the part of the medical profession by elevating the significance of a counter-indication for the use of this treatment which is neither serious nor a widespread consideration. These were certainly minor when compared to the safety advantages. Its lack of use was indicative of the all-pervasive use of concentrates with little regard for the safety consequences which dominated the practice of haemophilia clinicians in the late 1970s and 1980s.

4.106 Professor Ludlam was a keen advocate of the drawbacks of DDAVP, as a defence for the fact that he did not us it nearly enough, in his concentrate dominated culture. He stated that the likely response of DDAVP depends on basal factor VII levels, which is correct and could be measured. The higher the more likely to respond as you get a 3 to 5 times increase in the basal factor VIII. He said that that DDAVP needed to be used with tranexamic acid to prevent fibrinolysis[1633] – this is inaccurate. It can be used and was frequently in the 1980s without it. He mentioned significant were the side effects. In fact, these only occurred in a few patients. In any event, they were in fact insignificant were they when compared

---

[1632] "DDAVP in Haemophilia and von Willebrand's Disease"; The Lancet, ii, pp 774 — 775, 1 October 1983; mild patients should have been treated with DDAVP, if possible (UKHCDO guidance issued on 14th December 1984, PRSE0002282).

[1633] para 84 of first statement of Professor Ludlam at WITN3428001

with the alternative – the certain contraction of a potentially life-threatening disease from a concentrate. The side effects he mentioned were merely water retention which could lead to headache, which could be managed by not drinking any water.[1634] In any event, the published article provided a solution to the water retention issue.[1635] These were all attempts, commonplace in his evidence make arguments which ought not to be accorded the scientific weight he attributed to them.

4.107 In Edinburgh, it is recorded that DDAVP was used in Edinburgh in small amounts (between 6 and eleven international units) between 1984 and 1987, but not at any other time (see Penrose final report table at page 890) By contrast in Glasgow, although none was used in 1980, 1983 or 1984, in every other year between 1979 and 1987, use ranged between 229 and 978 international units (see Penrose final report table at page 892). DDAVP was unnecessarily underused in Edinburgh and more generally.

l) vWD patients

4.108 The nature of the condition and the absence of a vWD concentrate meant that the means by which bleeds are treated was inconsistent in Scotland. It affected women well as men, meaning that there were HCV infection in this community of both genders.

4.109 The key theme of the evidence heard by the Inquiry relating to vWD patients was the fact that they were consistently infected by exposure to factor VIII concentrates, even in light of the lack of any argument that its success in manging bleeds could be thought to be guaranteed. The less fractionated cryo was both more likely to contain vW factor and less likely to transmit infection. It was clearly the most appropriate treatment. The all-pervasive attitude to reach for the factor

---

[1634] para 245 of first statement of Professor Ludlam at WITN3428001

[1635] HHFT0001431_004 (Lancet, 1977)

VIII concentrate without really considering the risks described elsewhere in this submission applies to these cases. Concentrates were easier, available and reached for without consideration of the consequences, even to the extent of misdiagnosis on the assumption that the patient had haemophilia A (see one case discussed in this regard blow). Consentrates were often ineffective treatment for vWD patients. They were unnecessary.

m) The possibility of no treatment at all/ lifestyle advice/ reduction in treatment

4.110 This was an option, at least in mild or moderate cases which should have been considered/ offered to patients. The failure to do so was based on assumptions/ erroneous understandings that the historic mortality and morbidity consequences for severe haemophiliac would be the fate of every patient, no matter how mild their condition of not treated with concentrates. This was a scientifically unsound approach.

4.111 As far as HIV was concerned, the transmissibility of infection meant that the incidence of infection in Scotland could have been eradicated by a reduction in the amount of infective concentrate to which the infected patient were exposed. Professor Cash gave evidence at the Penrose Inquiry to the effect that the amount of virus, or viral load, to which one is exposed will have an effect on the likelihood of the recipient being infected with HIV.[1636] Professor Lever, an infectious diseases expert, confirmed in his evidence that the more one is exposed to HIV the more likely one is to get infected.[1637] He appeared to confirm this in more detail that HIV has a notoriously high particle to infectivity ratio, meaning that one could be exposed to a high number of particles of the virus before coming across one that was infective.[1638] He confirmed the theory that the more virus a patient was exposed to the more likely it would be for the patient to become infected in

---

[1636] Penrose Inquiry transcript for 13/05/11 (day 25); 82 (5 to 7) (Professor Cash); [PRSE0006025_0082]
[1637] Penrose Inquiry transcript for 17/05/11 (day 26); 62 (2 to 6) (Professor Lever); [PRSE0006026_0062]
[1638] Penrose Inquiry transcript for 17/05/11 (day 26); 62 (17) to 63 (1) (Professor Lever); [PRSE0006026_0062 to 0063]

response to material put to him about the infection of the Edinburgh cohort from the Penrose Inquiry preliminary report.[1639] Studies of the Edinburgh cohort confirmed the proposition that the greater the exposure to infective material results the greater the likelihood of seroconversion as the patients who had the most treatment were, alongside certain genetic factors, more likely to be infected.[1640]

4.112 Therefore, a reduction in the exposure of patients to lower amounts of concentrate, hence lower numbers of donors (and hence infected donors) and hence a lower viral load would have reduced the chances of patients becoming infected with HIV. Less use of concentrates, less reliance on home treatment and prophylactic treatment regimes and a greater emphasis on the use of small pool products such as cryoprecipitate would have reduced the infection rate amongst Scottish haemophiliacs. This would have been achievable by a frank discussion leading to clear safety-orientated decision-making in around 1983 when the risk of the products had become sufficiently clear to act. In addition, the avoidance of regimes involving heavy exposure to commercial concentrates, in particular at Yorkhill in response to the generally heightened risk of serious viral infection from those products based on their pool size, the make-up of their donor pools and the increased perception of the risk of serious consequences would, have substantially lessened the number of HIV infections. By the early part of the 1980s, work was being done on developing techniques to eradicate viruses from the products. Any change in product regime would only have required to have been temporary until they could be resumed safely, when science enabled them to be.

n) Further treatment considerations specific to the emerging threat of AIDS

[1639] Penrose Inquiry transcript for 17/05/11 (day 26); 115 (15) to 116 (25) (Professor Lever); [PRSE0006026_0115 to 0116]
[1640] PRSE0000903 (3 August 1985) and PRSE0004673_0003 (28 May 1988)

4.113 The failure to consider temporary solutions based on the realities of the situation. In light of the work being undertaken on a scientific solution/ the advancements being made in heat treatment of concentrates to eradicate the viral threat and in light of the known high mortality risk associated with infection, the availability cryoprecipitate as a safer option for haemophilia A patients and FFP for haemophilia B patients, all that was needed was a temporary solution. This was merited by the risk. The known severity of the disease and the emerging possibility (confirmed by December 1982) that the disease was spread by blood and blood products mandated a response. In response to the lack of conclusiveness about the transmission routes of the disease and the possibility that the white cell irregularities in haemophiliacs were not known (though ought to have been strongly suspected) as being due to AIDS as opposed to another aetiology, a precautionary approach (which was necessitated by the known risks of blood and, in particular pooled blood products) would have mandated a change in approach pending greater certainty about these matters becoming scientifically apparent. This would have been mandated as a result of what was known or ought to have been known about AIDS but also what was known or ought to have been known about the existing risks of hepatitis transmission.

4.114 False paradigm (propagated by the UKHCDO) that the only options were (i) continue as we are or (ii) suffering the kind of which might have afflicted severe patients historically. This was a line which created a false dichotomy between two stark options. The evidence heard by the Inquiry was that it was highly influential in persuading the government to do nothing, in effect meaning that there was no choice at all. Again, this is a manifestation of the reality that the patients had not been advised about the risks. To approach the patients in the first half of 1983 to discuss with them the possibility of changing their treatment regimes in light of the serious threat posed by the new virus/ disease (which should have occurred but did not) would have inevitably led to the failure of the clinicians to mention the risks in the first place coming to light. The domino effect described above had started;

4.115 The UKHCDO guidelines/ failure to produce guidance quickly enough in light of the fact that blood can kill. Not a proactive but a reactive system;

4.116 Incidence over risk was an inappropriate approach based on the known history of diseases transmitted by blood and blood products having extended latency periods. This was known to be the case with AIDS from the outset. It was known or should have been that to wait for cases of AIDS before taking action would inevitably involve such action being taken too late to save the "canaries in the mine". The lack of the ability of the system to react proactively and decisively in the face of such a risk was lamentable feature of the concentrate juggernaut;

4.117 The antigen overload theory was (a) based on a premise that treatment with concentrate was harmful anyway (b) based on the concentrate juggernaut blindness and (c) based on an inappropriate balancing of the risk when the disease from the outset was associated with a significant mortality risk. Professor Ludlam's adherence to this theory was described by Dr Boulton in his evidence as accepting the probability of infection but being unable to embrace the evidence the implications were emotionally so vast. He described him a "poor chap".[1641] This is a sympathetic description of wilful blindness in the face of a fatal threat.

4.118 The avoidability of the HIV infections in Scotland:

(a) The circumstances of the infections of patients in the haemophilia centres of Scotland where infections were found to have occurred (Edinburgh, Glasgow and Yorkhill) are analysed in detail below;

(b) In general terms, it is submitted that the HIV infections which occurred in Scotland should not have occurred. There were relatively few infections in Scotland. This is due to a combination of failings which could and should not have occurred, as follows:

(i) The HIV infections which occurred as a result of the use of commercially produced US concentrates ought not to have occurred. Generally these occurred earlier in the period. Commercial concentrates ought not to have been used at all in Scotland. Less aggressive and more precautionary

[1641] IBI transcript for 04/02/22; 119 (Dr Frank Boulton)

treatment regimes and a real as opposed to the illusory commitment to self-sufficiency would have enabled Scotland to become self-sufficient by the mid-1970s. properly counselled patients would have accepted the need to wait for advances in safety technology for an expansion in treatment into home treatment and prophylaxis to be achieved safely. The proximity to the achievement of self-sufficiency was frequently cited by the Scottish medical profession as being a feather in its cap. In fact, that it was practically possible to have got so near simply means that, contrary to the protestations of the UKHCDO elsewhere in the UK where there may have been a dependence on imported products, there was no need for there to have been any such reliance in Scotland. This was the goal of the SNBTS from the late 1960s based on the known risk of hepatitis B, and the possibility of the emergence of other viral threats.

(ii) In any event, an embargo on the use of commercial concentrates by the start of 1983 would have prevented some of those infections. That should have been implemented as a result of the known risks after the San Francisco baby case. A reduction in treatment regimes would have enabled their use to be brought to an end, predominantly in the two Glasgow hospitals and the bleeding disorders of the patients to have been manged safely and efficiently, on a temporary basis until the science allowed concentrates to be produced more safely and plentifully;

(iii) The HIV infections which were caused by HIV infections transmitted through domestically produced concentrates ought not to have occurred. Unlike the infections which occurred as a result of imported concentrates which generally occurred earlier in the period as a result of the virus having entered the US donor system earlier than its arrival in Scotland, the domestically caused infections occurred late. The international clarion call about the risks of AIDS constituted a warning to Scotland that action was urgently necessary. A more reactive approach could have enabled decisive action to be taken based on the known threat of the new disease (AIDS) assessed cumulatively with the known existing risk of NANB and HBV transmission. The culpability of the Scottish NHS lies in their failure to heed

the warnings which other did not get. This was the position of Dr Peter Foster based on his appreciation of international evidence gained at two international conferences. His evidence to this Inquiry was to the effect that at that time he had considered commercial blood products to be at increased risk not because they were commercial but because the plasma used for their production had been collected at the epicentre of the global epidemic. Further, he was of the view in 1983 that the epidemic would not be limited to the US and that the warning afforded to countries like Scotland was such that he thought that measures could be taken on a temporary basis (including for example stopping the use of imported concentrates and banning gay blood donors) to enable technological advances to be able to find a solution to the problem. He correctly pointed out that these technological advances in the form of heat treatment of domestic factor VIII cam in Scotland by December 1984. He described this temporary approach as a "time lag"[1642] This approach to the inevitability of the disease entering the Scottish donor pool accompanied by the need only for a temporary fix pending a technological solution being found was shared by Dr Foster's SNBTS colleague, Dr Brian McClelland in his evidence to the Penrose Inquiry, as discussed elsewhere in this submission. This realisation that what was required was a temporary solution is by way of stark contract with the way in which the haemophilia community would have the inquiry interpret the choice which was being faced, namely a permanent, binary choice between concentrate therapy and no treatment. That is an entirely inaccurate and misleading characterisation of the actual dilemma in light of the available evidence, which is was far more fairly and accurately described by Drs Foster and McClelland; and

(iv) A more robust, precautionary and patient centred approach to (a) donor deferral and (b) treatment regimes which should have involved a focus on cryoprecipitate use and temporarily minimising the use of products would have meant that the infections would have been avoided. The risk of the

---

[1642] IBI witness statement at WITN6914001 at page 62, para (vii) (Dr Peter Foster)

relatively few cases of HIV transmission would have been materially reduced by a regime based on such changes.

D) The treatment regimes in Scotland and resultant infections in the period – analysis of the treatment provided by centre

4.119 In this section pursuant to Term of Reference 1 for this Inquiry, we will deal with the treatment regimes in place in the places where bleeding disorders were treated in Scotland, more specifically.

1. Edinburgh – analysis of the specific treatment regime

General

4.120 The centre was run by director Dr Howard Davies until 1979 when he was replaced by Dr Christopher Ludlam. This led to a dramatic change in treatment regimes, described in detail elsewhere in this submission. The attitude to products moved from one based largely on local cryoprecipitate for haemophilia A patients to a huge increase in the use of factor VIII concentrate, almost all provided locally from the PFC. The change between the two regimes continued with one principle of the Davies treatment philosophy (the use of locally produced products made from the plasma of Scottish donors as paramount, except where not clinically possible due to inhibitors) but not the other (favouring the use of low pool product, namely cryoprecipitate the treatment of haemophilia A patients). In a 1981 meeting Dr Cash recommended that cryoprecipitate remain an important part of the service,

even at home.[1643] The haemophilia directors (including Dr Ludlam) were seemingly against that. The option was there. It was not taken.

4.121 Despite the evidence from his own research and from more general sources of which he was or at least should have been aware of transmission of both HBV and NANBH to his patients, he continued to prefer locally produced products, believing that the general population of Scotland was at the time relatively 'stable' and that the risks associated with the local donor pool were 'small'.[1644] This was a local manifestation of the delusion that voluntary donors were safe. Treatment records show that between 1979 to 1984:

(a) Commercial concentrates needed to be used which had not been before?
(b) The amount of factor VIII concentrate being used increased by 12.6 times?
(c) The amount of factor VIII units (including cryo) being used increased by 3 times?
(d) The proportion of cryoprecipitate being used decreased from 71% to 5.2%?
(e) The usage of factor IX concentrate increased by 5 times.

4.122 The culture of the Edinburgh centre after the arrival of Dr Ludlam is worthy of note. The evidence shows that he was very much in control of the centre and the treatment regime. When patients went away from Edinburgh they would be sent with a letter urging local centres not to treat them with whatever product they used there. This, coupled with Dr Ludlam's keen interest in conducting research on his patients, led them to believe that he was keen to maintain them on the local supply for research purposes. The control which Dr Ludlam exercised over the centre was considerable. One staff member described the friction between him and the nursing staff based on his desire to be in control of everything which happened in the centre.[1645] Another spoke about her professional relationship with Professor Ludlam. He told her to tell him everything that happened at the Centre when they had their first meeting soon after she was appointed as

[1643] PRSE0000144 - 30 January 1981 meeting of directors/ SNBTS
[1644] Penrose Inquiry transcript for 17/6/11 (day 35); 21–22 (Professor Ludlam)
[1645] see WITN4096001, statement of Alison Richardson at para 12

Haemophilia sister. She refused and told him that she would inform him about anything she felt he should know as Centre director and their relationship consequently deteriorated.[1646] She mentioned a meeting that she had with Dr Ludlam when she first started working in the centre where he told her not to mention anything about HIV to the patients. He told her it was ok if a patient initiated a conversation but she was not to initiate any conversation about it.[1647] This was not a culture built on professional or doctor/ patient partnership. It was a dictatorship.

4.123 It should be noted that although the general treatment philosophy of the Edinburgh centre in the period from the arrival of Dr Ludlam there in 1979 remained based on the use of domestically produced factor VIII concentrate, Dr Ludlam did use commercial products as well. In particular, he confirmed at a meeting of the Scottish directors on 21 January 1983 that he continued to purchase commercial concentrates where there was a clinical need but also more generally to cover the likely shortage which would be caused by the closure of the PFC for alterations to be carried out as recommended by the Medicines' Inspectorate.[1648] At that same meeting, the issue of the emerging AIDS risk in the US and the need for the directors to report unusual infections were also discussed.[1649] The risk that Scottish patients could become infected was thus acknowledged. This approach shows the precariousness of the supply situation at that time. Any interruption to the PFC supply required the basic commitment to the use of domestic products to be abandoned for the admittedly more risky commercial supply – the commitment to the principle of the greater safety of the domestic products would be abandoned for reasons of supply, despite the emerging acknowledged risks of them carrying a new, fatal disease.

[1646] See Billie Reynolds statement @ WITN0629001_0007
[1647] WITN0629001_0005

[1648] PRSE0001736_0003 (21 January 1983)
[1649] PRSE0001736_0007 (21 January 1983)

Research

4.124 The research value of haemophiliacs was neatly summed up as follows:

> "It just takes one contaminated blood donation to contaminate a whole batch of Factor VIII. People with haemophiliacs can be likened to the canary down the proverbial mine shaft. If there is an infection out there, they're gonna get it first" – Dr Paul Giangrande, Consultant Haematologist – BBC Panorama, "The Price of Blood" – 8 October 2006."

4.125 The Edinburgh centre was an important research centre and had a longitudinal sera store and had patient uniquely treated exclusively (or almost so) with domestic products. The specifics of the analysis of the research being undertaken at the Edinburgh centre are analysed in a separate section below. The precise extent of the nature of the research being undertaken on patients in centres like Edinburgh or Glasgow remains slightly unclear. It was of course possible for the nature of the HBV antigens to be studied directly by electron microscopy. This is analysed by Dr John Wallace in his 1977 text on blood transfusion, in the context of his earlier discussion in the same work about the limitations on the extent from the knowledge about the incidence of post transfusion hepatitis in the UK, in particular in light of the much higher reported rates from elsewhere in the civilised world.[1650] Thus, there was a considerable interest in the study of the fatal disease, its prevalence in post transfusion patients in the UK and the characteristics and prognosis for the disease as a public health issues in the UK. The limitations and problems which were experienced and hence the legitimacy of the results of the MRC study of 1974 into HBV in the UK were also highlighted, in particular concerning the unwillingness of those who may have contracted PT HBV to

[1650] PRSE0002052_0044 (1977)

participate pr the fact that many may have died on the months after their transfusion, either as a result of the acute effects of infection or the comorbidity which necessitated the transfusion in the first place.[1651] The Inquiry has heard evidence that the ALT levels of haemophilia patients were regularly monitored but the 1977 Preston et al study (referred to above) had cast some doubt over the link between ALT readings and actual liver damage. The possibility that the "canaries" were studied using all technology available (including electron microscopy) must be a valid theory, at least.

4.126 Patients in Edinburgh (or in other centres like Glasgow for that matter) were not aware that they were involved in research. In addition to the analysis of the ethical position in that regard above, specific ruled in that regard had been instituted in Edinburgh in the aftermath of the viral hepatitis outbreak in the renal unit in Dr Ludlam's own hospital. Minutes of a meeting of the Medical and Dental Staff Committee in Lothian in 1970 included consideration of issues of safety in the aftermath of deaths in the RIE hepatitis outbreak.[1652] These stated that involvement in research should involve the research being explained to the patient.[1653] This was to happen with another doctor or registered nurse present. An entry was be made in the notes. None of this happened in the Edinburgh centre. In light of this, it seems hard to understand how ethical consent could have been granted. If it was, it appears not to have been complied with. In 1976 local ethical guidance, it was required to have witness (preferably medically trained) for research, The taking of informed consent required to be recorded in the notes, even if not signed. It was noted that there was deemed to be a strong moral claim for compensation if things went wrong against the researcher. [1654]

[1651] PRSE0002052_0041 - _0042 (1977)
[1652] LOTH0000119_006 (22 July 1970)

[1653] Pages 4 to 5

[1654] LOTH0000038_008 (1 June 1976) - Physicians' advisory ethical committee (South Lothian District) - Notes for the Guidance of Applicants, page 2

HIV infections in the Edinburgh centre

General comment on the statistical information available to the Inquiry regarding IV infections in haemophiliacs

4.127 As is noted above in relation to the analysis of the total number of HIV infections amongst the haemophilia community in Scotland, the starting point for the Inquiry must be the statistical analysis made available to the Penrose Inquiry which suggested that the total number of infections in this group was around 59.[1655] This number was arrived at by the application of a certain methodology on the part of the Scottish haemophilia clinicians who were responsible for compiling the material. There are other sources which would suggest that the total number of such infections in Scotland is higher than this.[1656]

4.128 The material provided by Professor Ludlam to the Penrose Inquiry as regards the number of HIV infections in the Edinburgh centre identified a total of 23 patients whom he thought were infected in Edinburgh.[1657] All of these patients were listed as being severe haemophilia A sufferers and the details of the timing of their infections (compiled by reference to stored historic blood samples once HIV testing had become available) were produced to and by the Penrose inquiry in table 3.16 of its final report. Professor Ludlam identified 18 patients whom he claimed were members of the Edinburgh cohort, a group of patients infected with HIV who went on to be studied as part of a research project which is considered in detail elsewhere in this submission. It is unclear whether this is what was meant by Professor Ludlam when identifying these patients as members of the Edinburgh cohort or whether he meant that he thought all of these patients to have been infected by a single infected batch of concentrate known as the "implicated batch" (the significance of which is also discussed elsewhere in this submission). The

---

[1655] Penrose Inquiry transcript for 30/03/11 (day 14); 57 (16) to 58 (3) (Professor Ludlam); [PRSE0006014_0057 to PRSE0006014_0058]
[1656] Penrose Inquiry preliminary report, paras 3.60 to 3.61 and footnote
[1657] PRSE0004860

common feature of these infections is their timing. These patients were, importantly, identified as having been infected between March and May 1984. Importantly, this was late in the evolution of understanding about the nature and aetiology of AIDS. It is submitted that the lateness of the majority of these infections means that significant opportunity was presented for their avoidance had appropriate preventative action been taken.

4.129 The Inquiry heard some evidence about the steps taken to try to work out how the Edinburgh cohort members (in the sense of those infected by the implicates batch) had come to be so infected. Dr McClelland set out details of efforts which were made to try to have sampled of the around 3,000 donations to the complicated batch (samples of which donations had by that time been retained, since around 1981). He explained that he had tried to have the donation samples tested, that those at the PHLS (Dr Mortimer) had not had the capacity and that he should maybe have sought testing in the US.[1658] Despite this evidence of the failure of contemporaneous investigation, subsequent study has led to the conclusion that there were at least two batches of contaminated Factor VIII responsible for infections in the cohort, contrary to the initial impression that they had been infected by a single source. At least two or three infected donors must have donated to the local plasma pool in Edinburgh in 1983 to have resulted in the infection of the locally infected Edinburgh patients.[1659] The study postulated that two or three HIV-infected donors, who were not intravenous drug users or heterosexual males, contributed to the plasma pools, though this study is somewhat limited in the number of subjects infected via the IVDU or heterosexual male groups which is studied.[1660] This, its conclusions about the genetic profile of these entire groups within Scotland and hence the commonality or otherwise of their infection routes must be deemed to be limited. The study also shows that there was substantial viral diversity in Scotland at the time of the collection of the

---

[1658] IBI transcript for 28/01/22; 49 (23) to 52 (7) (Dr Brian McClelland)

[1659] PRSE0002082_0007 and _0009 – "The Molecular Epidemiology of Human Immunodeficiency Virus Type 1 in Edinburgh" (1995)

[1660] The small numbers from the IVDU community compared to the total number of infected individuals in Edinburgh from that community and the consequent limitations of the study in that regard are recognised by the authors at PRSE0002082_0008

donations which caused the infections of the Edinburgh haemophilia patients (1983), though only 54 positive patients were identified in Scotland as having been HIV positive in 1983 on retrospective analysis.[1661] There was a broad range of means by which the virus had penetrated the Scottish community by 1983. Dr Boulton indicated that it strongly thought that the implicated donation was received in early 1984 which infected the cohort and not in 1983, which meant there had been even more time to prevent it.[1662]

4.130 It is, of course, also known that the virus did spread quickly in the Edinburgh IVDU population from late 1983 onwards, a phenomenon discovered on retrospective testing of IVDUs in a particular locality of Edinburgh by a local GP, Dr Roy Robertson, who found himself at the forefront of an epidemic of AIDS amongst that community in the city.[1663] This was rendered possible as Dr Robertson had been storing samples of IVDUs under his care in order that he might monitor them for HBV infection.[1664] As is mentioned elsewhere in this submission, the apparent similarities between HBV infection and AIDS transmission in terms of persons susceptible and hence likely transmission routes were noted from the earliest reports of the disease, including at the Heathrow airport meeting in January 1983. It is important to note that research into this Edinburgh IVDU community undertaken after HIV testing became available indicated that it was during 1983 that HIV was introduced into that population, which later became the basis upon which Edinburgh was described as the AIDS capital of Europe, such was the extent of the outbreak of AIDS in that city arising from that infection route amongst its IVDU population.[1665] The study revealed that amongst a population of 164 IVDUs from a single general practice in Edinburgh, over half had tested positive for HTLV III and that retrospective testing indicated that the disease had become epidemic in this population in late 1983. One might assume that IVDUs who attended their GP would not have represented the whole of even the local IVDU community.

[1661] PRSE0002082_0008

[1662] Para 283 of Dr Boulton witness statement @ WITN3456002

[1663] See the 1995 article at PRSE0002082_0001 and 8 and 9 in 1995 article reference lists

[1664] WITN2189026 – "Epidemic of AIDS related virus (HTLV III/ LAV) infection amongst intravenous drug abusers, Robertson et al Br Med J [Clin Res] 1986; 292; 527 – 9"

[1665] WITN2189026

Recent testing (as per the 1986 paper) of IVDUs who had attended the RIE for various reasons revealed that 38% of the IVDUs so tested were positive for HTLV III (ie beyond the GP practice IVDU population which was the main subject of the study), which was a high and unexplained results compared to IVDU populations elsewhere. In his evidence to the Inquiry, Dr McClelland talked about a number of events relevant to the connection between the work he was doing in blood transfusion and the perceived risk of AIDS becoming part of the donor pool in Edinburgh, in particular:

(a) He spoke of the connection between him and Dr Robertson, a local GP having been established in 1982. This was confirmed by Dr Boulton Dr Robertson being in frequent discussion with Dr McClelland from 1982.[1666] They were aware of the risks to the donor population of the IVDU population and the extreme risk of AIDS in Edinburgh from that time.

(b) He spoke of work being done by Dr Peutherer, a virologist at the RIE having been doing testing on samples which were at risk for HBV as a means of investigating the local HIV risk. Indeed, he said that it was known that IV drug use was likely to be associated with both HBV and HIV, the latter if it was transmitted by an infectious agent (which is was thought by 1983 to be, as submitted elsewhere). This is why Dr Peutherer thought it useful "as a sensible virologist" to test for the presence of the latter in samples which had been collected for investigation of the former.[1667] Dr Peutherer was of course also involved as part of the team undertaking the AIDS study on local Edinburgh haemophiliacs and was also a co-author of the 1986 paper relating to the West Granton infection referred to above and presumably the source of the 38% figure for infection amongst IVDUs attending the RIE. Therefore, at the same time that Edinburgh haemophiliacs were being considered as a unique group on the basis that they were rendered in some way immune from HIV infection by the lack of the presence of the aetiological agent for the disease in the local community, active research was

[1666] Para 271 of Dr Boulton witness statement @ WITN3456002

[1667] IBI transcript for 27/01/22; 126 (6) to 127 (10) (Dr Brian McClelland); IBI transcript for 28/01/22; 165 (22) to 166 (24) (Dr Brian McClelland)

being done on a known local high risk group for HBV, which was known to create a risk of AIDS as well. There is a distinct inconsistency between the two branches of the research, one which assumes local immunity and one which is concerned about the vert factors which would render the local community susceptible, in particular amongst haemophiliac "canaries".

4.131 In addition, AIDS expert Ray Brettle was employed at the Edinburgh City Hospital from October 1983 (referred to in the Foster union correspondence[1668]). In his statement to the Penrose Inquiry on the B1 topic, Dr McClelland also referred to a May 1983 meeting with Dr Sandy McMillan (a GUM doctor at the RIE) who stated that he had some patients who may be showing the clinical signs of AIDS. He also quoted a Standard article by Dr Searle who was saying they needed to change transfusion practice in the UK at that time.[1669] Dr McClelland had a definite recollection of having had meetings with Dr Macmillan and Derek Ogg in the first half of 1983 at which he was told about his patients showing signs of a new form of immune deficiency. In the context of the information available about the nature of AIDS in patients in the US, this was a clear indication that AIDS had arrived in Scotland.[1670] Dr McClelland accepted that his contact with Dr Macmillan indicated to him that the Rubicon had been crossed by this stage.[1671] By the spring of 1983 the signs were such that the transfusion service needed to do something about it.[1672]

4.132 These materials indicate that from 1983 there was evidence that Edinburgh had a considerable AIDS problem. This cannot have come as a surprise to individuals in the medical second there at that time. Dr Peutherer, it would appear, was monitoring IVDUs for evidence of transmissible disease at the virology department in Edinburgh. Contact between Dr McClelland and Dr Robertson, a GP whose relevance to this area was due to the coincidence of in caring for a high risk

---

[1668] PRSE0001259

[1669] MACK0002264_021

[1670] Penrose Inquiry transcript for 06/05/11 (day 21); 130 (14 to 27) and 135 (1 to 11) (Dr McClelland); [PRSE0006021_0130 and 0135]

[1671] Penrose Inquiry transcript for 06/05/11 (day 21); 134 (22 to 25) (Dr McClelland); [PRSE0006021_0134]

[1672] Penrose Inquiry transcript for 06/05/11 (day 21); 135 (22) to 136 (2) (Dr McClelland); [PRSE0006021_0135 to 0136]

population in his part of the city had been developed by 1982. This group was deemed high risk at that time for HBV, such that blood samples were being taken and monitored. HBV was known to have the same transmission routes to AIDS. In real time these individuals were aware of the risk that this community would be a candidate community for AIDS. Dr Peutherer was also involved in the AIDS study, in which another high risk group (haemophiliacs) were being monitored for surrogate markers for AIDS in the form of white call abnormalities observed in US homosexuals with AIDS and others.[1673] These high risk communities had been identified and were being watched. The medical community sat back and watched them. Lo and behold, many of them became infected. Little was done to prevent it. At the time of the 1986 study:

(a) It was not known why the rate of infection had been so high in the Edinburgh IVDU community but it was assumed that sexual transmission as well as sharing needles played a part. No more information had come to light about the likely reasons for the infections by 1986. It had always been known from the outset that sexual transmission of AIDS, like HBV was possible. That these groups were at risk meant that the possibility of them being infected meant that there ought to have been a known possibility that they had or could spread the disease sexually – some protection against that possibility and infected blood donations being collected as a result was required;

(b) The study group include long term heroin addicts as well as much more occasional users in order to gain a fuller impression of those who might be infected. The fact that this group was selected indicates that it was known that it was not heroin addiction but IVDU, however, occasional, which created a risk of infection. Notably the emphasis on whether a blood donor was a "drug addict" is inconsistent with this definition of the at risk population;

(c) 84% of the population studied were positive for HBV markers, indicating a significant co-infection rate; and

[1673] PRSE0001987 (1984)

(d) It was stated that it was known not known whether needle sharing/ particular local injection practices had played a role in the high infection rate. However, that this was likely ought to have been known for the early part of the decade. Indeed, articles written by Dr Robertson himself confirms this. The 1986 article confirms that monitoring from the IVDU community in Edinburgh for which Dr Robertson was responsible had commenced in 1982 due to an outbreak of HBV there due to shared needle use after the local, legal needle facility had been closed local pharmacists had prohibited their provision. It was known from the early 1980s that the Scottish approach to IVDU problem was to criminalise it and not try to see it as a social evil which required a social solution.[1674] Needle exchanges were many years away. The solution was to send those involved to prison. This must have two effects, which ought to have been realised – that needle sharing would result and would increase the risk of spreading diseases like HBV and AIDS amongst the community quickly (as in fact happened from 1983) and the likelihood of IVDUs and hence infected individuals being in prison made prison donors all the more risky than they might have been before this policy of criminalisation was adopted. 40 early seroconvertors interviewed prior to January 1984 were discovered in the 1986 study to have been involved in regular needle sharing between 1980 and 1983, which increased when the availability of clean needles (identified as happening from 1982 in the 2007 Robertson article, alongside the rapid increase from 1983 identified in a Standing Conference on Drug Abuse report[1675]) ceased and the appearance of "shooting galleries" emerged from 1983. These practices were thus known about at the GP practice prior to the start of 1984.

[1674] EXPG0000033 which highlights the emergence of the IVDU problem in Edinburgh as having emerged due to various coinciding factors between 1980 and 1983 at _0001 and indicates that custodial sentences were being imposed for relatively small personal amounts of heroin, indicating the heavy handed response resulting in high number of heroin issuers ending up in prison at _0002 (due to even possession being tried at the more serious solemn criminal level) and the closure of attempts to provide those involved with clean equipment in September 1982, also at _0002

[1675] EXPG0000033_0002

4.133 The 1995 study shows a common source of infection between the IVDU infected individuals and the heterosexually infected, suggesting spread between these two communities.[1676] It is submitted elsewhere that the limited attention paid to the possibility of sexual transmission from the IVDU community into the (given the known sexual transmissibility of the disease from the outset) was one of the failures of the Scottish donor selection system. Concerns about the possibility of heterosexual sexual transmission from the IVDU community to the rest of the community appears from this later study to have occurred – the failure to take steps to exclude donors who might have fallen into this category may well have caused infections.

4.134 It is notable that the system in Edinburgh of storing donor samples had commenced in around 1981/ 82. Dr McClelland accepted that there was a known risk at the time there was a risk that donors could be infective for AIDS, such that it was not controversial at the time of the Edinburgh infections coming to light as to how they had been caused.[1677] He also accepted that the purpose of the system of storing donation samples was so that retrospective analysis could be done when infections occurred due to new pathogens.[1678] It was put to Dr McClelland in his oral evidence that the storage system had been due to the early reports of AIDS in the US. He said that he did not think so.[1679] The timing, however, suggests otherwise. Storage of samples in the bleeding disorder community had taken place in the virology department since the 1970s. The value of sample storage was well known in the context of pathogenic emergence. Dr McClelland offered no alternative explanation as to the timing, which coincides with the first intimation of AIDS being transmissible by blood and blood products from the US (1981/ 82). The analysis by Robertson and Richardson as to the reasons why samples from IVDUs in Edinburgh started to be stored seems to have involved a combination of the spreading IVDU problem, their known risk of HBV and the realisation at the time AIDS started to become part of the problem based on US evidence that IVDUs

---

[1676] PRSE0002082_0008
[1677] IBI transcript for 28/01/22; 48 (22) to 49 (6) (Dr Brian McClelland)
[1678] IBI transcript for 28/01/22; 167 (16) to 168 (10) (Dr Brian McClelland)
[1679] IBI transcript for 28/01/22; 168 (11 to 15) (Dr Brian McClelland)

presented a new facet of the AIDS problems, namely the ability to spread the virus quickly to the non-homosexual population.[1680] It seems likely on balance that the samples were stored so that when AIDS emerged in the Scottish donor pool (as Dr McClelland accepted was a risk, hence his efforts at donor selection) and indeed appeared inevitable based on (a) the large and expanding IVDU problems in Edinburgh and (b) the unique potential posed by the drug using group to spread the disease into the non-injecting, heterosexual population (as opposed to being confined within the self-limiting homosexual population), an analysis of the aetiology could be undertaken. The risk of spread to the donor pool was well known due to the characteristics of this community – maximum precautionary approach to its prevention was required. From 1982 and into 1983 it was known that AIDS was a powder keg waiting to explode in Edinburgh, in the whole community via the IVDUs and onwards into the recipients of blood and blood products. The fact that this risk was being or was about to material was the reason for the AIDS specialist Dr Ray Brettle being taken on at the City Hospital, where the AIDS patients notoriously received their care, in October 1983. As is analysed elsewhere in this submission, that risk was not shared with the recipients of the blood and blood products from those very donors whose samples were then stored.

4.135 The remaining 5 require separate consideration and are patients E5, E16, E19, E21 and E22 in the Edinburgh list.[1681] Information relating to the timing of their last negative and first positive tests gives some indication as to the timing of their infection ("the seroconversion window") and their treatment histories give some indication as to their likely infection route, subject to the reservations about the completeness and accuracy of the data set out elsewhere in this submission.

4.136 The infection window of patient E5 is between 21 June 1982 and 18 October 1984. This patient was treated exclusively with domestically produced products.[1682] This raises the possibility of a much earlier infection, perhaps in 1982. This possibility

---

[1680] EXPG0000033_0002 (2007)
[1681] This can be deduced from the identification of the 18 cohort patients on the list by Professor Ludlam in PRSE0002911_0004
[1682] PRSE0004860_0003

would be consistent with the infection of Glasgow patient G7 who was certainly infected by 1982 at the latest and would give some guidance as to when AIDS may have entered the donor population in Scotland (see below). The infection window of patient E16 is between 5 August 1982 and 15 September 1983. This patient was also treated exclusively with domestically produced products, again indicating a possible infection in 1982.[1683] The infection window of patient E21 is between 5 May 1984 and 11 October 1984. This patient was also treated exclusively with domestically produced products.[1684] This is an infection which occurred even after those of the cohort members. The treatment of these patients (as well as patient E19) appears to have been exclusively with NHS products. Given that these patients were not treated with the implicated batch, it appears likely that a number of other SNBTS products are likely to have been infective over a varied timescale 21 June 1982 and 17 November 1986. Further, the relatively late infection date of patient E21 is worthy of note, in light of developing knowledge of the risks of HIV infection by 1984 (covered elsewhere).

4.137 The seroconversion window of patient E19 is between 1 January 1985 and 17 November 1986. This patient was also treated exclusively with domestically produced concentrates.[1685] This very late infection is of considerable interest. By this time, a heat treated NHS factor VIII (NY) was available in Scotland which it had been claimed was safe as far as HIV transmission was concerned.[1686] The infection of this patient at this time should not have occurred due to the availability of a safe factor VIII concentrate product. It seems likely that that patient would have been infected as a result of a product which had not been rendered safe by heat treatment. Little attention appears to have been paid to this infection or how it occurred, though it should not have done. The SNBTS have repeatedly claimed that there were no infections after December 1984.

[1683] PRSE0004860_0007 to PRSE0004860_0008
[1684] PRSE0004860_0009 to PRSE0004860_0010
[1685] PRSE0004860_0009
[1686] See in this regard WITN2232039 – an example of an apparent circular letter to Edinburgh patients dated 31 January 1985 in which it is claimed that "all Scottish NHS factor VIII concentrate is now being heat treated to kill the AIDS virus" (the significance of this letter in the context of how patients were informed about their infections is considered below)

4.138 It has been confirmed by Professor Ludlam that two of the patients in his list were under 16 at the time of their infections, namely patients E17 and E20.[1687] The fact that infections of children occurred within the group (both members of the "cohort") also raises significant questions. As is raised elsewhere, their treatment with concentrates was contrary to contemporary guidance which recommended that children should be treated with cryo in light of the AIDS risk, as set out by Dr Ludlam himself.[1688]

4.139 The infection window of patient E22 is between 16 March 1981 and 1 December 1981. This patient was treated with domestically produced products, other than a single infusion of Armour Factorate in 1981.[1689] His early infection and his exposure to commercial concentrate on that one occasion seems to suggest that he was probably infected by a commercial product at a time similar to the infections of some of the boys at Yorkhill (see below) and by the product which they received (we address the appropriateness of commercial products being used at that time elsewhere). Of course, though haemophiliacs would not have been able to give blood at this time, this is further evidence that AIDS had arrived in Scotland by 1981, as at least haemophiliacs had been infected with HIV. They posed an infection and public health risk from that time as a result of infection by treatment given to them by the State. This also covers patients who may have been infected by commercial products in Glasgow (G1 may have been infected by 1981, G2 and G4 may have been infected by 1982, G12 was definitely infected by April 1981). They had a bleeding propensity and so posed an infection risk to those with whom they had domestic and other close contact. No doubt some of them had sexual relationships with spouses or others and so posed a risk of transmission to this fatal disease. This public health risk in Scotland and wider in the UK had been created by these imported products, possibly before risks existed from other sources. It is not beyond the realms of possibility that close contacts or sexual partners of haemophiliacs could have given blood and caused further infection at a time when they would not have been prevented from doing so by any test or

---

[1687] Penrose Inquiry transcript for 30/03/11 (day 14); 23 (Professor Ludlam); [PRSE0006014 _0023]
[1688] PRSE0001556_0002 (2 February 1984)
[1689] PRSE0004860_0009

screening measure. It was until after the event of actual infection in haemophiliac patients that spouses were prevented from blood donation.

The background circumstances in which these patients came to be infected

4.140 The Inquiry heard about the presence of an HIV patient in the haematology ward, also under the care of Professor Ludlam at the time many of the Edinburgh haemophilia patients came to be infected with HIV.[1690] As discussed above, Professor Ludlam was a sceptic about the vital aetiology theory of AIDS, or at least he portrayed himself as having been by the time of the Penrose Inquiry based on his early AIDS study which revealed a possible alternative aetiology for the white cell abnormalities in his haemophiliac patients who (at that time) he correctly surmised had not acquired AIDS (see the analysis of the antigen overload theory elsewhere in this submission). The case was spoken to in oral evidence by Mrs U and is discussed in detail elsewhere in this submission.

2. Glasgow Royal Infirmary ("GRI")

Treatment and the organisation of the centre

4.141 In theory the Glasgow centre at the GRI treated adult patients in the west of Scotland, children being cared for at Yorkhill. The multiplicity of treatments available there and the random policy of product selection adopted by Professor Forces are addressed elsewhere in this submission.

4.142 Information is available about treatment at the adult centre in Glasgow going back into the 1960s. The widow of one patient who was a mild to moderate

[1690] WITN0136001

haemophiliac who was infected there shows that prior to being treated with cryoprecipitate he received an early AHG concentrate. This led to his infection (thought to have occurred in the 1960s). His records showed him to have elevated liver enzymes (taken to be a sign of NANBH infection in at least 1979). He was severely ill by the mid 1980s.[1691] This shows that treatment with concentrated material was being linked with disease emerging in the late 1970s which was causing serious disease by the 1980s in these older patients. This ought to have had an impact on the attitude to treatment and potential effect of infection from transfusion of blood products in the 1980s, as well as other sources of such information. As had been the case with the industrialised vaccines such as the yellow fever vaccine from the war, serious infection resulted from treatment with industrialised concentrates in the 1960s in Glasgow.

4.143 Professor Lowe gave evidence to the Inquiry based on a study which he had carried out into the history of the Glasgow centre. The developments in the way that the centres had been run resulted in an apparent divergence between the treatment of mild patients and more severe patients with bleeding disorders, who were treated by different medical teams was described in the evidence of Professor Lowe, an amateur medical historian. It was far from clear as to how this had come to be the position. The factors which appeared relevant to this arrangement, which was unusual compared to any other centre in Scotland appear to have included the research which was being carried out in Glasgow, some of which is analysed elsewhere. The value of mild patients was that they tended to require less treatment, such that the value of their reaction to the fee treatments could provide more information about the effects of the treatment (including the infectivity of treatment). The Inquiry has heard evidence from a relatively large number of mild or moderate patients who were not treated until they were adults and hence fell into this valuable category. The evidence available to the Inquiry shows that Glasgow patients tended to be treated with concentrates as opposed to other treatments which might have been available which carried less infection risks. One mild patent who was not treated as a child at all received concentrates

[1691] WITN2092001, paras 1 to 9 (first statement of WITN2092)

in Glasgow in the 1970s. Despite the procedures which he underwent being relatively minor (dental procedures etc) he was regularly given factor concentrates. [1692] A father of boys who were mild patients who received no treatment until they were around 12 in the early 1970s. They were given factor VIII (presumably also an early version) as cover for dental work.[1693] Factor VIII concentrate was administered at the GRI as opposed to Yorkhill to young child who was a mild haemophilia A patient in 1984. He was infected with HCV.[1694] One mild haemophilia A patient only revived a small number of treatments. He was infected in 1978 after a hernia operation.[1695] He could have been treated with DDAVP or cryoprecipitate but was not or the surgery been deferred. He later died from HCV. Interestingly, this patient was told when he had a bad reaction post-operatively and was thought to have been infected with hepatitis that nobody else had it. Some years later when he was officially diagnosed in 1994 after another operation it was admitted by the centre that all of the haemophilia patients had been infected.[1696] It either was or ought to have been known in 1978 that others were similarly infected – the reaction was a guilty one. In any event, within 16 years the full extent of the tragedy had unfolded. The son of another moderate patient told the Inquiry that his father was a moderate haemophiliac and was not diagnosed until he was 14 and that he received treatment at the GRI. He was an elderly haemophiliac in whom chronic infection also started to come to light with extreme illness in 1978, when his diagnosis was made. He had been treated with factor VIII concentrates.[1697] As he was born in 1920, it seems likely that he also received early concentrates in Glasgow which by 1978 had caused what was known to be NANBH with symptomatic illness. Another witness was a mild to moderate patient who required only a few treatments. He had had no treatment before the age of around 11 and so was referred for treatment directly to the GRI and not Yorkhill where he was treated with the adults. He had a family history which meant that he could

---

[1692] WITN2122001, paras 4 and 6 (first statement of Joyce Donnelly)
[1693] WITN2174001, para 4 (first statement of Edward Jennings)
[1694] WITN4183001, paras 4 and 5 (first statement of Joseph Monaghan)
[1695] WITN2186001, paras 3 and 6 (first statement of Margaret Campbell)
[1696] WITN2186001, paras 6 and 14 (first statement of Margaret Campbell)
[1697] WITN2310001 @ para 7 (first written statement of WITN2310)

have been given lifestyle advice to avoid bleeds and had a minimum risk treatment plan set out in advance of a bleed.[1698] He was infected with NANBH in 1985 as a result of treatment with factor VIII concentrate.[1699] This was during the period when patients who were thought to be uninfected (like this witness) ought not to have been treated with PFC factor VIII which was known to continue to carry a risk of NANBH - as a mild patient this infection could and should have been avoided. Cryoprecipitate or DDAVP should have been used. The batch which infected this patient was followed up for other infections in other patients.[1700] The doctors involved in tracing the recipients noted that they would be "interested" to know if any of the recipients developed NANBH. There is no suggestion that the batch was recalled or that any effort was made to restrict its use in mild, untreated or minimally treated patients. It seems that the academic interests of the treating doctors prevailed over consideration of the risks of the recipients being infected with what was then known to be a potentially fatal disease.

4.144 It was frequently contended on the part of the clinicians who gave evidence to the inquiry that treatment with factor concentrates was necessary on the basis that without such treatment there was a significant risk that patients would bleed to death, by cerebral haemorrhage or otherwise – this topic is addressed separately in this submission with particular reference to the evidence of Professor Hay. It is contended elsewhere in this submission that that argument ought not to be accepted by the Inquiry or alternatively that treatment in the amounts used was certainly not necessary which would have reduced risk and viral load. Whilst the risk of death from spontaneous bleeding may have formed a legitimate part of the thinking around treatment in severe patients, this argument holds no water in treatment decisions relating to this significant group of mild or moderate patients in Glasgow. Their consistent evidence to the inquiry is that they hardly needed any treatment at all. Their risk profile was not that upon which treatment philosophy appears to have been based by the clinicians generally. Their treatment with

---

[1698] WITN2072001 @ para 4 (first statement of WITN2072)
[1699] WITN2072003 and WITN2072004
[1700] WITN2072005

concentrates was inappropriate and caused their infections. The assumption that concentrate treatment was necessary and necessary in large quantities for all patients based on the spontaneous bleeding risk in a few was a misguided and dangerous failure in treatment policy.

Research in Glasgow

4.145 Like Edinburgh the Glasgow haemophilia centre had an active research interest, of which patients had little or no knowledge and to which they had not consented. The Glasgow immune function study and the subsequent AIDS study collaboration with the Melbye centre in Denmark are considered in detail below. In addition, One Glasgow haemophiliac was aware that he had records relating to him held in a "research archive" without ever knowing what that was or what was held relating to him there.[1701] Another mild haemophilia A patient had a recollection of being involved in research and giving blood for it. Though he had been made aware that the blood was being taken for research, he was unaware of precisely what it involved.[1702] This was in fact the Glasgow immune function study and its follow up after AIDS diagnosis in 1985, which is demonstrated by the involvement of Dr Madhok (wrongly named Maddock in the statement) who was part of the team which did that work. It is interesting that a mild haemophiliac (described as a regular recipient of factor VII concentrate in correspondence[1703]) could have been thought to have been at risk of AIDS so as to have been include in the study group. This research is considered in more detail below.

HIV infections at the GRI

[1701] WITN2072001 @ para 5 (first statement of WITN2072)
[1702] WITN2185001 @ para 18 (first statement of WITN2185)
[1703] WITN2149007

4.146 The spreadsheet/ table provided to the Penrose Inquiry which set out the treatment and infection details of those who were accepted by them to have been infected with HIV at Glasgow Royal Infirmary indicated that 12 patients were so infected there.[1704] Nine of those were listed as being severe haemophilia A patients, one was a moderate haemophilia A patient, one a severe haemophilia B patient and one a moderate haemophilia B patient (see below for the others including "David", one of the patients who gave evidence to the Penrose Inquiry).

4.147 A number of the Glasgow patients were treated with a mixture of commercial and domestically produced products, making it more difficult to determine how and indeed when they are likely to have become infected. Those who were treated and infected by domestic concentrates merit some further consideration, as follows:

(a) The lateness of the infection of patient G3 (apparently between 15 December 1984 and 15 November 1985 – infected by imported product) is noteworthy. Heat treated PFC factor VIII concentrate was available from December 1984. Any infection after this time should not have happened. This must have happened either as a result of a seroconversion as a result of treatment before December 1984 with a non-heated product used before that date happening after December 1984, a non-heated product being used which had been made available to the patient before that date (for example at home) or the patient being issue with a non-heated commercial product after December 1984. Any of these options indicate, in our view, a failure in the system. An infection ought not to have occurred at that time, due to the availability or imminent availability of domestic concentrate which was heated to a standard which was known (after the Groeningen conference) to be likely to render the product non-infectious.

(b) Patient G5 (whose seroconversion widow is between 15 July 1982 and 15 December 1983) was treated only with PFC factor VIII over that period. He must have been infected by the end of 1983.

[1704] See PRSE0000442, PRSE0004681 and table 3.17 in the Penrose Inquiry final report

(c) Patient G7 was also deemed to have been infected at the GRI and only received PFC concentrates there (see below).

(d) Patient G8 (whose seroconversion widow is between 1 January 1982 and 15 February 1984) was treated only with PFC factor VIII over that period and was certainly infected by February 1984.

(e) Patient G9 (whose seroconversion widow is between 15 October 1984 and 15 October 1985) was treated only with PFC factor VIII over that period. It is possible (like patient G3) that he was infected, though by a different route, that he was infected after the heat-treated domestic factor VIII product became available in December 1984. Infections this late in the period as a result of domestic factor VIII concentrate product should not have occurred.

(f) Patient G12 was treated with a mixture of commercial and PFC products and so may have been infected by either. In any event, he has seroconverted by April 1981. Products being used in Scotland were infective by that time.

4.148 The patients who were infected with Scottish factor VIII concentrates over a period potentially lasting from 15 July 1982 to 15 October 1985. This suggests a long period over which (beyond the date on which successfully heat treated products were available domestically in December 1984). It suggests that multiple products were probably involved which and potentially multiple batches having been infected. In turn, this suggests that there were multiple breaches of the SNBTS's system for preventing products becoming infected. Patient G7 (a moderate patient[1705]) was certainly infected by domestic product (all he received) by 1982, his first positive test having been in November of that year. In his evidence to this inquiry, Dr Brian McClelland of SNBTS expressed the view that he had been surprised in late 1984 on hearing about the infections of the Edinburgh haemophilia patients late that year, not that AIDS had penetrated the donor pool in Scotland but that it had done so so soon (ie by late 1984).[1706] Dr McClelland's explanation that he had hoped that AIDS in the recipients of blood and blood products in Scotland was misguided. This was wishful thinking. In fact, as this

[1705] PRSE0000442

[1706] IBI transcript for 27/01/22; 128 (17) to 129 (2) (Dr Brian McClelland)

infection shows, the virus which caused AIDS had entered the donor pool long before he learned of the infections in the Edinburgh haemophiliacs. To test positive for HTLV-III in a sample collected on 15 November 1982, patient G7 must have taken some to seroconvert and for the antibodies to emerge which triggered the positive test. Before that, time would have elapsed between the donation being taken, the plasma being sent to the PFC, stored and processed, including the 17 steps involved and the subsequent inspection, labelling and other procedures which were undertaken before the batch could be released which would typically have taken three to four months, according to Dr Peter Foster.[1707] Thereafter, the product would have required to have been sent to the GRI haemophilia, stored there and used in accordance with the inevitable stock rotation system, all of which would have further required time to elapse. This means that the donation or donations which caused the infection must have been collected some months before the infected blood sample was taken, perhaps around the spring or summer of 1982 at the latest. Dr McClelland was surprised at infection being uncovered on late 1984, well over two years after the system had been breached. There was a lack of awareness within the Scottish system of the threat posed by AIDS. Dr McClelland was an example of a practitioner who was more aware of that threat than many, if not any others. That he was surprised that the system had been breached domestically, such that the Edinburgh cohort was infected in 1984 is indicative is how little attention had been paid by the system as a whole to a threat which we now know had penetrated that system many years before that.

4.149 The tables provided to the Penrose Inquiry suggested that there are only 2 haemophilia B patients who were infected with HIV in Scotland. Both of these were infected at the adult centre in Glasgow and both (at least potentially) very late. Patient G10 was infected between January 1985 (revealed in later evidence to the Penrose Inquiry by the anonymised witness "David", not the table) and 15 November 1985 (during which time he received only PFC factor IX). Patient G10

[1707] PRSE0000184, in particular at _0006; and Penrose Inquiry transcript for 06/09/11 (day 41) (Dr Peter Foster)

was a moderate patient[1708], the other haemophilia B patient was severe. That means that patient G10 must have been David. Both of these patients were infected long after the widely publicised infection of a number of haemophilia A patients including the Edinburgh cohort who were infected by SNBTS factor VIII concentrate and the availability of an SNBTS factor VIII concentrate (from December 1984). We know that commercial heat treated factor IX was available and used in Glasgow.[1709] It is certainly possible that this patient ought not to have received the domestic factor IX which had no heat treatment applied to it in 1985. Commercially heat treated factor concentrates had been licensed in the UK from February 1985. Those could have been accessed (and were in Glasgow). In light of the known risk of transmission from factor VIII concentrates, the same plasma for which had been used in the production of factor IX, they should have been deemed to be at risk of transmission of HIV. Treatment decisions and lifestyle advice should have been given to avoid them, in particular as the patient was moderate. The work being done on heat treating factor VII had been successful by December 1984. Work should have been expected to have the same result for factor IX, as it did in the autumn of 1985. Any change in treatment regime would have been short lived. In any event, heat treated commercial alternatives were available in Glasgow and were used That the analysis suggests that this patient must have been infected by the domestic product suggests that that must have been the source of the infection. It seems that this infection ought not to have occurred for these reasons.

4.150 Recommended treatment for patients with haemophilia B was covered in the AIDS advisory document dated 14 December 1984. [1710] This document was drafted in light of the knowledge that patients in England and Scotland had been infected with HIV. The recommendation for haemophilia B sufferers is so vague as to hardly constitute guidance at all. It (a) recommends fresh frozen plasma **or** NHS concentrate for mild patients (b) recommends continuing with NHS factor IX for moderate and severe patients, but qualifies this recommendation to the point of

---

[1708] PRSE0004681

[1709] PRSE0002887 _0022 – over 70% of the factor IX used in Glasgow in 1985 was the Immuno heat treated factor IX

[1710] PRSE0002282

removing its force by saying that individual directors will have to make up their own minds for individual patients and (c) gives non-committal advice about the relative safety of the available commercial heated factor IX, stating that virologists recommend it[1711] whilst at the same time stating that they cannot give any firm recommendation at all.[1712] Interestingly, unlike the detail given for the proposed arrival of NHS heat treated factor VIII, no advice is given about the current heat treatment programme for NHS factor IX.

4.151 In his evidence to the Penrose Inquiry Professor Ludlam was asked about the passage in his statement that in the aftermath of the infection with HIV of a haemophilia B patient in England, certain centres opted to switch treatment to the then available heat treated commercial factor IX product. He indicated that in Edinburgh patients continued to be treated with the unheated SNBTS factor IX product on the basis that (a) factor IX was manufactured in a way which may have excluded the virus and (b) the immune systems of haemophilia B patients seemed to be less abnormal than the haemophilia A patients (although he accepted that the reason for this was not quite clear even now as they were also infected with hepatitis C).[1713] His confidence in the likelihood of unheated factor IX being free from the virus seemed limited. Further, his comment should be seen in light of the fact that, in the aftermath of the infection of the Edinburgh cohort patients, the batch of factor IX made from the same plasma was withdrawn from use.[1714] Given his own concession, it appears that the immune function difference could hardly be reliable enough to form the basis of any sound judgement, in particular after February 1985 when the English patient with haemophilia B was known to have been infected.

4.152 In our submission, it was imperative over the period between the infection of haemophilia A patients in Scotland from SNBTS concentrates in late 1984 and the introduction of heat treated factor IX that the patients who were on treatment

---

[1711] PRSE0002282_0003
[1712] PRSE0002282_0002
[1713] Penrose Inquiry transcript for 04/05/11 (day 19); 74 (16) to 75 (1) (Professor Ludlam); [PRSE0006019_0074 to 0075]
[1714] PRSE0004684_0003 (8 November 1984)

programmes with factor IX concentrates be reviewed and their exposure to concentrates reduced to the minimum necessary. This should, in our submission, have included cessation of home treatment and/or prophylactic treatment and advice given on lifestyle for what was envisaged would be a short, though crucial period.

4.153 It appears that the Penrose witness "David" was receiving prophylactic treatment at home with non-heat treated factor IX in the first half of 1985, when that treatment regime came to an end. He commented that he "continued it [that regime] until he thought it was no longer necessary".[1715] The regime had been started due to problems he had experienced with his knees. He was a moderate patient. He received no warnings about the prophylactic regime.[1716] The patient who gave evidence to the Penrose Inquiry as David has also provided a statement to this Inquiry.[1717] He was initially treated at Yorkhill and was transferred to the GRI in the normal fashion. He was born in the 1960s and received treatment with FFP in his early years and then was moved onto factor IX concentrate. His treatment was under Dr Willoughby, who would have been responsible for his treatment plans. The witness significantly told the Inquiry that he did not recall ever meeting Dr Willoughby, despite being regularly treated at the hospital and not going into home treatment until 1982, by which time he was being treated at the GRI.[1718] The fact that this witness was put onto home treatment in July 1982 at the GRI is relevant to the circumstances of his infection. Despite the fact that he had not been on home treatment until he was around 16 (and thus had not been used to being on home treatment for long) there is no suggestion that his home treatment or indeed treatment regime at all were reviewed in 1985, after the infection of haemophilia A patients in Scotland and before the factor IX was heat treated. Lowering the amount of treatment he received or even temporarily suspending home treatment pending a heat treatment breakthrough appear not to have been considered, despite the known HIV transmission risk. He was also

---

[1715] Penrose Inquiry transcript for 09/06/11 (day 30); 102 (12 to 14) ("David"); [PRSE0006030_0102]
[1716] Penrose Inquiry transcript for 09/06/11 (day 30); 104 (12 to 15) ("David"); [PRSE0006030_0104]
[1717] WITN2212002 @ para 21 second written statement of WITN2212)
[1718] WITN2212002 @ paras 6 and 7 (second written statement of WITN2212)

tested for HIV without his knowledge in 1985 which indicates that that was a practice which continued at the GRI even after the 1984 infection revelations. It was also known at this time that he also had NANBH but this was not discussed with him for over a decade after his HIV diagnosis in December 1985.[1719]

4.154 The only other haemophilia B patient who is listed in the HIV spreadsheets produced by the UKHCDO is patient G11 in the GRI spreadsheet, a severe haemophilia B sufferer. Patient G11 seroconverted between 15 October 1985 and 15 July 1986 (during which time he received domestic factor IX). It is possible that this was a result of the heat treated DEFIX and also possible that it was due to the unheated DEFIX used before the heat-treated version was available. The unheated product could have been used before October 1985 and seroconversion happening after that date. It may be that the heat treatment was ineffective on a product used after that date. This patient should not have been infected. The successfully heat treated DEFIX was available in October 1985. Prior to that we know that heat treated commercial factor IX concentrate was available and was used in Glasgow. These patients should, at the very least, have been informed of the infection of patients with HIV amongst the haemophilia A community, so that they could make informed choices about their treatment in light of the known risks.

4.155 As Dr Winter observed in his evidence to the Penrose Inquiry, without any detailed scientific explanation, the position internationally was that the manufacturing process of factor IX tended to result in less viral transmission than was the case with factor VIII.[1720] It could be that lower numbers of infections of haemophilia B patients is due to national self-sufficiency in factor IX being achieved much earlier than with factor VIII. The apparently lesser infectivity in factor IX seems (as much over this period was) to be somewhat of an anomaly or fluke of the manufacturing process, rather than as a result of any patient safety directed initiatives on the part of the manufacturers. In any event, the two haemophilia B patients infected with

---

[1719] WITN2212002 @ para 3 (second written statement of WITN2212)

[1720] Penrose Inquiry transcript for 27/04/11 (day 16); 58 (24) to 59 (9) (Dr Winter); [PRSE0006016_0058 to PRSE0006016_0059]

HIV in Scotland were definitely infected by PFC factor IX.[1721] Their infections could and should have been avoided.

Conclusion

4.156 The GRI infections ought not to have occurred. Some could have been avoided by commercial products having been avoided in the treatment of Scottish patients, as is submitted elsewhere ought to have occurred. Other could and should have been avoided by treatment plans being adapted suitably to the risk, patients being properly engaged in the choice of their products patients being treated with the safest available products, or for the other reasons listed above. The multiplicity of infections over a wide time period suggests that domestic system was breached multiply over that time and from at least 1982.

3. The Royal Hospital for Sick Children, Glasgow ("Yorkhill")

The background to the centre

4.157 The centre was theoretically responsible for the treatment of children in the west of Scotland. This was a large catchment area and so the centre operated as a hub for the treatment of children in diverse parts of the country. Despite this, the evidence heard by the Inquiry was to the effect that facilities and staffing were minimal and attention was not focussed by the haematologists (under both Dr Willoughby and Professor Hann) on haemophilia care but on leukaemia care. The

[1721] Penrose Inquiry transcript for 27/04/11 (day 16); 59 (20 to 25) (Dr Winter) and Penrose Inquiry transcript for 03/05/2011 (day 18); 49 (1 to 3) (Professor Ludlam); [PRSE0006016_0059 and PRSE0006018_0049]

department was overstretched, which had significant consequences for the treatment regimes and the safety of them.

Treatment

4.158 The UKHCDO records made available to the Penrose Inquiry indicated that the commercial factor VIII product used at Yorkhill was almost exclusively the Factorate product made by Armour, which was used at Yorkhill from the year after was licensed for use in the UK in 1977, that being the earliest year for which the record sere provided.[1722] Small amounts of other commercial concentrates were used there in 1977 and 1978 before the huge surge of Factorate usage in 1979 (which coincided with the commencement, it would appear of the home prophylactic regime). This was consistent with the evidence heard by the Inquiry from one severe haemophilia A patient whose records showed he had also received Baxter and Bayer products as well as Factorate.[1723]

4.159 A typical treatment pattern at Yorkhill can be seen in the testimony of WITN2149001. He was born in 1974 and was treated at home from the age of 5 in 1979 with factor VIII concentrates.[1724] The regime was instituted by Dr Willoughby. The UKHCDO materials given to the Penrose Inquiry indicate a huge surge in the amounts of factor VIII concentrate being used at Yorkhill from 1979 and Factorate being the only commercial factor VIII concentrate being used there.[1725] The amount of training which his mother had to undergo and the difficulty of treating young children at home is set out in the letter describing how the regime was instituted. It is clear that significant effort was put in to get the children to a position that they could be treated at home, including home visitation to make sure things were going smoothy. He was on a prophylactic regime with weekly

[1722] PRSE0002887_0025
[1723] IBI transcript for 08/06/2019; 88(12) to 89(2) (WITN2245, aka Mr V)
[1724] WITN2149001, para 2 (first statement of WITN2149)
[1725] PRSE0002887_0025

infusions and further factor VIII concentrate in the event of a bleed. One of the objectives of this regime is listed as being minimising hospital attendance.

4.160 It was envisaged that he would only attend for a joint orthopaedic clinic and that his mother would pick up his treatment at the hospital.[1726] He ultimately found out that he had been infected with HIV as a result of his treatment with a US concentrate (which would have been made by Armour) as part of this regime 2 years later, in 1981.[1727] He made clear that the regime expanded to treatment 2 to 3 times a week and every day of he had a bleed.[1728] This is a good example of the amount of product these boys were receiving but also confirms that the prophylaxis did not prevent bleeding.

4.161 For some reason not all Yorkhill patients received the same treatment regime. One severe haemophilia A patient who was born in 1963 and diagnosed in 1967 was treated at GRO-B during his childhood, until the mid 1980s, when his treatment was transferred to the GRI in the normal fashion. At GRO-B he was treated on demand. He was treated with domestic factor VIII concentrate and has US factor VIII concentrate when he went on holiday. He was not treated prophylactically until 2000 and so did not receive prophylactic treatment at GRO-B, unlike others.[1729] Though infected with HCV, he was not infected with HIV. It may be that as this patient was around 10 years older than certain others who contracted HIV, he was not included in the prophylactic regime which others had and which was fuelled by imported factor VIII concentrate, as is discussed elsewhere.[1730] The propensity to treat patients with factor concentrate automatically appears also to be consistent with the evidence by a mild haemophilia A patient who was treated in response to any bleeds from around 1977, despite the availability from that time of DDAVP and cryoprecipitate which would have carried a lower infection risk, in particular with appropriate lifestyle advice to manage and avoid bleeding.[1731]

[1726] WITN2149003

[1727] WITN2149001, para 3 (first statement of WITN2149)

[1728] WITN2149001, para 5 (first statement of WITN2149)

[1729] WITN2118001 @ para 3 (first statement of WITN2118)

[1730] One such example is WITN2149 who was born in 1974, 9 years later

[1731] WITN2185001 @ paras 4 and 5 (first statement of WITN2185, infected with HCV – no risks or alternatives explained, para 7)

4.162 For small children, the Inquiry has heard evidence that practitioners like Dr Ludlam advocated the use of cryoprecipitate in children up to the age of 4. Indeed, there is one record in which he was keen that cryoprecipitate for children generally (at least in light of the AIDS risk)[1732], though as we know, he did treat children in his own unit with factor concentrates even at the time of the AIDS crisis, as two of the Edinburgh cohort were children. Very little cryoprecipitate was used at Yorkhill in the period when Dr Willoughby was in charge, up to 1982 inclusive, though slightly more was used in 1981 then in other years from 1977 when the record begins.[1733] Dr Hann concurred with Dr Ludlam's suggestion that cryoprecipitate was the preferred treatment for children by February 1984.[1734] One patient who was born in 1981 received being given cryoprecipitate only until the age of 2 as opposed to 4, after which he was given factor VIII concentrates.[1735] Had he been kept on cryoprecipitate until he was 4 (1985) he would have avoided the risk of HIV completely as the PFC product had been heat treated for HIV by then. He avoided HIV infection but was infected with HCV, though he was unnecessarily exposed to the risk of it. The use of factor VIII concentrate as opposed to cryoprecipitate in children extended even to mild patients at Yorkhill. It should not have done. One such patient's widow gave oral evidence to the Inquiry under the name Mrs Y.[1736]

GRO-D

GRO-D He ought not to have been as he was only a mild patient, whose haemophilia did not have a big impact on his life so treated and thereafter contracted HCV. In her oral evidence, despite his mild condition, she reported that no lifestyle advice had been given to her late husband or his mother. This would have reduced and maybe avoided completely the need for treatment. In any event, she gave evidence that he was treated with DDAVP later and so could have been treated with that throughout from the time of his first treatment in

---

[1732] PRSE0001556_0002 (2 February 1984)
[1733] PRSE0002887_0025
[1734] PRSE0001556_0002 (2 February 1984)
[1735] WITN2119001 @ paras 1 and 3 (first statement of John Dickson)
[1736]
[1737] GRO-D

1977. This case shows a culture of treating with concentrate where they could and should have been avoided.

4.163 The assertions about product usage at Yorkhill made by Professor Hann and the material provided by the UKHCDO to the Penrose Inquiry suggest that he was able to move away from the use of commercial material, in particular the Armour factor VIII concentrate which had been used by his predecessor. These sources suggested that the Armour Factorate product was used in a very small quantity at Yorkhill in 1984, the year after Professor Hann's arrival there. By 1985, no such material was reported as having been used at Yorkhill, according to the UKHCDO records.[1738] The impression was being given that there was a new found commitment to domestic products. However, material provided to the Inquiry suggests that this is not an accurate portrayal. One mild haemophiliac witness reported that his records contained a letter from March 1984 relating to the possible use of a heated Factorate HT product at Yorkhill, of which they had a supply in March 1984 for clinical trial. The letter suggests that this patient would have been suitable due to his limited treatment history but that he eventually did not need treatment at all. The patient has no awareness of the possibility that he might have been treated with such a product.[1739] This suggests that there was indeed an ongoing relationship between Yorkhill and Armour and that a mild patient like this might have been used in the trial. At this time, such a patient should not have been treated with a factor concentrate at all, far less an untested commercial product. DDAVP or cryoprecipitate would have caried a low infection risk, if treatment had been required. The possibility of such a treatment being used is consistent with evidence analysed elsewhere in this submission of 2 HIV infections occurring at Yorkhill as a result of treatment with Factorate HT in 1986.

<u>The emergence of the infective treatment regimes</u>

[1738] PRSE0002997_0026

[1739] WITN4183001 @ para 16 (first written statement of Joseph Monaghan); WITN4183002

4.164 Dr Willoughby was responsible the emergence of the home treatment and prophylactic regime at Yorkhill. It is submitted that this was inappropriate in light of the resources then available to the NHS in Scotland for the treatment of children with haemophilia. It required to be supported by huge amounts of commercial concentrates which were known to be more dangerous at the time when (in the late 1970s) when Dr Willoughby switched to them.

4.165 No information was provided to parents/ children about the way in which these treatment regimes would benefit the children (addressed in more detail below). Information was provided was about the benefits – leading normal lives, assuaging the guilt of the mothers who considered themselves to be responsible for the boys having the limiting condition in the first place.

4.166 It was an important element of the inadequately resourced system in Yorkhill where the treatment of the boys was clearly an "add on" service to the leukaemia treatment with which Dr Willoughby and Dr Hann were clearly primarily charged. The home treatment regime had the advantage of the boys not need so much of a resource in the hospital. Treatment which was sold to the patients as being about freedom and choice was actually about switching resource away from the inadequately resourced hospital.

4.167 The Yorkhill treatment regimes and conditions cannot favourably be compared with the treatment regimes in the rest of Scotland over this period under Dr Davies, in particular Edinburgh and its commitment to locally sources cryoprecipitate until the arrival of Dr Ludlam in 1979/ 80. Yorkhill's treatment regime was the elephant in the room for Scotland's haematology services in the late 1970s and early 1980s. This was not assisted by the fact that the system permitted, by the standards said to have been applied elsewhere in Scotland which promoted local and low risk over imports, autonomous decision making by a clinicians whose primarily area of responsibility was leukaemia and not haemophilia. There appeared to be no management structure where by Dr Willoughby (a) was required to ensure he was keeping up to date with the developments in knowledge about the danger of his treatment regime (given that he rarely if ever attended meetings of the Scottish haemophilia directors) and (b) was required to be accountable to any peer or manager for his unilateral

treatment decisions, which by their own clear admission would, if scrutinised, have been deemed highly questionable at the time by anyone else in Scotland. However, the system allowed a degree of wilful blindness to what was going on in Scotland, given the fact that its reliance on commercial products was of considerable advantage to the other centres – the limited use of domestically produced factor VIII concentrate in Yorkhill conveniently allowed other centres to continue to use what was available from that source more freely.

4.168 There is another element of the treatment regime at Yorkhill which is worthy of mention. The statistics available to the inquiry about product usage at the hospital show that the amount of cryoprecipitate being used there fell to almost nothing in the period between 1978 and 1982. A fair amount was used in 1977 and again it started to be used in greater quantities again in 1983 when Professor Hann became the director. [1740] What this must mean is that virtually all of the treatment being dispensed over the period from 1978 to 1982 inclusive was with factor concentrates for patients with haemophilia A. Dr Ludlam's policy at this time was that a patient who was under 4 ought to have received cryoprecipitate anyway. Dr Ludlam himself later provided an expert opinion to the effect that a child in the first few years of life could have been treated with cryoprecipitate for bleeds which would have been adequate treatment in another case which caused HIV in the first half of the 1980s. This was because cryo was the product of choice for young children with haemophilia A in the 1970s and early 1980s, in his assessment.[1741] That case concerned a child who was treated between 1981 and 1985 and was infected with HIV. In the same case that practice for that period was described as negligent by Dr Savidge, who also provided an expert opinion.[1742] This was presumably due to the known far higher risk of hepatitis risk from concentrates of any origin than from cryoprecipitate and the efficacy of cryoprecipitate in these young patients. As no cryo appears to have been available over this period at Yorkhill, the children under 4 who were treated there must not have received it (or FFP). They must have been treated with factor concentrate

[1740] PRSE0002887_0025
[1741] DHSC0043164_067_0009
[1742] DHSC0043164_068_0004

which on the view of Dr Savidge was negligent. Dr Ludlam appears to have agreed. It is notable that no FFP was being used either which means that all patients with haemophilia B, even those who were very young were also treated with factor IX.

Analysis of the detailed breakdown of the HIV infections at Yorkhill

4.169 The spreadsheet provided to the Penrose Inquiry explaining the infections at Yorkhill indicated that 21 boys were infected there.[1743] The statistical information concerning product usage available to the Inquiry demonstrates that Yorkhill was heavily reliant on commercial concentrates in the treatment of its young patients. As noted above, this appears to be connected to their prophylactic, home-based treatment.

4.170 The statistical material provided by the UKHCDO to the Penrose Inquiry relating to twenty-one of the boys infected at Yorkhill gives is some indication as to the timing of their infection. The information is incomplete (mainly due to the lack of last negative tests for all of the boys) and not entirely accurate (as for some of the boys first positive tests were not performed, it would appear, until quite late in the decade) but we think that certain relevant conclusions can be drawn. In the first place, the proportion of the boys treated there who were infected with HIV is relatively high. The Penrose UKHCDO materials suggest that 55 boys with haemophilia A were being treated at Yorkhill in 1980, which would tend to suggest that around 40% of the boys with haemophilia A were infected with HIV there.[1744] By way of comparison, 156 people with haemophilia A were registered as being treated at Edinburgh at that time, which indicates the far higher proportion of HIV infections at Yorkhill, compared with anywhere else (Edinburgh being the only centre with a higher number of infections but with around 3 times as many patients). It is also notable on the Yorkhill figures that the total number of patients

[1743] PRSE0004862 and Penrose report, table 3.18
[1744] PRSE0002887_0031

registered there in 1980 (70) had grown very significantly since 1975 (8).[1745] This is significant, given the evidence which is available to the Inquiry of this being the period over which the home and prophylactic regimes were increased significantly, along with the evidence of the limited resources (in terms of staff and accommodation) available to the centre. This supports the submission that the regime changes were based on the inability of the hospital to treat its patient as inpatients. A near 9-fold increase in the number of patients appears to have been met with no corresponding increase in staff or facilities. It is submitted that the treatment regimes which were (a) based away from the hospital and (b) based on avoiding bleeding episodes which might need treated there was the result.

4.171 The Penrose infection table for Yorkhill shows that none of the twenty-one boys was definitely infected after the start of 1983. Ten were definitely infected before the start of 1983. Another six were definitely infected by the middle of 1983. For the other five, the precise time of infection is hard to define either due to the lack of a last negative test or the significant time lapse between last negative and first positive tests. The balance of the evidence would seem to suggest that most of the boys were infected before evidence emerged of the threat of AIDS from blood products was generally accepted by haemophilia and other clinicians, which Dr Winter put at December 1982.

4.172 However, it was unreasonable for their treatment with commercial products to have been instituted as it was and these boys ought not to have been infected. None of the children treated there was definitely infected before 1 January 1980 (this being the earliest first negative test to which we have access). The Inquiry has access to details of first negative tests for 12 of the 21 boys. For the other 9, there is no negative test and we only know the date of the first positive test. For the 12 for whom we do have the details of a last negative test, only 2 have their last negative test in 1980, 6 have their last negative test in 1981 and the remaining 5 have their last negative test in 1982 (one as late as November 1982). The evidence which we have would, therefore, tend to suggest that the infection of boys at Yorkhill probably did not start until around 1981 at the earliest. Even by 1980, in

[1745] PRSE0002887_0030 and _0031

our submission, reliance on commercial concentrates in such high quantities as were being used at Yorkhill was entirely inappropriate in light of the well-known increased infection risks from US products. That the risks of these products were well known is illustrated clearly by the contents of the 1975 World in Action documentary. That the risks from those products were predominantly bound up with infection with hepatitis is neither here nor there. The low standards at blood donation sessions, the payment of donors and the enormous pool sizes would increase the risk not only of hepatitis infection but of transmitting any infectious agent, including HIV, which were known to come along periodically.

4.173 Between 1975 and the date of infection of the boys at Yorkhill with HIV in the early 1980s there had been significant advances in the understanding of the severity of NANB hepatitis, in particular in papers published in the Lancet in the late 1970s (as addressed more fully above). The continuation of the home based, prophylactic regimes fuelled by commercial concentrates ought not to have continued in light of the knowledge of potential severity of NANB hepatitis. There is no evidence that these treatment regimes were reviewed in light of this emerging evidence, an example of the "domino effect' where by a clinician fails to provide warnings at the start of the treatment regime and so can do little to stop the treatment which has become the norm by the time that the harms emerge. A review of the treatment regime would have found it to have been unacceptable before the HIV infections occurred. On the clear evidence that has been given by every other major figure involved in the fractions, transfusion of haemophilia community in Scotland over this period, any peer review of the practice would have rejected it as unsafe. In turn, this would have meant that these boys would not have been infected with HIV as they were.

The reasons why this treatment regime was selected

4.174 It is difficult to know with precision why it was that Yorkhill used so much commercial concentrate in the late 1970s and early 1980s, in particular why that

product appears to have been predominantly Factorate, produced by Armour. This is predominantly because the Inquiry does not have access to testimony from members of staff who can answer this important questions, in particular Dr Willoughby who was the centre directors at Yorkhill over this period. Some insight into the type of marketing which would have accompanied the product was found, however in the evidence of former Armour employee, Christopher Bishop. He accepted that Armour had achieved a dominance of the market after its licensing in 1976, in part due to the fact that it was cheaper than the other products in the market. However, he also explained that there was considerable evidence that patients were being undertreated in the UK, along the line of the Karolinska and Bonn models.[1746] This had the ring of a marketing pitch. One can only imagine that it was music to the ears of Dr Willoughby, less aware of the risks than others due to his infrequent attendance at meetings and keen to get the boys off his ward to facilitate the care of his leukaemia patients. This was essentially medical advice which Mr Bishop was providing which did not accord with the standard practice of the day. Had Dr Willoughby resisted this, many infections could have been avoided. As is known from evidence considered elsewhere, these products (the most dangerous used in the Scottish market) were presented with all of the required equipment and marketed to children via things like Mr Men plasters. Mr Bishop despicably tried to deny that this was the marketing objective of that approach by suggesting that adults might like Mr Men badges (which he accepted were provided) too.[1747] Though Mr Bishop denied it, correspondence from Armour to consultant haematologists at about the time that the Yorkhill home treatment programme started regarding Factorate which came onto the market in UK in June 1976 included prices, reducing the more they committed to with information about packaging for convenient use. The letter says a data sheet can be made available but nothing about risks.[1748]

[1746] IBI transcript for 04/11/21; 46 to 47 (Christopher Bishop)
[1747] IBI transcript for 04/11/21; 50 and 57 (Christopher Bishop)
[1748] CBLA0000796 – 1978

4.175 Though Dr Willoughby and Dr Pettigrew have claimed that it was the pharmacist Mr Jewell who had responsibility for buying the products, this cannot have been for the source of the material or merely the fact of placing the orders. If it was, this was a dereliction of Dr Willoughby's responsibility as the director.

4.176 Mr Bishop agreed that the attitude taken by the company was that unless it had been conclusively proven that the Armour product had transmitted AIDS, it was assumed to be risk free.[1749] Despite being keen to express what he (a marketing executive) thought were the clinical advantages of the product, it can be taken from that, that he is unlikely to have presented any risks to the hospital. As the Inquiry is aware, there was a parents' group at the hospital which sought frequently to obtain information, including about the safety of the commercial products from Armour. Dr Willoughby the Yorkhill regime were complicit in that wilful blindness approach to the known risks as a pay-off for cheap volume.

4.177 Professor Forbes was asked about this at Penrose and he suggested that the reason for the commitment to commercial concentrates. He answered that concentrates might be more suitable for young children due to problems with the amount of volume they could handle.[1750] He did not say that this was a reason for using specifically commercial concentrates. Further he suggested that the perception may have been that commercial concentrate was more effective or efficient than the NHS concentrate at that time.[1751] Such issues did not appear to trouble others in Scotland who used predominantly NHS materials. Further, at the UKHCDO meeting on AIDS held on 13 May 1983, it was considered circumspect for clinicians who had already reserved a stock of NHS concentrate for use for mild patients and children under 4 to continue with that policy which had already been implemented by certain clinicians in order to protect the these patients against the hepatitis risk from imported concentrates.[1752] Domestic concentrates had therefore been specifically reserved for young children in some centres. Further,

---

[1749] IBI transcript for 04/09/21; 180 (Christopher Bishop)
[1750] Penrose Inquiry transcript for 28/04/11 (day 17); 21 (21) to 22 (4) (Professor Forbes); [PRSE0006017_0021 to 0022]
[1751] Penrose Inquiry transcript for 28/04/11 (day 17); 23 (16 to 19) (Professor Forbes); [PRSE0006017_0023]
[1752] PRSE0002212

Professor Ludlam indicated at a later meeting that he could not agree to the discontinuation of the production of cryoprecipitate on the basis that he preferred to use it in the treatment of children. Interestingly, Professor Hann (by then the director at Yorkhill) agreed.[1753] Cryoprecipitate was less convenient to administer and contained unpredictable amounts of factor VIII. The fact that clinicians in Scotland favoured cryoprecipitate in the treatment of children over this period suggests that it was far from necessary for children to be treated with concentrates and, indeed, even before the HIV crisis emerged, it was considered by some to be unsafe to do so. In his evidence, Professor Ludlam confirmed that he was able to treat babies and young children in Edinburgh using only NHS material.[1754] The suggestion that the preference for commercial concentrates was necessary in order to meet the need for greater precision or to deal with fluid tolerance issues cannot be accepted. Any such suggestion indicates an unreasonable preference for convenience over patient safety.

4.178 As it noted above, Dr Willoughby had expressed an interest in the prophylactic treatment of the boys at Yorkhill. As observed above, such regimes require very large amounts of concentrate to be used. The prophylactic regime must have played a significant part in the reliance at Yorkhill on commercial concentrates on the basis that the PFC would have been unable at the relevant time (from the late 1970s to the end of Dr Willoughby's tenure) to provide enough material for the hospital to be self sufficient with such demand. Dr Pettigrew explained that the commercial concentrates were more user friendly and that the boxes contained the equipment one needed, making them more attractive for home treatment.[1755] Dr Willoughby had explained to Dr Pettigrew on her appointment (in 1976/77) that he used commercial concentrates as he could not get sufficient guarantees from the SNBTS that his home treatment regimes (which one assumes to cover prophylaxis) could be covered by domestic concentrates.[1756] These considerations

---

[1753] PRSE0001556_0002
[1754] Penrose Inquiry transcript for 03/05/2011 (day 18); 77 (Professor Ludlam); [PRSE0006018_0077]
[1755] Penrose Inquiry transcript for 05/05/11 (day 20); 17 (14) and (17 to 20) (Dr Pettigrew); [PRSE0006020_0017]
[1756] Penrose Inquiry transcript for 05/05/11 (day 20); 18 (9 to 23) (Dr Pettigrew); [PRSE0006020_0018]

ranked convenience above safety. Further, there is no evidence that the capacity of the SNBTS to meet Dr Willoughby's demands was kept under review. Once the commitment to commercial products was decided upon, that continued to be the supply source into the 1980s. It is interesting to note that Dr Pettigrew recalled that, if not on home treatment, boys tended to be treated with cryoprecipitate. The UKHCDO tables for the use of products at Yorkhill (at page 566 of the preliminary report) seem to show however that miniscule percentages of cryoprecipitate were used in the treatment of the boys in the early years of the 1980s.

4.179 It was suggested elsewhere in the evidence that the amount of factor VIII in the commercial concentrates was standardised and that the amount on the domestic concentrates was variable. However, as Dr McClelland pointed out although the amount of factor VIII in the domestic concentrates was variable, it was printed on the label and so all that was required was some arithmetic of numbers which were different to work out how much was needed.[1757] This minor practical inconvenience should not have outweighed the safety advantages of the domestic concentrates.

4.180 At the first joint meeting which he attended on 2 February 1984, Dr Hann pointed out that he had inherited a large amount of commercial concentrate at Yorkhill. He planned to dispose of it, despite the fact that it was obviously expensive.[1758] In light of this decision, it appears questionable as to whether the previous regime, which relied heavily on commercial products as can be seen from the statistical material available to the Inquiry, was a necessary or even a reasonable one. Although it cannot be submitted that the treatment regime at Yorkhill under the Willoughby directorship should have been altered due to the emerging risk of AIDS (as the relevant information did not emerge until too late for many of the infections there to have been avoided), we would submit that the practices adopted at Yorkhill were both unnecessary and also unsafe. One might argue that had there not been reliance on commercial concentrates in Yorkhill there would

---

[1757] Penrose Inquiry transcript for 06/05/11 (day 21); 171 (14) to 172 (13) (Dr McClelland); [PRSE0006021_0171 to 0172]
[1758] PRSE0001556_0003

not necessarily have been any more PFC concentrates for them In assessing this, one must remember that there were relatively few patients at Yorkhill and so the demand may not have been impossible to meet. It was suggested by Counsel to the Inquiry and the Chairman that the 21 infections constituted 35% of the total number of patients there at that time, meaning that there would only have been 60 patients.[1759] Further, given the fact that they were children, they would have required relatively small amounts of concentrate each, in particular if they were not being treated prophylactically as appeared to be the norm over this period in most other centres in the UK.

4.181 It is interesting to note that only one of the patients in Edinburgh appears to have seroconverted before over the same period as the seroconversions of the children infected at Yorkhill (patient E22 on Professor Ludlam's statistics list). We know that patient was one of the few in Edinburgh who did receive commercial product and the product he did receive was Armour Factorate, which was the product predominantly used at Yorkhill. This shows, in our submission, that had the Yorkhill children been using PFC concentrate as opposed to commercial concentrate it is likely that they would not have been infected. We would argue, consistent with the practices adopted for some children by a number of clinicians in the country, that treatment with cryoprecipitate (for the youngest children at least) would have been preferable and would have lessened the risk of HIV infection even further.

The later infections – Factorate HT

4.182 Evidence available to this Inquiry suggests that, contrary to the evidential material and the assertions made by the then director of the centre, Professor Hann, commercial concentrates from Armour continued to be used at Yorkhill in the period after 1983. In March 1984, Dr Pettigrew had procured a supply of heat treated Armour factor VIII for possible use in this virgin patient, at a time when

[1759] Penrose Inquiry transcript for 28/04/11 (day 17); 21 (7 to 8) (evidence of Professor Forbes); [PRSE0006017_0021]

she did not know his F8 level, which turned out to be 20% and his bleed settled spontaneously.[1760] He did not need to be treated with a concentrate at all. DDAVP is likely to have worked and was used at Yorkhill.[1761] The use of the product not appear in the UKHCDO tables for Yorkhill for 1984 (PRSE0002887 _0026). That patient went on to become infected with HCV.

4.183 The use of Armour commercial HT material also caused the HIV infections of 2 boys at the centre, as a result of the ineffective heat treatment regime applied to the product by Armour, as more fully explored by the Inquiry and causative of infections elsewhere in the UK.[1762]

4.184 Given that there appears to have been no clear acceptance in the Inquiry's evidence that use of commercial material went on at this time, exploration of why commercial material was still being used at Yorkhill in 1986 was limited. As this was long after the date at which self-sufficiency in factor concentrates was being claimed by the SNBTS (which was asserted to have been achieved by 1983), it seems unreasonable that such a product was still in use at that time. Its usage seems inconsistent with the general assertion of self-sufficiency and also the philosophical preference which Professor Hann claimed to have for domestically produced material. It may be that the product was being used due to the absence of an HCV-safe factor VIII SNBTS factor VIII concentrate (which was not introduced in Scotland until the following year, April 1987). The lack of recognition of its usage in the UKHCDO tables produced to the Penrose Inquiry seems to indicate that it could not have been in widespread use, however, and suggests that a widespread commitment to commercial concentrates had not been reinstated at Yorkhill at that time. There remain two other possibilities. Either it was being used as a

---

[1760] WITN4183002 (letter dated 15th March 1984)

[1761] PRSE0002887 _0026 – appears to have been used in 1984

[1762] See MACK0002301_021 – letter from 31 January 2000 from Aileen Keel to Mike McGovern at the DoH with comments about heat treatment and development of BPL and PFC products safe for HCV. Mentions discussing with Dr Foster the withdrawal of an Armour product which was responsible for 4 HIV transmissions in the UK< 2 of which occurred at Yorkhill; DHSC0006801_033 which is his letter of 29 December 1999. The reference to Armour relates to the product (HT Factorate) withdrawn in 1986 after having caused HCV infections, which Foster corrects; MACK0002301 _022 - *Armour - HT Factorate - 18 HIV transmissions published in 1988 & 1990 1 + **2 in Scotland not published), 2 NANB transmission reported 1990***

product in previously untreated patients on the basis that it might offer an advantage over the domestic product in terms of HCV infectivity or it was part of a trial. On either basis, it is submitted that the use of this product at that time was unjustified. If the former was the reason, the arguments presented in the section below relating to the treatment if untreated or minimally treated patients in the period between December 1984 and April 1987 apply – depending on the severity of the disorder the patients should have been treated with minimal cryoprecipitate or DDAVP. As it was after the widespread testing of donors for anti-HIV (instituted in Scotland in October 1985) the HIV risk from cryoprecipitate would have been deemed to have been minimal. As such, it is likely that infection is likely to have been avoided completely, or at least the infection with HIV. There is no possible reason why Yorkhill ought to have been entering patients into a clinical material of commercial products in 1986. The SNBTS had a clear commitment to producing its own products. No benefit to Scottish patients could be gleaned by entering patients into such a trial. If this is deemed to be the most likely explanation, that should not have occurred. The fact that the very same company had been the cause of the majority of the HIV infections of the boys so infected at Yorkhill in the early 1980s ought to have meant that any product emanating from them (in particular the more expensive Factorate HT product) ought to have been avoided.

4.185 In any event, no explanation has been offered to the Inquiry as to why these infections occurred or indeed what was done to try to assist or explain to the infected patients and their parents how this had occurred. The infections seem not to have been apparent to the Penrose Inquiry, which relied on the UKHCDO statistical material. The occurrence of the infections and the absence of any clear explanation as to how they were unreasonable and are matters for which the hospital and the NHS in Scotland ought to be criticised.

Prophylaxis

4.186 The UKHCDO statistical material available to the Penrose Inquiry makes it clear that large amounts of concentrate were used in the treatment of the children at Yorkhill in the late 1970s and early 1980s. In particular, there was a greater reliance than in other centres on commercial concentrates as part of a prophylactic regime. Dr Willoughby, who was in charge of haemophilia care there over that period intimated to a meeting of the UKHCDO on 30 September 1980 that "it was clear that using factor VIII concentrate on children would give the possibility of non-crippled adults".[1763] In his evidence to the Penrose Inquiry, his successor as the director, Professor Hann confirmed that Dr Willoughby was "ahead of his time" in that he was very interested in prophylaxis. This interest is what required him to rely on a supply of commercial concentrates, as well as perceived issues with the purity and potency of the SNBTS intermediate purity concentrates, also spoken to by others.[1764] This preference for prophylaxis led to a requirement to rely on dangerous commercial concentrates at Yorkhill. It was misguided. Whether or not it offered advantages for the mortality or morbidity risks to the children, it was a regime which could at the time not be offered safely, in that it required a reliance on imported concentrates which should not have been used in Scotland at that time, due to the availability of sufficient factor concentrates to supply a safe but clinically acceptable treatment regime.

4.187 No evidence is available to the Inquiry that any such widespread prophylactic regime was undertaken anywhere else in Scotland at that time. No other centre was forced to rely on commercial products to anywhere near the extent of Yorkhill under the control of Dr Willoughby. He did so in order supply his extensive home based prophylactic treatment regimes, instituted as a result of a judgement of medial theory which seemed completely oblivious to the known risks of the imported products which their institution required to be used in large quantities and at huge expense. There was no evidence that Dr Willoughby monitored the success of the treatment regimes at the time. There is no evidence of these regimes having done any good at all for the bleeding conditions of the boys.

[1763] PRSE0003946_0006

[1764] Penrose Inquiry transcript for 06/05/11 (day 21); 28 to 29 (Professor Hann); [PRSE0006021_0028 to 0029]

however, the evidence that it caused widespread HIV and HCV infection, resulting in the deaths of many of the boys from AIDS is clear.

4.188 The institution of these home and prophylactic treatment regimes in the late 1970s (at a time when such a regime was not widely favoured by haemophilia directors more generally – as is examined above) the practical advantage of keeping the patients out of the hospital. This allowed him to carry on with his multiple other medical commitments, including his primary interest in the treatment of childhood leukaemia and took pressure off his meagre hospital staff and accommodation. The medical theory that prophylaxis at home would be beneficial in the long term and the immediate practical advantages were allowed to displace what ought to have been the primary concern – the protection of the boys from infection.

4.189 The known increased risks of viral hepatitis from the commercial products and from the greater usage of any concentrates from viral hepatitis, in particular in children were generally accepted to outweigh the theatrical advantages of home-based prophylactic therapy in the late 1970s. this was why the like of Dr Howard Davies used no commercial products and favoured minimising donor exposure by using cryoprecipitate, a product which greater efficacy amongst children due to their size and thus lesser therapeutic factor VIII replacement requirements. The system in place at the time did not appear to admit of any system of peer review or central control. Despite the fact that many disagreed both with the use of imported concentrates and the haematological benefits of prophylaxis, other directors in the field were powerless to stop the regime in place at Yorkhill in the late 1970s to 1983 when Dr Hann replaced Dr Willoughby. No system of professional control existed. Regular meetings of the directors took place over this period. The guilty secret of what was going on at Yorkhill appears not to have been discussed, whether Dr Willoughby was in attendance or not. In fact, the Yorkhill regime must to some extent at least have been advantageous to the other centres in the sense that its reliance on commercial material must have created the opportunity for more domestic material to be made available to the other centres. In these circumstances, it hardly seems that such a system provided any incentive for the other directors, getting an increased share of the products they wanted, to

draw any attention to the admittedly unsafe practices at Yorkhill. Some misplaced sense of professional deference to the judgement of Dr Willoughby must also have played a part.

4.190 In addition, no internal control of the massively increased cost within the hospital of the profligate use of commercial concentrates not in use elsewhere within the Health Board, the SNBTS, the CSA or the SHHD appears to have existed. These systems were completely unfit for purpose. They permitted these unsafe practices to be undertaken without any challenge, control or limitation.

4.191 Most of the 21 definite infections with HIV at Yorkhill were caused by commercial factor VIII concentrate produced by Armour. As is submitted elsewhere, these infections ought not to have occurred. They were used These products ought not to have been used or at least they ought not to have been used at that time in such quantities. On his arrival at the centra in 1983, Dr Hann was able to eliminate such usage relatively quickly. It had not been necessary or safe before that.

Armour Factorate

4.192 As this particular factor VIII concentrate was responsible for so many of the HIV infections (and no doubt countless more HCV and possibly also HBV infections) at Yorkhill, where its usage was so much more prevalent than at any other centre in Scotland (subject to comments made about specific instances of its usage, elsewhere in this submission) this is an appropriate point to consider the impact on Scotland of the use of the Armour unheated factor VIII concentrate, Factorate. When asked about the situation relating to the use of commercial concentrates in children at Yorkhill, Dr Foster expressed the view that priority to the PFC products should have been given to children.[1765] It was not.

4.193 **GRO-D**

[1765] IBI transcript for 25/03/21; 147 (Dr Foster))

(ie Armour Factorate) was marketed for the use in the treatment of children[1766], given that the box in which it came contained equipment for the use of the product, including Mr Men plasters which (it is submitted) were clearly designed for the marketing of the products to children.

4.194 The availability of litigation as a remedy for the victims of the blood contamination disaster is discussed elsewhere in more detail in this submission. However, the Inquiry has heard evidence that some limited remedy made available to some of the Yorkhill families from Armour. This evidence was provided to the Inquiry by campaigner, Carol Grayson. It is clear that this remedy was limited both in terms of the numbers of infected boys to whom it was made available and also the amounts of money offered in settlement, which represented a fraction of the insufferable loss which the boys and their families endured. As is submitted elsewhere in connection with litigation more generally, various practical impediments would have made this an unrealistic route to redress for the Yorkhill families. The settlements which were made indicate, however, that Armour must have accepted that there was some risk of them being found legally liable to make greater reparation. We submit that Dr Willoughby, the NHS in Scotland and the SHHD were morally culpable in allowing the boys infected there to be exposed to these imported products. They ought never to have been. HIV and HCV infections were caused as a result.

Conclusions

4.195 The home treatment, prophylactic treated regime instituted by Dr Willoughby was misguided at the time when it was implemented. Though it may have been Dr Willougby's genuine belief at the time when it was so implemented that it was in the best interests of preventing bleeds and thus preserving the joints of the boys this was a misguided belief in that (a) at best this was a marginal emerging

[1766] Mr Men evidence of Mr AB, WITN2239001

philosophy at the time, which was experimental at best (b) it could not be supported safely given the inevitable reliance it would have on the use of large amounts of imported concentrates in the treatment of the boys. These misguided decisions were the cause of the infection of 21 boys with HIV, many of of whom subsequently died from AIDS.

4.196 This development in the treatment regime there was contributed to also by the lack of proper facilities at Yorkhill to allow treatment and care of the children who suffered from haemophilia within the hospital. This is exemplified by the fact that Dr Willoughby who made these decisions was largely absent from the care of the boys with haemophilia as he was predominantly occupied by his duties in the care of patient with leukaemia and the description given by Professor Hann of the way in which, on arrival at the hospital in January 1983, he was expected to undertake as role which would now be performed by multiple consultants. Informed consent to the use of concentrates in this way from the mid to late 1970s was not taken by Dr Willoughby. This was a breach at least of the applicable ethical standards of the time and certainly now would be considered to be a breach of the legal duty he owed to the children and their parents.

4.197 Dr Willoughby did not operate as other centre directors did, given his significant commitments in other areas. In fact, Dr Willoughby did not consider it to be a haemophilia centre at all.[1767] His approach was described by the social worker, Christina Leitch who gave evidence about the relative ways in which the cancer and haemophilia patients were treated as follows:

"My social work colleague expressed her concern to me that children with bleeding disorders were treated like "second class citizens" when they were in-patients. That applied to all haemophilia patients and not just the ones who had

[1767] PRSE0004648

contracted HIV. It seemed to be that because they were not ill but perhaps admitted with e.g. a knee bleed that they were viewed with less sympathy."[1768]

4.198 Dr Pettigrew confirmed that in her dealings with him there was never really very much discussed about haemophilia.[1769] She described his treatment regime as having been given in good faith without being fully aware of the risks involved.[1770] Records show that he was a non- or infrequent attender at meetings regularly attended by other directors. He sometimes sent proxies.[1771] This allowed him to operate outwith the normal system and for his non-standard treatment approach not to be exposed to the gaze or scrutiny of others, though the amount PFC factor VIII he was getting must have been known to SNBTS as well as what it was being used for. He was not confronted with information regularly discussed about the risk of foreign products or the emerging information about the risks of and consequences of viral hepatitis. For completeness, it should be noted that Dr Willoughby does appear to have attended meeting of the UKHCDO in September 1981 but this was in Glasgow. It was arranged by Dr Forbes (see page 15), Dr Cash also attended (not a haemophilia director) and Dr Willoughby appears to have made little contribution to the discussion.[1772] Professor Hann had had impression that Dr Willoughby had attended UKHCDO meeting very infrequently if at all.[1773]

4.199 In a statement he provided to the Penrose Inquiry, he said that through a close contact with US colleague from the leukaemia background, he obtained the idea

---

[1768] PRSE0001619_0007

[1769] IBI transcript for 07/12/20; 54 (Anna Pettigrew)

[1770] IBI transcript for 07/12/20; 112 (Anna Pettigrew)

[1771] See minutes of meetings of SNBTS and the haemophilia directors as follows (a) PRSE0000507 – 8 May 1975 (Dr Willoughby not in attendance or on apologies) (b) PRSE0002823 - 14 November 1975 (Dr Willoughby not in attendance or on apologies) (c) 14 November 1975 – referred to in next meeting minutes (d) PRSE0000983 - 4 October 1976 (Dr Willoughby not in attendance or on apologies) (e) DHSC0001767 – 30 May 1977 (Dr Willoughby not in attendance or on apologies) (f) PRSE0004327 – group in abeyance from 1977 and invitation by SHHD for it to meet again (November 1980) (g) PRSE0000181 – 4 March 1981 (Dr Willoughby not in attendance or on apologies, despite there being discussion of project in west of Scotland using freeze dried cryo, involving children from Yorkhill about which Dr Gabra gave evidence to the Inquiry) (h) PRSE0000144 - 30 January 1981 - apologies from Dr Willoughby – first and only time mentioned

[1772] PRSE0003946 (September 1981)

[1773] IBI transcript for 08/12/20; 18 (Professor Hann)

of using US concentrates to try to develop home treatment programme from the late 1970s.[1774] This was also a prophylactic programme which required much mor product than even just a normal home treatment programme. In the statement he said that the commercial packs were much easier than using cryoprecipitate. Whilst this may be true, it places convenience over safety. He does not mention PFC concentrate. Crucially he went on to say in the statement that he idea about viral risks which only started to emerge after he left in 1983. This is simply not true – the increased risks of hepatitis were from foreign products and increased usage were well known, as were the potential consequences of NANBH from 1978 at the latest. In Dr Willoughby's book on paediatric haematology, he recognises the risk of hepatitis in concentrates saying they are not hepatitis free.[1775] As he was often not available for the treatment of patients, Dr Pettigrew often provided the clinical function. She said in her evidence that she and Dr Willoughby had never had a conversation about the relative safety of NHS and commercial concentrates and (b) that was not a matter which he had brought to her attention. She had not seen the World in Action programme.[1776] What that evidence meant, it is submitted, is that it was very unlikely that there could ever have been a conversation with parents about the known increased risks. Dr Willoughby was not aware of that until 1983. Dr Pettigrew was not aware of them at all. In fact, when asked about the relative risks of concentrates and cryoprecipitate, Dr Pettigrew was not aware of the risk of NANBH at all, thinking that the only risk was HBV.[1777] That this was the system which was provided when the parents asked these questions (as they did in their parents group) was a significant and dangerous flaw. Dr Willoughby was a subscriber to the flawed treatment philosophy that concentrates were the only and a necessary treatment. In this regard, he appears to have commented at

---

[1774] PRSE0003454

[1775] PRSE0001500

[1776] IBI transcript for 07/12/20; 40 and 41 (Anna Pettigrew)

[1777] IBI transcript for 07/12/20; 41 (Anna Pettigrew)

the time that concentrates are needed to avoid crippled adults in haemophilia patients.[1778]

4.200 In the statement he accepts they knew that the commercial concentrates were expensive but worth it and that they were ordered via the hospital pharmacy. The hospital also knew about his regime and said nothing. Other haemophilia directors, in particular Forbes knew. They did nothing.

4.201 The advantage of the home-based, prophylactic system was rooted in the lack of facilities and staff in the hospital. Treatment at home meant these did not need to be exposed. The system was easy to sell to parents based on promises of normal lifestyles, which never came. Dr Pettigrew confirmed that convenience was the main factor for them. They could not have known of the risks as the staff were not aware of them.[1779] The system turned a blind eye to this cavalier treatment philosophy which caused unnecessary and avoidable HIV infections, exposed patients unnecessarily to extra viral load and foreign pathogens. It clearly disapproved but did nothing about it. It caused many deaths and untold grief which lives to this day.

4. Aberdeen

4.202 The Inquiry has evidence from patients who received treatment in Aberdeen. The widow of one mild haemophilia A patient told the Inquiry that despite having had a traumatic injury offshore he was treated with cryoprecipitate in Aberdeen in 1977. However, he had already been given a Lister factor VIII concentrate earlier that year for s dental extraction in Sheffield which is likely to have infected him with HCV as these were the only treatment he was ever given. On this occasion, it appears that he was correctly treated to minimise infection in Aberdeen, though he had already been infected elsewhere. The case goes to show that treatment of

---

[1778] PRSE0003946 @ PRSE0003946_006 (September 1980)

[1779] IBI transcript for 07/12/20; 43 - 44 (Anna Pettigrew)

such patients with cryoprecipitate was effective to promote clotting even in case of trauma.[1780] As this patient was never otherwise treated it also shows that treatment could be avoided in mild patients over many years, possibly even completely. As he was working in 1977, he was never treated as a child, for example. His diagnosis was coincidental as his wife was a nurse and had read something which prompted him going to get tested in 1994.[1781] It seems that in Aberdeen though mild patients were treated with cryoprecipitate, they were not followed up for possible infection. This patient never received any more treatment. But for the action on the part of his wife, he may have been lost to follow up and hence never diagnosed. This could have denied him access to treatment and exposed his family to an unnecessary infection risk. This case also alerts the Inquiry to the fact that other mild patients who were infected may never have been located as they did not benefit from the attention of this patient's wife, who worked in the medical profession.

Analysis of the HIV infections in Aberdeen

4.203 The spreadsheet provided to the Penrose Inquiry analysing for the infections in Aberdeen indicated that 8 patients were infected there.[1782] By the time of the final report, this number seems to have been reduced to 3.[1783] At the time of the paginal spreadsheet was produced, there appeared to be some confusion as to whether the figure of 8 is accurate as even the spreadsheet itself seemed to discount some of the listed patients (which may to some extent explain the confusion in the total number of HIV infections in Scotland spoken to in evidence by Professor Ludlam). Inquiry Counsel certainly only appeared to be counting 3 infections in Aberdeen, a proposition with which Professor Ludlam agreed.[1784] The

[1780] WITN1500001 @ paras 5 to 7 (first written statement of Lorna Rusling)
[1781] WITN1500001 @ para 14 (first written statement of Lorna Rusling)
[1782] PRSE0004864
[1783] Penrose final report para 3.829
[1784] Penrose Inquiry transcript for 30/03/11 (day 14); p.58 (Professor Ludlam); [PRSE0006014_0058]

spreadsheet for Aberdeen did not provide the dates of the last negative tests so conclusions about timing are difficult. Dr Cuthbertson indicated in evidence that at least one of the patients in Aberdeen is likely to have been infected with a product which was not part of the "implicated batch".[1785] If this is correct, there must have been at least two breaches of the system responsible for the infections there. The patients identified as Aberdeen infections appear to have been patient A1 to A3 in the original table

4.204 It is far from clear why patients A4, A6 and A7 from the original table produce to the Penrose inquiry were discounted as Aberdeen infections. All tested positive for the first time after treatment in Scotland. Patient A7 was a mild patient who only appears to have been treated only once in Aberdeen (in 1984) with a PFC factor VIII concentrate. If infected in Scotland at that time, this patient ought not to have been infected. It is likely that treatment could have been avoided (as the patient was mild) or that treatment could have been undertaken with cryoprecipitate or DDAVP. If patients A4 and A5 were infected in Scotland they, like patient A7, were infected by PFC factor VIII concentrate.

5. Dundee

4.205 The evidence available to the Inquiry suggests that the Dundee centre was not a proper centre, in the sense of the centres at Edinburgh or Glasgow and was run largely as an adjunct to other facilities.

4.206 The evidence related to the Dundee centre was that there was no real dedicated haemophilia centre operation there until after the period of infections with which this Inquiry is concerned, 1991. It was described as disorganised in the evidence of one witness at the oral sessions who attended as a child. He said that there was no proper director and that products just came from SNBTS, meaning that there can have been no proper advice about treatment regimes, risks and benefits etc.

[1785] PRSE0001396_0002

A conversation about the AIDS risk and possible testing (after all infections in this group had happened in Scotland from domestic products, in 1985) was said to have been a special clinic in the records but was in fact just a normal review.[1786] This appears to have had a number of effects. One was that there was little sophistication in the way that products were selected there, with what one might describe as a self-sufficiency and to an extent old fashioned approach to treatment. This had the result that patients were not treated in accordance with the more progressive treatment regimes which were used (we argue unsafely) elsewhere like home treatment and/ or prophylaxis. The result of this was that patients were treated more at the hospital and had less treatment. One patient recalled being treated predominantly at the hospital with cryoprecipitate.[1787] One severe haemophilia B patient diagnosed in the 1950s was also treated at the hospital when he needed treatment, as his daughter has narrated to the Inquiry.[1788] One of the results of this more limited treatment regime is that there were no HIV infections at the centre. One severe haemophilia A patient was treated with cryoprecipitate during the 1970s and with factor VIII concentrate only in the 1980s, relatively late compared to other parts of the UK where concentrate products were used from the time they began to be licensed in 1973.[1789] The statistical information about product usage in Dundee made available to the Penrose Inquiry was broadly consistent with this evidence. It showed a relatively large amount of cryoprecipitate being used in the centre until 1982 when its used dropped off. Relatively little factor VIII concentrate (all domestic) was used until 1981 when the amount used increased considerably, around 2.5 times between 1980 and 1981. There was a drop off in 1982 (presumably due to supply) and a greater amount used again in 1983.[1790] This shows a trend which broadly mirrors the position in the Edinburgh centre, though slightly delayed by about a year, with a far greater amount of concentrates being used from around 1981. The severe

---

[1786] IBI reference for 09/07/19; 63 to 65 (Graeme Malloch); WITN2091001 @ para 8 (first written statement of WITN2091 – widow of long term haemophilia B patient treated in Dundee)
[1787] WITN2083001 @ para 4 (first written statement of William Barry)
[1788] WITN2087001 @ para 5 (first written statement of WITN2087)
[1789] WITN2086001 @ para 3 (first written statement of Barclay Bisset)
[1790] PRSE0002887_0012 and _0013

haemophilia A patient's treatment history is of interest. He was a severe patient and considered himself to be treated quite frequently – meaning about once a month.[1791] This of course was a comparatively infrequent treatment regime which may go some way to explaining why there were no HIV infections in Dundee. Professor Ludlam's research into those who sero-converted in the Edinburgh cohort and those who did not amongst his patients showed that those who received less treatment were less likely to seroconvert. This was related to the amount of treatment and also (separately) the fact that less treatment meant a lesser likelihood of being exposed to an infected batch. It also goes to show that the amounts of treatment being given to patients elsewhere (like Edinburgh and Yorkhill in particular) over this period was, contrary to the assertions of the clinicians, not necessary. That patient was able to work and reported no adverse haemophilia related concerns.[1792]

4.207 One of the consequences of this regime was that patients, it would appear, were not routinely told about the risks associate with the products they were given. It was suggested to one (now deceased) haemophilia B patient that he might have become aware of the hepatitis risk of the products he was receiving from the Dundee centre as these were listed on the packaging which was provided with the factor IX concentrate which he has given. It is argued elsewhere in this submission that the scant reference to hepatitis risk in products was insufficient to constitute proper informed consent to their use. However, as he, like other Dundee patients, only received treatment at the hospital and not at home he never saw the product packaging or inserts as they were administered by a nurse at the hospital.[1793]

4.208 Another result of this rather unsophisticated regime was that the options for treatment given to some patients appear rather unsophisticated and not sufficiently attuned to the risks of infection. One mild haemophilia A patient was treated only in 1980 and 1991. Though he thought he was likely to have been infected in 1991 this was unlikely as the products which was used (factor VIII) was

---

[1791] WITN2086001 @ para 3 (first written statement of Barclay Bisset)
[1792] WITN2086001 @ para 27 (first written statement of Barclay Bisset)
[1793] WITN2087001 @ para 12 (first written statement of WITN2087)

likely to have been heat treated by that time. The 1980 treatment was with factor VIII for a dental extraction at the age of 18. This treatment should have been with DDAVP or cryoprecipitate which is certain or likely to have avoided the infection.[1794] Another mild vWD patient was infected with HCV in Dundee. He ought not to have been treated with factor concentrates at all as he had no day to day problems with bleeding at all and was only treated for the first time (with factor concentrate) in advance of a hernia operation when he was 9 or 10 in 1984, which in fact also exposed him to a risk of HIV. He was treated with factor VIII and cryoprecipitate at that time and had no bleeding at all. This was unnecessary.[1795] Despite the timing, no information was provided to the patient or his parents about these risks.[1796]

4.209 The evidence available to the Penrose Inquiry suggested that there were no HIV infections in the Dundee[1797] centre, subject to the limitations on the material presented at the oral hearings in that Inquiry by haemophilia clinicians referred to above.

6. Inverness

4.210 The treatment regime in Inverness was a geographically complex one as its catchment area it covered rural communities across a wide area. One severe haemophilia A witness described how he would be treated in a local hospital in GRO-C which meant that he was generally treated with cryoprecipitate in that hospital, though he was affiliated to the Inverness centre. He did not recall receiving information about the risks of products, in particular when he started to be treated at home with factor VIII concentrate in 1980.[1798]

[1794] WITN2290001 @ para 4 (first written statement of WITN2290)
[1795] WITN2175001 @ paras 2 to 3 (first written statement of Ian Joy); WITN2175002
[1796] WITN2175001 @ para 7 (first written statement of Ian Joy)
[1797] PRSE0000768
[1798] WITN2306001 @ paras 3 and 4 (first statement of Hugh MacInnes)

Another patient said that there was no information about viruses provided.[1799] It seems hardly surprising, though no more acceptable, that patients in Inverness received no information about the risks of products when patients in urban centres with more patients and more experienced directors equally provided no such information.

4.211 As far as product usage is concerned, the statistical information available to the Penrose Inquiry suggests that the products used at the Inverness centre were almost exclusively PFC products and almost exclusively factor concentrates.[1800] Very little cryoprecipitate appears to have been used there at all – this would tend to suggest that reverting to cryoprecipitate at times of particular danger would have been likely not to have been considered or even possible, even for children with haemophilia A. There were no HIV infections in Inverness. The products usages show a pattern broadly typical of the national pattern though at lower levels. Very little treatment at all seems to have been used until 1975, with a rise thereafter. In 1980 considerably more factor VIII as used, indicative of a national trend for using more concentrate at around that time in Scotland. In 1982 there was a dip, when the amount of factor VIII used roughly halved. This looks like it was to do with supply issues, as the total returned to more normal levels the year after.[1801] This pattern is consistent with the evidence of one witness who was a very mild patient with a high factor VIII level. GRO-B had been diagnosed as a mild patient and he was diagnosed in 1980 at the age of around 12. The extracts which he presented to the Inquiry from his medical records showed that the clotting investigations which were done for him were done not in Inverness but in Aberdeen (though he as an Inverness patient) and that his care was being delivered from the paediatric department of Raigmore Hospital as opposed to a specialist haemophilia centre. He claims to have been treated with factor VIII concentrates despite the mildness of his condition (his statement also reveals that he was able to be treated with DDAVP as he reacted to it on other occasions[1802]).

[1799] WITN2275001 @ para 14 (first statement of David Thomson)

[1800] PRSE0002887_0028

[1801] Ibid.

[1802] WITN2258001, para 4 (first statement of WITN2258)

GRO-D

7. Elsewhere in Scotland

4.212 The Inquiry heard evidence that treatment for bleeding disorders was also administered by hospitals which were beyond recognised centres. There does not appear to be any evidence that HIV infections were caused there. However, this is not surprising as the evidence derived from evidence presented as part of the annual returns from haemophilia centres to the UKHCDO or as part of the product of those annual returns. Patients would only have been included in those annual returns if they were somehow registered with a centre, though receiving their treatment elsewhere. It is therefore possible that such HIV infections occurred as a result of blood products administered other than as part of a treatment regime supervised by a haemophilia centre.

4.213 In any event, given the use of factor concentrates beyond the haemophilia centres and the likely high infection rates with HCV from those, even on first infusion (whether commercial or domestic), it is likely that significant HCV infection from the use of factor concentrates beyond the recognised centres occurred. Indeed, the Inquiry has available to it evidence of such infection.

8. Conclusions

1803
1804 GRO-D
1805

4.206 In response to the threat of AIDS some haemophilia clinicians in the USA, including the prominent Dr Oscar Ratnoff of Cleveland, advocated that haemophilia patients should suspend the use of concentrates and revert to cryoprecipitate, prepared from pools of ten donors or fewer.[1806] Reversion to cryoprecipitate was also advocated in an editorial in the New England Journal of Medicine as early as 13 January 1983 by Dr Jane Desforges.[1807] She commented that, in view of the results from the Lederman[1808] and Menitove.[1809] She was keen to point out that in light of the threat current modes of treatment would have to be scrutinised. She suggested that, if cryoprecipitate use reduced the risk of haemophilia patients contracting AIDS, the current home treatment programme (using concentrate) needed to be revised. These warnings resulted in no change to home treatment programmes in Scotland or to changes in the use of cryoprecipitate. The specific early US warnings in regard had not been heeded. No changes were made as time went on and further information about the disease became available.

4.214 The system for dealing with emerging viral threats was essentially reactive. As is highlighted in detail above, the polling of large number of blood donations into factor concentrates, as well as their regular treatment with them, made those with bleeding disorders unwitting canaries in the introduction of new viral threats into the NHS, both via products imported from abroad and those produced domestically. The changes in the system of worldwide blood collection and blood production creation noted in the Afterword to revised edition of Douglas Starr's book ""Blood – An Epic History of Medicine and Commerce"[1810] characterised the system becoming less reactive and more proactive as a consequences of the changes to the industry in the aftermath of the disaster. In the UK, the reactive nature of the system was a key element of how the infections were allowed to happen. This has a ripple effect throughout the stem of decision making. By the time those with the power to make decisions found out about the extent of the

---

[1806] Starr, D, Blood page 267, PRSE0003210_0007; Penrose Inquiry transcript for 04/05/11 (day 19); 29 to 30 (Professor Ludlam); [PRSE0006019_0029 and PRSE0006019_0030]
[1807] PRSE0002410
[1808] PRSE0004470
[1809] PRSE0001320
[1810] See PRSE0002303_0002

threat, the infections in the community of those who received blood and blood products had already become widespread, particularly amongst those exposed to factor concentrates. The new system of "hemoviligance" (sic) which Starr identifies as having been instituted internationally in the years after the disaster identify a clear failing of the system with which this Inquiry is concerned. It was well known and understood that blood was dangerous, that concentrates were very dangerous and that haemophiliacs would be the first exposed to any emerging threat. Yet there was no clear system of reporting of the emergence of viral threats or even their emergence in the at risk population. In an area were a precautionary approach was not only justified but essential given the likelihood of transmission of insidious diseases caused by undetectable viruses.

4.215 In fact conclusive proof was the opposite of the precautionary approach which was necessary in light of the known risks of insidious viruses, the inevitability of them coming to light at some point. The patients were unwittingly engaged in a game of Russian roulette in which bullets would inevitably be in the revolver as it was fired in their direction. At one extreme those who received pooled products differed only from those who received transfusions by the fact that as their infections were inevitable, all of the chambers of the revolver aimed at them contained bullets.

4.216 There was plan (b) when the system of concentrate therapy turned out to be dangerous and centrally controlled system of disease surveillance or "haemovigilance" which was rendered necessary by the nature of the treatments. AIDS was seen as an American problem. It was unreasonable, indeed reckless of those with the power to make decisions about the care of those receiving blood and blood products to do so.

E) The treatment of patients with bleeding disorders in Scotland in the period between December 1984 and April 1987 (C3A)

The reasons for separate consideration of this topic

4.217 As is addressed in more detail above, this was a period in which the risks of transmission of what was when known as NANB hepatitis were well understood. In essence, the evidence analysed above makes it clear that:

- It was or should have been known that NANB hepatitis would be transmitted on first infusion of a factor concentrate over this period; and
- There was a significant risk that such infection would lead to serious consequences in the form of a chronic infection with potentially fatal or at least very serious life-limiting sequelae.

4.218 The Inquiry has heard evidence that by December 1984, the PFC had produced for use in the treatment of all haemophilia A patients a factor VIII concentrate (NY) which had been dry heat treated for 2 hours at 68 degrees. This product was subsequently dry heated at that temperature for 24 hours. Though is the PFC's position that this product had not been tested in humans, the evidence that the inquiry has heard was that there was confidence within SNBTS that that product had been treated so as to inactivate HIV, based on international comparisons with the apparent results of that heat treatment regime. A further product was issued for general use in the treatment of haemophilia A patients in April 1987 (Z8) which was dry heated to a temperature of 80 degrees for 72 hours. This was the first product produced at the PFC which claimed to attenuate or eliminate the virus which was thought to be the cause of NANB hepatitis. This is an important period in the treatment of patients with bleeding disorders in Scotland. Infections occurred which would not have occurred elsewhere in Scotland due to the availability from April 1985 of a factor VIII concentrate manufactured at the BPL which did not transmit HCV. The very fact that such significant investment in the viral inactivation of both HIV and NANBH had been made, both at PFC and BPL shows that the severity of these diseases and the urgent need to eradicate them was well understood, despite the fact that the aetiological agent of NANBH would not be discovered until 1988.

4.219 Numbers thought to have been infected over this period were deemed to have been around 21 in number in an investigation undertaken in around 2000.[1811]

The need for very clear internal vigilance for patients unlikely to have been exposed or minimally treated before

4.220 These patients were at risk. Those who were older than a few years old who fall into this category were likely to be mild or moderate patients who had not been treated or had been minimally treated before. These patients are likely not to have been infected with NANB hepatitis due to their lack of or minimal exposure to concentrates or other plasma derived treatments before. Many of them could have been treated with DDAVP. If not, use of cryoprecipitate for their occasional or infrequent bleeds could have been undertaken using cryoprecipitate at significantly less risk.

4.221 This risk also applies to those who were children who suffered from haemophilia A over this period. They would not have been or would have been minimally treated. In accordance with the treatment regime advocated by the UKHCDO and implemented in Scotland post December 1984, they would likely have been treated with cryoprecipitate. They ought to have been and so their exposure to concentrates was unnecessary due to the limited amount of factor VIII content which would be necessary to treat their bleeds. Along with appropriate lifestyle advice, these patients ought not to have been exposed to factor VIII concentrate.

More severe patients

4.222 Given the high infectivity rate of concentrates and the frequency of their use in treatment, it is highly likely that patients who had previously been treated with

[1811] Scottish Executive investigation in 1999/ 2000

factor concentrates would have been infected by the commencement of this period, in particular more severe haemophiliacs who had been multiply so infused due to the severity of their condition. Though the treatment of those patients should have been kept at a minimum over this period to minimise the viral load of the NANBH to which they were being exposed and appropriate counselling should have been offered to them about other lifestyle factors (for example, alcohol consumption, diet, exercise) to minimise the risk of re-infection and/ or liver deterioration, those patients were in a slightly different category from those who were likely to be uninfected, who could be spared from infection at all. In reality the significance of the severity of an individual's bleeding disorder was that it was an indicator of (a) the likelihood that they would already have been exposed to concentrates and therefore already infected with NANB hepatitis (in addition to their ALT test levels)[1812] (b) the amount of the treatment which they might require to achieve haemostasis and (c) the likelihood that they would require to have treatment which might infect them in the future. Equally, those who had not been treated or who had received treatment with products other than concentrates in the past were likely not to have been infected when presenting for treatment over this period. Therefore, such patients deserved special and careful product selection.

4.223 However, as a matter of causation, the Inquiry has also heard evidence that there are multiple genotypes of the hepatitis C virus.[1813] The failure to keep the amount of treatment to which more severe patients were exposed to a minimum (both before and during this period), in fact, increased the chances of these patients being infected with multiple genotypes of the disease. There were "significant differences" in the success rate of treatment depending on the genotype with which a patient is infected[1814]. Thus, infection with multiple genotypes will lessen the likelihood of successful treatment. At Penrose, Professor Thomas recognised the existence of infection of haemophiliacs who were treated around this period (a) with multiple genotypes of the virus (which he described as not uncommon)

[1812] Penrose Inquiry transcript for 13/10/11 (day 54); 37 (4 to 11) (Professor Lowe); [PRSE0006054_0037]
[1813] Penrose Inquiry transcript for 11/10/11 (day 52); from 39 (Professor Thomas); [PRSE0006052_0039]
[1814] Penrose Inquiry transcript for 11/10/11 (day 52); 40 (4 to 9) (Professor Thomas); [PRSE0006052_0040]

and (b) with multiple viruses/ increased viral load (which may have been the case with severe haemophiliacs treated before this period but who continued to be exposed to the hepatitis C virus during it), which would also create a worse prognosis.[1815] Further, the fact of repeated multiple exposure to infected products would reduce the chance of the infection which one received being one which would not progress to the chronic phase of the disease based on the likelihood of constant re-infection by multiple exposures.[1816] Haemophilia patients have tended, therefore, to be infected with genotype 1 hepatitis C[1817] which was less susceptible than genotypes 2 or 3 (the other genotypes prevalent in the UK population) to treatment[1818]. According to Professor Thomas, the level of viraemia increases the likelihood of rapid progression of the disease to the irreversible cirrhotic phase. Haemophilia patients exposed regularly to infected products would, therefore, be more likely to progress to the worse stages of the disease.[1819]

4.224 This is not something which could have been appreciated until knowledge emerged about (a) the existence of different genotypes and (b) the varying responses of the different genotypes to treatment, in particular in the case of multiply infected patients. Knowledge about genotypes emerged only gradually from the end of the 1980s[1820], by which time factor concentrates were already heat treated to inactivate the hepatitis C virus. Professor Thomas informed the Penrose Inquiry that there would not have been knowledge about genotypes until around 1991.[1821] However, as matter of fact, the continued exposure of even the most severe patients to their previous treatment regimes over this period and indeed before increased the risk that treatment would be unsuccessful for more severe patients as it made their infections worse. Like the infection of the minimally treated patients in Scotland over this period, this additional viral insult,

---

[1815] Penrose Inquiry transcript for 11/10/11 (day 52); 60 to 61 and 84 (11 to 13) (Professor Thomas); [PRSE0006052_0060 to 0061; 0084]
[1816] Penrose Inquiry transcript for 11/10/11 (day 52); 82 (20 to 23) (Professor Thomas); [PRSE0006052_0082]
[1817] Penrose Inquiry transcript for 11/10/11 (day 52); 49 (4 to 6) (Professor Thomas); [PRSE0006052_0049]
[1818] Penrose Inquiry transcript for 11/10/11 (day 52); 40 (4 to 9) (Professor Thomas); [PRSE0006052_0040]
[1819] Penrose Inquiry transcript for 11/10/11 (day 52); 58 to 59 (Professor Thomas); [PRSE0006052_0058 to 0059]
[1820] Penrose Inquiry transcript for 11/10/11 (day 52); 36 (10) and 39 (5 to 8) (Professor Thomas); [PRSE0006052_0036; 0039]
[1821] Penrose Inquiry transcript for 12/10/11 (day 53); 64 (24 to 25) (Professor Thomas); [PRSE0006053_0064]

exposure to multiple genotypes and consequent lower chance of the success of treatment are phenomena which are uniquely Scottish in nature in the sense that they were not consequences suffered by those treated with concentrates produced domestically at BPL over this period.

Treatment choice for the most at risk patients

4.225 The choice of treatment for a patient will inevitably depend to a certain extent on the severity of the bleeding incident for which the treatment is being administered. The requirement to stop the bleeding requires, however, to be considered in the balance with other factors in the selection of treatment. However, in response to questioning about the position where there would require to be greater weight placed on the urgency of the procedure for which the coagulopathy was being administered, in his Penrose evidence Professor Thomas restricted his answer to referring to the most severe types of surgery, where very good coagulopathy would be needed such as major brain surgery or liver surgery.[1822] Patients who had received no or minimal theory should have been advised (where a diagnosis had been made) of the need to avoid serious bleeds by avoiding risky activities over this period. There is no evidence that they were.

4.226 The size of the patient was also a relevant factor in product choice. There is evidence that at one stage Professor Ludlam counselled against the abandonment of cryoprecipitate specifically on the basis that it required to be used in the treatment of small children. This proposal was agreed to by Professor Hann, who was the director at Yorkhill at that time.[1823] They required less factor VIII to achieve haemostasis and so cryoprecipitate was a more acceptable choice for therapeutic and risk minimisation considerations.

4.227 Further, for both of the most at risk sets of untreated or minimally treated patients, any limitation of their exposure to factor VIII concentrate would have

[1822] Penrose Inquiry transcript for 11/10/11 (day 52); 161 (15 to 20) (Professor Thomas); [PRSE0006052_0161]
[1823] PRSE0001556_0002 (2 February 1984)

been likely to have been temporary only. The increasing evidence of the success in the viral inactivation of 8Y emerging from the clinical trial which was ongoing over this period and the consequent likelihood that the PFC would in time be able to develop a similarly safe factor VIII concentrate for use in Scotland should have given reassurance that the avoidance of factor concentrates would only require to be temporary. The priority should have been to avoid elective surgery and minimise exposure to donors for what was likely only to be a relatively limited period of time. The risk of spontaneous bleeding in moderate or mild patients was small in any event. The risk of spontaneous bleeding in young, previously untreated or minimally treated patients (even of severe) must also have been, given the preference for the use of cryoprecipitate in their treatment anyway. For both minimally treated or untreated at risk groups, a clear explanation of the treatment alternatives, their risks and benefits was necessary, in particular due to the limited amount of previous experience which milder patients or the parents of young children would have had previously with the haemophilia services and the significant risks of viral exposure through treatment with factor VIII concentrate.

4.228 The evidence shows that there was no system, or at least no effective system in place for the identification and separately protection of these untreated or minimally treated patients or at least that any such system was not adequately enforced. No patients should have been infected over this period.

The background to this period

4.229 By December 1984 a factor VIII concentrate made by SNBTS at the PFC for the general use of haemophilia A patients in Scotland was available. The circumstances in which that became available for general use are examined in more detail elsewhere in this submission. Again, as examined elsewhere, patients were told that the causative agent of AIDS had been eradicated from the product. A factor IX concentrate which could tolerate treatment to a higher heat for longer had emerged by October 1985 in Scotland. The factor VIII produced at the PFC

over this period (NY) was not heated to that higher level. A new product which was so heated was not generally available for use until April 1987 (Z8). As is examined in detail above, it had been known since at least the time of the paper by Fletcher et al in 1983 that all concentrates produced abroad or domestically were likely to transmit NANBH on first infusion. Until April 1987, there was no reason to depart from this safe assumption being made about the likely consequences of any first infusion with NANBH.

4.230 As was accepted in his evidence to the Penrose Inquiry by Professor Ludlam, the general guiding principle over this period was (or should have been) to avoid treatment unless it was unavoidable.[1824] Given that patients were treated and infected over this period, the question become how this happened if this was the guiding principle, as it rightly should have been.

The identification and diagnosis of new patients

4.231 Previously untreated or minimally treated patients were of significant value to the medical community for research purposes, as is examined in more detail elsewhere in this submission. The value of identifying such patients for those purposes was long-established. At this point in the period over which patients were being treated in Scotland, it was important that effective systems were developed for the identification and diagnosis of such patients, given the need for careful choices to be made about the treatment which was in their best interests, in light of the likelihood that any first infusion with concentrate would be likely to infect them with a potentially fatal liver disease.

4.232 Patients who had never before received treatment were most likely to be mild patients who had had little experience of bleeding episodes in the past or children whose condition might be more severe but who had not yet been diagnosed, perhaps as a result of there being no family history. In his evidence to the Penrose

[1824] Penrose Inquiry transcript for 13/10/11 (day 54); 74 (20 to 25) (Professor Ludlam); [PRSE0006054_0074]

Inquiry, Professor Lowe (who became a consultant in the department around the start of this period, in 1985, though had had experience working in it before then) spoke of the system at the GRI over this period whereby newly diagnosed patients with mild haemophilia would be tested for their response to DDAVP and, as most had the predictable (favourable) response, they would be told that this was the treatment which would be used for them.[1825] He accepted that at the GRI there was quite a large group of patients with mild haemophilia.[1826] This evidence demonstrated the reality of treatment for such patients – that it would normally be able to be undertaken with DDAVP which should always have been the front line treatment when such patients required it.

4.233 However, that system assumed that the patient had made it to the haemophilia ward. Professor Lowe accepted the importance of establishing what the reason for the bleeding was and the nature of the deficiency before any treatment decision could be taken.[1827] In his evidence to the Penrose Inquiry, Professor Ludlam stated that the haemophilia department would do quite a lot of clotting screens for patients who had presented to the accident and emergency department with a haemorrhage.[1828] One would require to make a diagnosis before any treatment could be administered.[1829] There was this a step before the patient benefitted from the care regimes in the specialist haemophilia ward via which such a patient, not yet treated and so as yet undiagnosed, may well present. Given the risks of infection for such patients with a potentially fatal disease if not treated correctly and safely as Professor Lowe's DDAVP regime was designed to achieve), a clear system was mandated to ensure that those involved in primary care linking the presentation, such as a haemorrhage with a possible diagnosis of haemophilia and reacting properly by seeking a clotting screen and the intervention of the specialists.

[1825] Penrose Inquiry transcript for 13/10/11 (day 54); 24 (14 to 24) (Professor Lowe); [PRSE0006054_0024]
[1826] Penrose Inquiry transcript for 13/10/11 (day 54); 25 (8 to 10) (Professor Lowe); [PRSE0006054_0025]
[1827] Penrose Inquiry transcript for 13/10/11 (day 54); 61 (20) to 62(16) (Professor Lowe); [PRSE0006054_0061 to 0062]
[1828] Penrose Inquiry transcript for 14/10/11 (day 55); 69(1 to 3) (Professor Ludlam); [PRSE0006055_0069]
[1829] Penrose Inquiry transcript for 14/10/11 (day 55); 70(9 to 10) (Professor Ludlam); [PRSE0006055_0070]

4.234 Professor Ludlam was asked detailed questions about the system in place in Edinburgh for patients who may have failed into these at risk categories and presented to the hospital through accident and emergency, as opposed to at the haemophilia centre. It was likely that undiagnosed patients would present this way as they would have no reason to attend the centre. The evidence he gave in this regard was confused and unreliable. At one stage he claimed that that, in Edinburgh at least, there existed at this time a non-written system for how patients presenting in the accident emergency department for treatment for a bleed should be managed. Subsequent to this period, according to him, a written protocol of this nature was produced.[1830] He then corrected himself and suggested that there was indeed at this time some written form of guidance for accident and emergency staff as to how to deal with patients presenting with potential haemophilia[1831] There is no evidence of any such written protocol at all, either in this period or subsequently, at the RIE or at any other Scottish hospital. It is submitted that no such system existed or at least that it was inadequate. As is noted below, Mr Wight's first attendance at the casualty department in 1986 did not result in any such referral. No history of his potential bleeding problems in the past was elicited. Professor Ludlam also thought that an A&E doctor would have a "low threshold" for sending the blood off for a clotting test.[1832] That they would think to do that in response to unexplained bruising would simply have been part of their general medical education (and not any specific written or unwritten system), in his view.[1833] The case of Mr Wright shows that this was clearly not a system which functioned well in his hospital. Reliance on general medical education to ensure that such patients were indeed identified, properly diagnosed and taken into the haemophilia care system was insufficient. Even before a patient presented to the hospital, there is no evidence available to the Inquiry that any system existed in GP primary care whereby these patients might have been

---

[1830] Penrose Inquiry transcript for 14/10/11 (day 55); 81 (Professor Ludlam); [PRSE0006055_0081]
[1831] Penrose Inquiry transcript for 14/10/11 (day 55); 86 (Professor Ludlam); [PRSE0006055_0086]
[1832] Penrose Inquiry transcript for 14/10/11 (day 55); 74(6 to 8) (Professor Ludlam); [PRSE0006055_0074]
[1833] Penrose Inquiry transcript for 14/10/11 (day 55); 75(25) to 76(3) (Professor Ludlam); [PRSE0006055_0075 to 0076]

identified. It was entirely predictable that a previously untreated patient may well have presented in the first instance at accident and emergency or at his GP, as was the case with Mr Wright (see below).

4.235 Even within the haemophilia department of the day, it was necessary for all staff to have a clear understanding of systems in place to identify and protect at risk patients. As is identified above, the directors (in particular the reference centre directors in Glasgow and Edinburgh centres) were or should have been privy to all of the latest information which necessitated such systems being put in place. Information needed to be disseminated and the systems to minimise risk devised, the details of them promulgated and understood and those systems observed and enforced. The infections of patients over this period indicate either that such systems were not in place or that they were not properly observed. Either way the centres failed these patients.

4.236 Professor Ludlam was questioned about the system he had put in place in Edinburgh to deal with these risks in detail at the Penrose Inquiry. He was unable to explain when questioned on the subject what systems existed for the vertical dissemination to his staff of guidance such as that emanating from the UKHCDO on treatment.[1834] No written material was made available suggesting that any such information relating to the risks over this period was disseminated to the staff or that any such preventative system existed. In the case of previously untreated patients, Professor Ludlam suggested that he would almost certainly have been contacted by more junior members of staff.[1835] When asked as to how junior doctors knew to contact him in these circumstances, he could not point to any clear method by which this system was communicated to them.[1836] There was no written document to which Professor Ludlam could point which made it clear to staff members that in situations where virgin or minimally treated patients (ie the most at risk patients) presented for treatment at the RIE over this period, the protocol was to contact the consultant, who was best placed to make the most

---

[1834] Penrose Inquiry transcript for 14/10/11 (day 55); 45 to 47 (Professor Ludlam); [PRSE0006055_0045 to 0047]

[1835] Penrose Inquiry transcript for 14/10/11 (day 55); 51(1) (Professor Ludlam); [PRSE0006055_0051]

[1836] Penrose Inquiry transcript for 14/10/11 (day 55); 51 to 52 (Professor Ludlam); [PRSE0006055_0051 to 0052]

informed treatment decisions. Whilst on the one hand suggesting that the consultant could not be too prescriptive in his guidance given junior staff, he also suggested in his evidence that it would have been useful for the CMO to have provided some guidance to him.[1837] This was a characteristic attempt on the part of Professor Ludlam at self-exoneration. In this instance, the CMO's advice could only have been in general terms. Professor Ludlam had already claimed that his general thinking at the time was to avoid treatment unless it was unavoidable. He was the director who required to instigate a suitable system for him to become involved in the important treatment decisions relating and advice given to such patients about it. No such system existed, as is clearly demonstrated by the failures in the case of Mr Wright, analysed below. If this is not accurate, any system was inadequate and did not protect these patients. It should also be noted that despite the detailed analysis of the systems over this period in the Penrose Inquiry, there was equally no written or oral evidence to support there having been any consideration of or system for the minimisation of exposure of more severe patients, which it is submitted above were also necessary over this period.

4.237 The objective of getting the person with the most experience and knowledge of the risks to such patients and the most likely chance of selecting the most appropriate treatment was, in theory, the appropriate one for virgin and minimally treated patients over this period. There is no evidence of any such system or any effective system existing anywhere in haemophilia care Scotland over this period. Professor Thomas pointed out at Penrose that information would be exchanged between haemophilia centre directors around a year before it would be published in a journal.[1838] This, in our submission, would place an even greater requirement within haemophilia centres for the directors (who may have been privy to current information which more junior members of staff do not have) to make themselves available to make treatment decisions about the most at risk patients.

[1837] Penrose Inquiry transcript for 14/10/11 (day 55); 126(7 to 8) (Professor Ludlam); [PRSE0006055_0126]
[1838] Penrose Inquiry transcript for 11/10/11 (day 52); 94 (9 to 14) (Professor Thomas); [PRSE0006052_0094]

Alternative treatment regimes for cases of clear clinical need

4.238 Patients ought to have been treated with DDAVP or cryoprecipitate which, in particular after the screening of blood for HIV from October 1985 had the indirect effect of eliminating donations containing HIV, would not have resulted in infections or at least would have materially decreased the risk of them occurring. Even before that time, there had been no evidence (and indeed there is none now) of HIV having been transmitted through the use of cryoprecipitate in Scotland. The fact that cryoprecipitate could not be heat treated whereas NY had been was therefore, not a material reason why a concentrate should be preferred over cryoprecipitate at any time over this period, given the certainty that the concentrate would be infective for NANBH, a potentially fatal disease.

4.239 Patients were identified as at risk in studies identified in the knowledge of risk section above which recommended that that factor concentrate exposure should be avoided from the 1970s and into the 1980s. The reason why certain groups of patients were singled out by these studies was a combination of (a) the increasing awareness of both the likelihood of transmission of NANB hepatitis and the possibility of that infection leading to serious, chronic disease and possibly death and (b) the consequent need for a re-consideration of the benefits of treatment with concentrates, in particular in less severely afflicted haemophiliacs, whose conditions would not make the assumption that treatment with concentrates would at some point be necessary a safe one. These patients needed to be protected all the more in the period after December 1984. The likelihood that they required treatment remained low. The avoidability of concentrates therefore remained an option. The likelihood that such patients could benefit from advanced technological progress in the field of heat treatment meant that their avoidance of concentrates would, in all likelihood, only be temporary, lasting until a safe product became available in early course.

4.240 Dr Rosemary Biggs, the director of the Oxford Haemophilia Centre, published the 2nd edition of "The Treatment of Haemophilia A and B and von Willebrand's

Disease" in 1978.[1839] Even at this time, it had been suggested that, due to the hepatitis risk, mildly affected patients who had never or rarely been transfused should not receive large pool commercial concentrates. Instead, they should be given cryoprecipitate or small pool concentrates. By October 1980, in his paper entitled "The epidemiology of factor VII and IX associated hepatitis in the UK"[1840] Dr Craske advised that small pool concentrates or cryoprecipitate should be considered for patients with mild coagulation defects until testing was available for the NANB virus where they require treatment cover for surgery only. This was on the basis that ran a high risk of contracting transfusion hepatitis if exposed to concentrates for the first time.[1841]

4.241 At the time of the AIDS crisis, the use of small pool products to minimise the risk for mildly infected/untreated patients was clearly recommended to minimise the risk of exposure. In a letter from Professor Bloom and Dr Rizza to Professor Ludlam dated 24 June 1983, it was recommended (a) that DDAVP should be considered for mild patients with haemophilia A or vWD (this was the practice of many directors at this time anyway due to the risk of hepatitis from large pool concentrates) and (b) that it would be circumspect to reserve stocks of NHS products (cryoprecipitate or freeze dried) for children, mildly infected patients or unexposed patients as a result of the discussions at the Reference Centre directors meeting on 13 May 1983.[1842] The minimisation of the risk of viral transmission by not exposing probably uninfected patients to concentrates was, therefore, a recommendation at the time of the AIDS crisis. It would appear that this may have been forgotten about when the HIV crisis was over after HIV-safe factor VIII concentrate arrived. The principles being proposed here apply equally to the prevention of HCV as HIV.

4.242 It has been suggested in evidence heard by the Inquiry that treatment with cryoprecipitate over this period may have resulted in infection with NANBH in these high-risk groups anyway. This is a peculiar argument as it proceeds on the

---

[1839] Penrose Inquiry preliminary report, para 6.62
[1840] PRSE0003209
[1841] Penrose inquiry reference DHF.003.0656
[1842] PRSE0000835

basis that even the safer products provided by the NHS in Scotland were unsafe. In any event, it is not borne out by the evidence. An article written by Ludlam et al about antibody positivity of bleeding disorder patients in his care revealed that 85% of those patients who had been treated with non-heated factor concentrates were HCV antibody positive.[1843] It was assumed that they would be and was not known why the infection rate was not higher. The 6 patients who had been treated with cryoprecipitate only were all antibody negative.

4.243 In an article from 1985 submitted by Professor Thomas and others in June 1984, it was observed that "the absence of hepatitis amongst our cryoprecipitate treated patients probably reflects their relatively low exposure as none received more than 70 donor units."[1844] Professor Thomas gave evidence about this article to the Penrose Inquiry to the effect that patients who required relatively small amounts (such as mild patients and children) could avoid infection if treated with cryoprecipitate.[1845] He gave evidence to the effect that cryoprecipitate was relatively safe in terms of its likelihood to transmit NANB hepatitis given the relatively small numbers of donors per batch. It was for this reason even in the early years of the 1980s according to Professor Thomas, that infants would be "first up with a call on cryo".[1846] In the study, none of the patients who had been treated with cryoprecipitate only were infected with NANB hepatitis[1847]. Against this, in the conclusions of the paper, it was pointed out that "Whether prepared from volunteer or commercial donor plasma, clotting factor concentrates carry a very high risk of acute NANB hepatitis in first exposure recipients".[1848] The material in this Thomas and Kernoff study constitutes contemporaneous evidence of the strong likelihood that patients who would be likely to require low doses of cryoprecipitate, such as mild patients or infants, would have a good chance of avoiding infection with NANB hepatitis. In his evidence, Professor Thomas

---

[1843] WITN6914068 (September 1989)
[1844] PRSE0003439
[1845] Penrose Inquiry transcript for 11/10/11 (day 52); (Professor Thomas); [PRSE0006052]
[1846] Penrose Inquiry transcript for 11/10/11 (day 52); 99 (21) to 100 (2) (Professor Thomas); [PRSE0006052_0099 to 0100]
[1847] PRSE0003439
[1848] PRSE0003439_0009

expressed the view that in the period between 1985 and 1987 cryoprecipitate would be "a way forward" for mild patients based on this evidence that it did not have a high risk of transmitting NANB hepatitis[1849] (the risk of HIV from cryoprecipitate is addressed below).

4.244 In an article entitled " A prospective study of cryoprecipitate administration: absence of evidence of virus infection" by Colvin & Ors (Clinical and Laboratory Haematology, 2 October 1986) looked at NANBH infection rates amongst the recipients of cryoprecipitate.[1850] 6 patients previously untreated with concentrates were treated with cryoprecipitate tested for a year and no signs of hepatitis developed. The article observed that "until the recent epidemic of AIDS, cryoprecipitate was widely used as the safest form of treatment for patients with mild coagulation defects who were unsuitable for DDAVP injection". It recommended that following the screening of blood donors for HIV in October 1985, the use of cryoprecipitate in selected cases should be reconsidered. The study was carried out between October 1982 and July 1984. By the time it was published (in 1986) Professor Colvin indicated at Penrose that the world had really moved on[1851] but this was really because of the apparent success of viral inactivation making concentrates more attractive. He was of course speaking from an English perspective.[1852] At the time when this data was collected (prior to the availability of heat-treated concentrates which were NANBH safe in Scotland) it demonstrated the genuine advantages of cryoprecipitate from the point of view of NANBH infection.

4.245 In practice, the system had rather removed the ready availability of cryoprecipitate by this stage. The product should still have been available and would have been required only in relatively small quantities for the treatment of the most at risk (ie probably uninfected) patients. By February 1986, Professor Cash commented in a paper designed to help for future planning for the needs of blood and blood products by SNBTS that over the previous few years “it is probable

---

[1849] Penrose Inquiry transcript for 11/10/11 (day 52); 156 (4 to 7) (Professor Thomas); [PRSE0006052_0156]
[1850] PRSE0003838
[1851] Penrose Inquiry transcript for 14/10/11 (day 55); 136 (22 to 25) (Professor Colvin); [PRSE0006055_0136]
[1852] Penrose Inquiry transcript for 14/10/11 (day 55); 137 (13 to 15) (Professor Colvin); [PRSE0006055_0137]

that a substantial proportion of the issued cryo was not used in the management of haemophilia A patients".[1853] Professor Ludlam gave evidence to the effect that cryoprecipitate started to be used less in the period between 1984 and 1988. This was partly, at least, due to the greater number of patients on home treatment.[1854] This would seem to imply that considerations of safety required to be subordinated to considerations of practicality. Cryoprecipitate had fallen out of favour. It should not have done given its clear advantages in terms of viral transmission for these at risk patients. At Penrose, Professor Lowe expressed the view in his evidence that faced with a mild patient who had a bleed that was not stopping post October 1985, he would have preferred cryoprecipitate over a concentrate.[1855] As noted above, DDAVP should have been the first line treatment in Glasgow for such patients.

4.246 The likely infectivity of cryoprecipitate with other diseases merits some consideration as the available NY concentrate was safe from HIV. Professor Thomas expressed the view in his evidence to the Penrose Inquiry that it was known that it was improbable that cryoprecipitate would transmit HIV due to its low frequency within the population.[1856] Further, by the second half of the 1980s, he was of the view that it was known that there were no cases of HIV occurring or having occurred from cryoprecipitate.[1857] He considered the risk of HIV from cryoprecipitate prepared from plasma where the gay community had been excluded as donors to be negligible.[1858] We would submit that the safety of cryoprecipitate as far as HIV was concerned must have increased even further (to the point of a non-existent risk) from the point where blood used in its preparation was screened for anti-HIV in October 1985. Professor Thomas accepted that for patients at the mild end of the spectrum, cryoprecipitate would be the treatment of choice.[1859] Though Professor Thomas responsibly qualified his answer by

---

[1853] PRSE0004139_0003
[1854] Penrose Inquiry transcript for 13/10/11 (day 54); 141 (5 to 11) (Professor Ludlam); [PRSE0006054_0141]
[1855] Penrose Inquiry transcript for 13/10/11 (day 54); 30 (4 to 6) (Professor Lowe); [PRSE0006054_0030]
[1856] Penrose Inquiry transcript for 11/10/11 (day 52); 100 (2 to 6) (Professor Thomas); [PRSE0006052_0100]
[1857] Penrose Inquiry transcript for 11/10/11 (day 52); 156 (8) (Professor Thomas); [PRSE0006052_0156]
[1858] Penrose Inquiry transcript for 11/10/11 (day 52); 156 (25) to 157 (7) (Professor Thomas); [PRSE0006052_0156 to 0157]
[1859] Penrose Inquiry transcript for 11/10/11 (day 52); 159 (8 to 10) (Professor Thomas); [PRSE0006052_0159]

pointing out that he is not a haemophilia clinician, he clearly, in our view, demonstrated throughout his evidence a deep knowledge of haemophilia care through his contact with patients with bleeding disorders in the preparation of his research, his experience on general medicine and contact with haemophilia clinicians like Dr Kernoff, with whom he co-authored the paper referred to above.

GRI

4.247 In his Penrose evidence Professor Lowe stated that the policy in Glasgow over this period continued to be that moderately severe haemophilia A patients or vWd sufferers who had not previously been treated or received "very minimal" previous treatment would be treated with cryoprecipitate due to the pool size of around 20, rather than thousands of donors.[1860] As far as mild patients were concerned, the treatment of choice for mild patients at this time in Glasgow was DDAVP and that, even in unplanned treatment, most of the time DDAVP would be effective.[1861] The evidence available to the Inquiry shows that despite this, patients were treated with concentrates in Glasgow over this period. Professor Lowe stated you discuss having tried to procure such a supply of 8Y in 1988.[1862] He was unaware that that such a supply for such patients was made available to Scotland in 1986 as it had not been publicised to beyond Edinburgh.

<u>Conclusion about available treatment alternatives over this period</u>

[1860] Penrose Inquiry transcript for 13/10/11 (day 54); 12 (16) to 13 (7) (Professor Lowe); [PRSE0006054_0012 to _0013]

[1861] Penrose Inquiry transcript for 13/10/11 (day 54); 24 (14 to 24) and 25 (23) (Professor Lowe); [PRSE0006054_0024 to _0025]

[1862] WITN3486013 in answer to question 39

4.248 Minimally treated patients included those who had received treatment in the past for their bleeding disorder, but not with factor concentrates or with large volumes of cryoprecipitate. They were likely to be uninfected at the start of this period. The treatment of virgin and minimally treated patients over this period merited special consideration by treating doctors on the basis that (a) the state of knowledge was such that it was highly likely if not certain that they would be infected with a potentially lethal disease if treated with the then available Scottish factor VIII concentrate (NY) on first infusion and (b) it was probable that such patients would not yet be infected with that disease. The then available Scottish factor VIII concentrate (NY) should not have been given to virgin or minimally treated patients unless it was unavoidable over this period. [1863]

4.249 The priority in the treatment of bleeding episodes in such patients should have been to try to achieve haemostasis with other treatments which carried less of a risk of transmission of NANB hepatitis, such as DDAVP (for mild patients) or cryoprecipitate or alternative products sourced outside Scotland (see below) [1864] before resorting to the use of the inevitably infective SNBTS factor VIII concentrate.

4.250 As far as the use of cryoprecipitate is concerned, it has been claimed that it too could have become infective of used in sufficient quantities. That assertion is epidemiologically self-evident. If patients were infected with HCV by blood transfusion (as of course they were), perhaps as a result of exposure to a single unit of blood, clearly cryoprecipitate also had the potential to be infective. However, the use of this less risky product would have minimised the risk. The use of concentrates for the treatment these patients over this period unnecessarily increased the risk of infecting bleeding disorder patients with a potentially fatal disease. Furthermore, there is the evidence of the Thomas paper detailed above in which everyone treated with only cryoprecipitate avoided infection. All got less than 70 units.

[1863] Penrose Inquiry transcript for 13/10/11 (day 54); 19 (20) (Professor Lowe); [PRSE0006054_0019]

[1864] The concept that the correct approach was to try less risky treatments first was accepted in the context of a discussion about DDAVP with Professor Lowe - Penrose Inquiry transcript for 13/10/11 (day 54); 73 (2 to 6) (Professor Lowe); [PRSE0006054_0073]

4.251 Dr Hay provided a report to the Penrose Inquiry suggesting that an uninfected patient might have been likely to become infected after an infusion of around 100 units of cryoprecipitate anyway.[1865] Dr Hay was of course purporting to give evidence to that inquiry in an expert capacity but his views were far from independent, as is explored elsewhere in this submission. In his evidence at Penrose, Professor Lowe stated that each bag of cryoprecipitate was from a single donor but one required to pool together 20 bags for the average adult.[1866] Professor Ludlam told the Inquiry that the average adult dose was from 20 donors.[1867] The amount of product which would be required would vary from case to case. Untreated children would have required less due to their size. Professor Ludlam expressed the view in evidence that one would be infected with NANB hepatitis after exposure to between 100 to 200 donors based on an incidence of around 1 percent.[1868] On this basis it would take 5 days of treatment to become infected.[1869]

4.252 There will be likely to be emergency clinical situations in which the infusion of a concentrate is clinically unavoidable. If the assertions made by these clinicians are accurate (and they were mere assertions made by non-independent witnesses) situations may arise where even the administration of cryoprecipitate in sufficient quantities would have resulted in infection with NANB hepatitis. However, such situations would require a sufficient amount of that product to have been administered for the value of the small pool production system to be lost and the likelihood to become that the patient would be infected. Given that virgin and minimally treated patients would be likely to be at the milder end of the haemophiliac population and consequently have higher resting factor VIII levels, it would be likely, in our submission, that they would require lesser amounts of cryoprecipitate than others to achieve haemostasis, if DDAVP had not worked. Evidence was given by Professor Lowe to the effect that the objective in the

---

[1865] PRSE0003616_0022/ 0023
[1866] Penrose Inquiry transcript for 13/10/11 (day 54); 65 (18 to 19) (Professor Lowe); [PRSE0006054_0065]
[1867] Penrose Inquiry transcript for 13/10/11 (day 54); 136 (8) (Professor Ludlam); [PRSE0006054_0136]
[1868] Penrose Inquiry transcript for 13/10/11 (day 54); 133 (5 to 7) (Professor Ludlam); [PRSE0006054_0133]
[1869] Penrose Inquiry transcript for 13/10/11 (day 54); 136 (10 to 14) (Professor Ludlam); [PRSE0006054_0136]

administration of treatment would be to get the levels up to "30, 40, 50 per cent which is approaching the levels required to achieve normal haemostasis".[1870] This would be more readily achievable, the higher the resting factor level. Other virgin patients are likely to include children, for whom smaller amounts of product would be likely to be required to achieve haemostasis anyway. Thus, a significant number of infections could and should have been avoided over this period.

4.253 As had been the consequence of the treatment of all patients over years before this, the consequence of the excessive treatment regimes had been to expose to unnecessary viral load and genotypes which worsened their disease and lessened their chances of successful treatment. In this period those treatments were known to be virally infectious with a potentially fatal disease. They ought to have been thought to pose a risk of these consequences.

4.254 As is noted above, Professor Lowe gave evidence to both this Inquiry and the Penrose Inquiry about the fact that there was a large cohort of mild patients in the adult centre in Glasgow etc. He gave evidence to the Penrose Inquiry to the effect that the policy at the GRI over this period continued to be that moderately severe haemophilia A patients or vWd sufferers who had not previously been treated or received "very minimal" previous treatment would be treated with cryoprecipitate due to the pool size of around 20, rather than thousands of donors.[1871] There appears to have been a plan at least which recognised the difference between those who were unlikely to have been infected previously and those who were likely to have been infected. As far as mild patients were concerned, he then gave evidence to the effect that the treatment of choice for mild patients at this time at the GRI was DDAVP and that, even in unplanned treatment, most of the time DDAVP would be effective.[1872] Professor Ludlam had given that when bleeding mild patients were usually in the most distress, given their inexperience of dealing with bleeds. Tt seems that despite this, such a standard instruction to use DDAVP,

---

[1870] Penrose Inquiry transcript for 13/10/11 (day 54); 26 (12 to 14) (Professor Lowe); [PRSE0006054_0026]
[1871] Penrose Inquiry transcript for 13/10/11 (day 54); 12 (16) to 13 (7) (Professor Lowe); [PRSE0006054_0012 to 0013]
[1872] Penrose Inquiry transcript for 13/10/11 (day 54); 24 (14 to 24) and 25 (23) (Professor Lowe); [PRSE0006054_0024; 0025]

if implemented carefully, would have been effective most of the time.[1873] The statistics referred to below for the west of Scotland certainly suggest that patients were treated for the first time with products other than DDAVP over this period. No information proving DDAVP use in these patients has been provided to support the effectiveness so this system. It should be noted that those statistics only relate to patients treated for the first time. Amongst this cohort of mild patients could have been patients who had been treated (and are therefore not in the list) but who did receive non-DDAVP treatment.

4.255 There is no evidence of any such consideration being given to patients who were les likely to be infected already (be they mild or moderate, minimally or untreated previously) and their possible treatment in any of the other haemophilia centres. Further, there is no evidence also to suggest that any system existed to promote the identification of patients who may present for treatment other than at the centre. Though is applies to all centres, whose remits extended well beyond the walls of the hospitals in which they were based, it is particularly acute for Glasgow (which had a large catchment area) as well as Yorkhill, which covered the same area for children. The focus on treatment at the centre rather missed the point for these at risk patients. They were far more likely to present at local hospitals or GPs with possible bleeding problems, wither because they were undiagnosed or because as mild or even moderate diagnosed patients they did not have regular contact with the centre. There was a need for the centres to consider these patients (which it appears they did not) and promulgate advice to the places. As there appears to have been evidence of a culture of reaching for a concentrate for treatment of bleeding disorders even within the centres, it would be reasonable to infer that this culture existed elsewhere as well. This is precisely the culture which needed to be stopped, in the interests of these patients. There is no evidence at all that it was. If patients were being infected unnecessarily over this period at the expert centres, it is reasonable to assume that they were afforded no suitable protection at non-expert medical facilities around the country.

[1873] Penrose Inquiry transcript for 03/05/11 (day 18); 53 (5 to 25) (Professor Ludlam); [PRSE0006018_0053]

The infection of Mr Wright

4.256 The infection of Mr Wright (WITN2287) is an example of a case which needs to be examined closely in order that the Inquiry can understand properly the systemic failings which undermined the safety of patients like him over this important period in Scotland. He suffered a thigh bleed in May 1986. He was a previously untreated patient, though he had had investigations into a possible bleeding condition when he was a young adult. No member of the haemophilia department was contacted on his first visit to the casualty department at the RIE with an ongoing bleed at the beginning of May 1986. This was despite the fact that his GP had postulated a diagnosis haemophilia on his initial assessment. No history of Mr Wright's previous investigations for a bleeding disorder was elicited. Further, on his admission on the night of 13 May 1986 (when he was infused with a factor VIII concentrate) he was treated by doctors within the haemophilia department. No consultant was involved in his treatment, despite the fact that he was an untreated patient. He was infused with factor VIII concentrate (NY) which infected him with hepatitis C. He was given that without a clotting screen having been undertaken. It could not have been known that he was in fact a very mild sufferer from haemophilia A. The infection has devastated and dominated all aspects of his life. The system failed multiply to identify or treat him as such. He was unnecessarily infected with a potentially fatal condition as a result.

4.257 The evidence presented to the Inquiry by Mr Wright (to which it is understood a response was requested by the Inquiry from Professor Ludlam which was never received) clearly demonstrates such failings. The circumstances his infection are clearly evident from his statements and do not require to be repeated here, beyond this general presentation of the key aspects.[1874] Alternatives treatments including DDAVP (with which he was successfully treated later in life) or cryoprecipitate were not even contemplated. The case is clearly demonstrative of

[1874] WITN2287001; and WITN2287002

the fact that, despite the horrors of the HIV years and the multiple AIDS infections in Edinburgh, no effective change from the previous treatment regime had occurred. Bleeding was simply equated with treatment with a factor concentrate. No consideration of the necessity of that treatment took place. No consideration or discussions of the inevitable infection with a potentially fatal disease took place either.

4.258 That systemic lessons about patient safety were not learned from this case is evident in a number of respects. As a virgin patient had been infected in early 1986 without a change of system being instituted as a result[1875] (which could have avoided Mr Wright's infection), so patients continued to be treated without consultant care of Dr Ludlam being made available after May 1986. Dr Boulton was able to administer a trial dose Z8 to a patient at the RIE as part of a trial in 1987 in the absence of Dr Ludlam and Dr Parker.[1876]

4.259 In addition, his evidence clearly demonstrates also that the possible consequences of his infection were well known to Dr Ludlam. Of course, he knew perfectly well that the factor VIII which his staff had administered unnecessarily to Mr Wright would inevitably result in his infection with HCV. Since at least 1983, it had been known that this was the consequence of a first infusion with any factor VIII concentrate. Mr Wright's had been unnecessarily and recklessly exposed to a potentially fatal disease. His fate, like those of the severe patients infected with AIDS 2 years before, was now purely to be determined by chance. Some of them had fortuitously escaped infection with HIV, despite having been treated with products which infected others. Others were not so lucky. Similarly, Mr Wright's only hope was that he might clear the virus naturally or not progress to the more severe forms of the disease. His clear and unchallenged evidence about his catastrophic medical course thereafter makes it clear that he too was not lucky. Like the others infected before him in the very same hospital, they had been the victims of a "concentrate first, ask questions later" culture, their futures left not

---

[1875] HSOC0011756

[1876] para 217 of Dr Boulton witness statement @ WITN3456002

to their own choices (as none were consulted) or to good medical judgement, but instead to luck in this cruel game of Russian roulette.

4.260 This position was well known to Dr Ludlam. He knew that Mr Wright ought not to have been infected and that a system should have been put in place to protect him and patients like him. The desire to know whether, in years to come, these mistakes could come back to haunt him and the hospital was why (without Mr Wright's knowledge) Dr Ludlam attempted follow up the progress of his liver disease when Mr Wright moved to Manchester in 1987, a move he had made for work reasons in total ignorance of the risk to his health and that of his family which was carrying around every day. It is submitted that this was the reason why those attempt to follow Mr Wright up was made, along with Dr Ludlam's customary research instinct to try to derive medical information about the disease and its progression from the infection of this previously untreated patient. There was no other reason for Dr Ludlam to ask to know that information. He was no longer to be Mr Wright's doctor.

4.261 Of course, none of this information was shared with Mr Wright. The possible consequences were downplayted by Dr Ludlam. This led to the horror of the realisation in 1988 that he may have only 10 years to live and the consequent years of painful and debilitating treatment and destructive *sequelae* which are set out clearly in Mr and Mrs Wright's written statements and powerful oral testimony. Again, nothing appears to have been learned from the AIDS crisis. Once again, the domino effect of secrecy and defensiveness had been set in train, which were to compound the harm of the Wright family to this very day. The failure to confront the issue at the time, explain the mistake that had been made and be clear about the potential consequences had (as had happened with the HIV patients) led to a relationship based on misinformation which would destroy the any trust which these patients had in the medical profession, on whom they would require to continue rely all the more heavily due to their infections.

4.262 Professor Ludlam gave evidence to the Penrose Inquiry that in Edinburgh they had regular educational meetings in his department.[1877] It seems clear that these

[1877] Penrose Inquiry transcript for 14/10/11 (day 55); 57(7) (Professor Ludlam); [PRSE0006055_0057]

sessions did not convey adequate information for the prevention of the infection of patients like Mr Wright. As is noted above, he claimed that there was a system in place for the protection of such patients both within the department and more widely in the hospital and also in primary care. The suggestion that such a system existed at this time is refuted. If it did, it failed at almost every stage.

The role of others in decision-making over this period

4.263 In his statement to the Penrose Inquiry on this period, Professor Brian Colvin maintained that *"clinicians were obliged to make their own judgements on product safety"*.[1878] This gives rise to the question of whether poor outcome for patients over this period were contributed to by other failures which may have played a role in the poor, non-patient focussed decision-making of those responsible for their care.

Government

4.264 As noted above, Professor Ludlam indicated in his evidence to the Penrose Inquiry that, as a clinician, he would have found some guidance from the CMO on these difficult treatment decisions to have been of assistance to him. None was available.[1879] As is set out below, the responsible minister within the Scottish office (Lord Glenarthur) from around 1986 was unaware that this was an issue. The then CMO (Dr Iain Macdonald) provided a written response to Professor Ludlam's claim to the Penrose Inquiry.[1880] He stated that decisions of this nature would have been considered to have been medical policy and not public policy. The fact that Dr Macdonald (in the final paragraph) feels that he would have been bound to decline

[1878] PRSE0003534 @ _0002, para 3.2
[1879] Penrose Inquiry transcript for 14/10/11, (day 55); 62 (20- 21) (Professor Ludlam); [PRSE0006055_0062]
[1880] PRSE0001672

a request from Professor Ludlam for guidance on this matter rather shows, in our submission, the defect in the system. Professor Ludlam clearly disagreed. The system was clearly deficient and did not operate in the interests of the safety of patients.

UKHCDO

4.265 Professor Ludlam explained in his evidence at Penrose that UKHCDO guidance would be sent directly from its secretariat in Oxford to the haemophilia centres who would issue advice on haemophilia care to other non-centre hospitals.[1881] The most up to date guidance available from the UKHCDO over this period was contained in the AIDS advisory documents dated 14 December 1984.[1882] As the title suggests, this material was intended to deal primarily with the HIV risk at that time. It notes that there would still be a risk of NANB hepatitis from UK heated concentrates.[1883] This made it clear that a re-assessment of the position was necessary, once the AIDS crisis was over. For example, there appeared to be no appreciation that the heat treatment process for the BPL factor VIII and the PFC factor VIII was different and had a different level of expected protection. Once this started to become clear in 1985, this needed to be re-assessed and was not. The December 1984 advice recommended that DDAVP be used in the cases of mild haemophilia A or vWd patients, if possible.[1884] For patients not previously exposed to concentrates and children with haemophilia A, the recommendation was to use "cryoprecipitate or NHS heated factor VIII (if available)". This is ambiguous and unhelpful. As patient who were untreated tended to be mild patients, it was unclear which category they were in. As DDAVP offered protection from both viruses (HIV and NANBH) this ought to have been made clear as being the first line

---

[1881] Penrose Inquiry transcript for 13/10/11 (day 54); 147 to 148 (Professor Ludlam); [PRSE0006054_0147 to 0148]
[1882] PRSE0002282
[1883] PRSE0002282_0002
[1884] PRSE0002282_0002

treatment. In addition, there was no evidence of cryoprecipitate having transmitted HIV. It offered huge advantages over factor VIII concentrate from the point of view of NANBH risk, the latter being likely to be 100% infective on first infusion. Cryoprecipitate should have been clearly ranked above heated concentrate. No general therapeutic disadvantage of cryoprecipitate when compared to concentrate seems to have been identified, as was constantly claimed to be the case by clinicians giving evidence to the Inquiry.

4.266 For severe or moderate patients with haemophilia A previously treated with concentrates, the recommendation was heat treated UK factor VIII or US commercial factor VIII. As far as patients not previously exposed to concentrates and mild patients with haemophilia B were concerned, the recommendation was that they be treated with fresh frozen plasma. It is noted that in individual patients there may need to be a choice.[1885] This document is fraught with uncertainty (for example about funding supply and the long-term effects of using heat treated products) and appears to have been issued in recognition that some guidance was necessary to deal with the variety of products available and the HIV crisis. As stated, it was not clear what is being recommended for mild virgin patients. Despite this, Professor Lowe told the Penrose Inquiry that the unit policy at the GRI from December 1984 was very much in accordance with these recommendations.[1886] Professor Ludlam made it clear that such guidance documentation could only exist in situations where there had been consensus at the UKHCDO.[1887] This may well be the reason why is lacked the clarity which was required. However, for present purposes the lack of any revision or Scottish specific guidance to cover the period from 1985 where the factor VIII concentrate remained infective for NANBH meant that the rules lacked clarity. On the assumption that they did remain relevant, they advocated the use of DDAVP for mild patients. This was the apparent policy (in theory at least) in Glasgow.

4.267 Evidence was given by the anonymous witness "Alex" to the Penrose Inquiry. His case is illustrative of the kind of guidance which was passed on to Scottish

---

[1885] PRSE0002282_0003
[1886] Penrose Inquiry transcript for 13/10/11 (day 54); 16 (15 to 16) (Professor Lowe); [PRSE0006054_0016]
[1887] Penrose Inquiry transcript for 13/10/11 (day 54); 149 (10) (Professor Ludlam); [PRSE0006054_0149]

hospitals having to deal with treatment dilemmas over this period. A letter from a consultant paediatrician to Alex's GP after his admission to Raigmore Hospital, Inverness and diagnosis with severe haemophilia A (referred to in evidence[1888]) described the circumstances of his diagnosis with haemophilia A. Guidance as to further treatment was given to the local hospital in the following terms:

"Obviously he will require replacement therapy with cryoprecipitate or factor 8 infusions from time to time following trauma and before any operative procedure"

4.268 He received an infusion of cryoprecipitate at this time.[1889] This letter was written by a consultant paediatrician at the hospital where Alex was diagnosed, in part advising as to the future care of his haemophilia. Despite the fact that he had been given cryoprecipitate there, the future treatment options include cryoprecipitate or factor VIII. No further guidance is given in the letter as to the circumstances in which one would be preferable over the other. The terms of the guidance mirror the terms of the recommendations for treatment of an untreated infant with haemophilia A in the UKHCDO guidance of December 1984. Alex later received treatment with factor VIII concentrate in January 1987 at his local hospital, as set out in a letter to Dr Hann dated January 1987.[1890] His subsequent treatment as an infant was at Yorkhill hospital, where he was looked after in the early months of January 1987 with cryoprecipitate. By this time, it was clear to Dr Pettigrew at Yorkhill that (a) at that time treatment with cryoprecipitate was "preferable in an infant from the point of view of NANB hepatitis" and (b) that his future treatment needs would be likely to be able to be catered for with heat treated factor VIII concentrate, the arrival of which was imminent at that time.[1891] The result of the guidance given by Raigmore to those responsible for Alex's care locally appears to have been that it was not until after he arrived at Yorkhill (by which time we was

---

[1888] Penrose Inquiry transcript for 10/01/12 (day 81); 9 (10 to 12) ("Alex"); [PRSE0006081_0009]
[1889] Penrose Inquiry transcript for 10/01/12 (day 81); 10 (2 to 10) ("Alex"); [PRSE0006081_0010]
[1890] Penrose Inquiry transcript for 10/01/12 (day 81); 13 ("Alex"); [PRSE0006081_0013]
[1891] Penrose Inquiry transcript for 10/01/12 (day 81); 16 ("Alex"); [PRSE0006081_0016]

already infected) that the relative advantages of cryoprecipitate over factor VIII concentrate as far as infectivity risk for an infant was concerned was set out. It seems likely that this infection resulted from the lack of up to date guidance.

4.269 New UKHCDO guidelines and/ or Scottish guidelines should have been introduced from 1985 which (a) made it clear to hospitals that virgin or minimally treated patients who may not yet be infected presenting for treatment should be treated by senior members of staff and (b) the preferred treatment in such patients should be DDAVP if possible and if not cryoprecipitate. Such guidance should at least have been put in place after the infection of the virgin patient in Edinburgh in February 1986.[1892] It was clear at least at that time that guidance was needed to protect such patients, though in fact this was reasonably foreseeable before that. This would have enabled the infections of Mr Wright in May 1986 and "Alex" to have been managed differently and avoided.

The procurement of a limited supply of 8Y for uninfected patients

4.270 The Scottish factor VIII concentrate available over this period (NY) was heat treated to 68 degrees centigrade for 24 hours. That heat treatment regime had rendered the product free from infectivity with HIV. However, there was no evidence to suggest that that heat treatment regime would inactivate the NANB virus.[1893] Dr Perry accepted that the product available in March 1986 was known to infect with NANB hepatitis or, at least, that it was probably not free from that virus.[1894] That a virgin patient became infected with NANB hepatitis in May 1986 as the result of a first infusion with the Scottish concentrate was "not wholly surprising" according to Dr Perry.[1895]

[1892] HSOC0011756

[1893] See Penrose Inquiry preliminary report paragraph 11.249 and PRSE0001470 - Dr Perry was informing BPL as late as July 1985 that as far as this product was concerned "it is unlikely we will achieve freedom from NANB"

[1894] Penrose Inquiry transcript for 7/12/11 (day 74); 7 (20 to 23) and 8 (13 to 16) (Dr Perry); [PRSE0006074_0007; 0008]

[1895] Penrose Inquiry transcript for 7/12/11 (day 74); 10 (15 to 16) (Dr Perry); [PRSE0006074_0010]

4.271 Professor Ludlam gave evidence to the Penrose Inquiry to the effect that they did not know until the infection of a virgin haemophilia A patient who had been treated with this factor VIII concentrate that it was known that the product was infective. In our submission, and on the assumption that this statement related to the infection of Mr Wright in May 1986, this was a wholly unreliable and inaccurate description of events. It was well known since the Fletcher paper at least that domestic concentrates were likely to be infective on first infusion. There was no reason to think that it was non-infective. It was also wholly foreseeable that such an event may occur, due to the infection of at least one other similar patient earlier that year in Edinburgh (see above). This is yet another example of Professor Ludlam having attempted to construct an *ex post facto* explanation for his actions or the actions of those for whom he was responsible. It is wholly inconsistent with other evidence and ought not to be accepted.

Evidence on the safety of 8Y

4.272 In England, a factor VIII concentrate product heat treated to 80 degrees for 72 hours (known as 8Y) was routinely available from at least September 1985.[1896] The product was discussed at the CBLA research and development committee meeting on 9 July 1985.[1897] It was noted that a number of patients in a clinical trial of 8Y, had already passed the point at which it would be expected that they would be infected. An application for a product licence was being prepared. This meeting was not attended by anyone from Scotland. Indeed, the meeting received the apologies of Dr Forrester, who was the SHHD representative who was meant to have been in attendance. It is understood that the meetings of this committee were carried out confidentially.[1898] However, one assumes that the subsequent minutes would have at least allowed those within government to be made aware

[1896] PRSE0004183 - the 8Y launch letter dated 24 July 1985
[1897] PRSE0002420_0003
[1898] PRSE0002420

of the existence and potential benefits of the 8Y product. Professor Ludlam gave evidence to the effect that he was not aware of the existence of the CBLA.[1899] He indicated that maybe that high level guidance on 8Y would have been something which haemophilia clinicians would have appreciated.[1900] Again, when seen in the context of other evidence, in particular the responsibility accorded to haemophilia directors to keep appraised of developments of this nature through their various contacts within the profession, this evidence can be characterised as Professor Ludlam attempting illegitimately to exonerate himself from blame in this regard. Again, he attempted to shift the blame onto the government. When he eventually instigated the procurement of a supply 8Y and procured a supply himself, no high level guidance was sought or required.

4.273 The launch letter for 8Y dated 24 July 1985 (addressed to haemophilia directors in England and Wales) asked clinicians to identify "those patients likely to benefit most" from the new product.[1901] There was clearly an understanding that patients who were unlikely to be infected should get the product first and that it was thought to be non-infective for either HIV or NANBH. As had been pointed out at the CBLA meeting, clinical trials of the product were underway in 6 haemophilia centres and several patients had passed the point at which it would normally be expected that they would have been infected with NANBH by an unheated concentrate. The letter does not appear to have been sent to haemophilia directors in Scotland.[1902] However, in his evidence to the Penrose Inquiry, Dr Perry thought that haemophilia directors in Scotland would have been likely to have seen this launch documentation through their contacts.[1903] The English directors were asked to identify the patients who were most at risk so that the products could be directed towards them.[1904] It seems to have been an omission on the part of Scottish directors, once they found out about this trial, not to have sought to have their "at risk" patients included in this trial. The letter presupposes that there

---

[1899] Penrose Inquiry transcript for 14/10/11 (day 55); 96 (23 to 24) (Professor Ludlam); [PRSE0006055_0096]
[1900] Penrose Inquiry transcript for 14/10/11 (day 55); 111 (21 to 23) (Professor Ludlam); [PRSE0006055_0111]
[1901] PRSE0004183
[1902] PRSE0003388
[1903] Penrose Inquiry transcript for 7/12/11 (day 74); 27 (16 to 19) (Dr Perry); [PRSE0006074_0027]
[1904] PRSE0004183_0002

was some benefit to those patients most at risk. This comes from the manufacturer. However, even at this early stage participation in such a trial would have given an uninfected patient who needed concentrate some chance of avoiding infection which would not have been available if treated with an SNBTS concentrate. This letter (as Professor Lowe also confirmed in his Penrose evidence) indicated that the product was also achieving the appropriate rise in factor VIII levels.[1905] There was no reason not to have sought access to it.

4.274 By the time of the meeting of the CBLA research and development committee on 19 December 1985, Dr Rizza had reported that he had been using 8Y in a clinical trial for 9 months and that none of his patients (including children) had become clinically ill. He considered this to be encouraging. This contrasts with his report on the heat treated factor IX product, in which he reported that the incidence of NANBH was hard to assess.[1906] It is interesting to note that this meeting was the first attended by Dr Forrester on behalf of the SHHD.[1907] He is not minuted as having made any contribution at the meeting. There is no evidence of which we are aware of him having reported these encouraging findings to anyone. He ought to have done, thought he information conveyed ought also to have been available to the haemophilia directors though other established channels.

4.275 At a joint meeting between representatives of the BPL and the PFC on 24 March 1986, Dr Smith outlined that after 12 months of trials there had been no infections in virgin haemophiliacs from the 8Y product. [1908] The BPL annual report to March 1986 (which was not published until September 1986 but which is indicative of the position as it stood at that time) pointed out that there were still no reported cases of NANB transmission.[1909] The document also refers to the BPL's "promotional activities". [1910] The superiority of the 8Y product over the Scottish factor VIII concentrate was well established in a relative sense. This was or ought to have been known in Scotland but no action was taken.

[1905] Penrose Inquiry transcript for 13/10/11 (day 54); 42 (22 to 23) (Professor Lowe); [PRSE0006054_0042]
[1906] PRSE0001229_0002
[1907] PRSE0001229
[1908] PRSE0003764_0003
[1909] PRSE0000793_0005
[1910] PRSE0000793_0032 to 0033

4.276 In a report by Dr Perry, PFC, for an SNBTS/Haemophilia Directors meeting on 5 March 1986[1911], Dr Perry noted that *"Directors will be aware that [BPL] are currently issuing a FVIII product which has been heated at 80 degrees/72 hrs and preliminary clinical data indicates that this material is non-infective with respect to HTLV III, NANB and Hepatitis B."* In an "Addendum to Development of New Products 1986/87" it was observed that "The heat-treatment procedure now being applied to FIX concentrates (PFC & BPL) and to FVIII (BPL) may well be effective in ensuring non-infectivity of products." [1912] Further, Dr Perry accepted in his Penrose evidence that by March 1986, the signs [as regards the emerging evidence non-infectivity of 8Y] were looking promising.[1913] It was clearly thought that 8Y was safer in July 1986 as it was contemplated that it would be used for Edinburgh virgin patients by Dr Boulton and Dr Perry.[1914]

4.277 Professor Ludlam's response to this data in his Penrose evidence was to say that it was unreliable because (a) they did not know how many patients had been tested (b) they were not all previously untreated patients and (c) the frequency of liver testing applied did not meet international standards.[1915] Therefore, Professor Ludlam was of the view that the viral safety of the product was unknown with respect to NANB hepatitis. [1916] This was yet another example of Professor Ludlam trying to apply an *ex post facto* justification if inaction at the time. It smacks of the "conclusive proof" line taken by clinicians and the government with regard to the aetiology of HIV and the risk from blood and blood products earlier in the decade. if this was indeed the justification at the time for not taking steps to secure a supply, it suggests that nothing had been leaned about the need to prioritise patient safety though the HIV crisis. The data was clear that it offered a significant safety advantage over a product which was highly likely to be infectious on first

---

[1911] PRSE0003457
[1912] PRSE0002156
[1913] Penrose Inquiry transcript for 7/12/11 (day 74); 7 (9 to 12) (Dr Perry); [PRSE0006074_0007]
[1914] PRSE0002783 appended to PRSE0001784]
[1915] Penrose Inquiry transcript for 13/10/11 (day 54); 101 (22) to 102 (1) (Professor Ludlam); [PRSE0006054_0101 to 0102]
[1916] Penrose Inquiry transcript for 13/10/11 (day 54); 104 (1 to 3) (Professor Ludlam); [PRSE0006054_0104]

infusion. The achievement of international standards was irrelevant. By that approach, nothing would ever be done until it was too late.

4.278 The data on 32 patients (the emerging data which had been reported upon by Dr Smith above) who had received 8Y was presented by Dr Smith to a UKHCDO meeting in September 1986. This was described by Professor Ludlam at Penrose as being "soft data" (under reference to a comment made by Dr Kernoff at that meeting). However, Professor Ludlam also accepted that it was interesting and reassuring data.[1917] That the data was soft did not mean, in our submission, that it contained no indication at all that 8Y was not looking like it was likely to be non-infective. Against a background of increasing concern about the severity of NANB hepatitis, there should have been greater weight accorded to this data (the thrust of which had been available at least the middle of 1985) especially when one considers that it would otherwise take many years for sufficient virgin patients to prove anything conclusively. In his Penrose evidence, Professor Ludlam was of the view that it was in July 1986 that evidence became available which convinced him of the merits of 8Y. That was before Dr Smith's report was presented to the UKHCDO. There was simply no good reason why it was only at that point it should have suddenly become apparent that 8Y was safer than the SNBTS factor VIII. This could and should have been realised earlier that year, at the latest. On the evidence available to this Inquiry, it was not the emergence of greater information or more reliable information in July 1986 that prompted this shift in attitude on Professor Ludlam's part. This date was selected by Professor Ludlam in his Penrose evidence as he knew that it came after the date (May 1986) when Mr Wright had been unnecessarily infected in his hospital. It was that infection which prompted Professor Ludlam to instigate the procurement a supply of 8Y. For Mr Wright and others, that move came after the horse had bolted.

4.279 The interim report by Dr Smith contained data on patients with no previous exposure to large pool concentrates but did have variable previous exposure to cryoprecipitate based on difficulties getting people for the study.[1918] None of the

---

[1917] Penrose Inquiry transcript for 13/10/11 (day 54); 116 (10 to 16) (Professor Ludlam) and PRSE0003273; [PRSE0006054_0116]
[1918] PRSE0003273

patients had an ALT above 2 and a half times the upper limit of normal. This included a number of virgin patients.[1919] There were no cases of HIV conversion in over 100 patients. There was a great deal of caution about not making unjustified claims of safety for products at this time, according to Professor Colvin in his Penrose evidence, based on the disappointments of previous commercial products which had claimed to be non-infective but had not been.[1920] As far as use for untreated or minimally treated patients was concerned, Professor Colvin gave evidence to the effect that he used cryoprecipitate for children until he started using 8Y around July 1985.[1921] One requires to differentiate between claims being made for the conclusive safety of a product and there being sufficient evidence for it to be used as the treatment of choice for the probably uninfected patient. That point was reached in 1985.

4.280 In his evidence to the Penrose Inquiry on this subject, Professor Thomas pointed out in response to questioning about a paper he had written[1922] that "when the inactivation procedures started to become a possibility then if there were even one or two patients who didn't develop NANB then that would be significant".[1923] Further, he pointed out when comparing the partially heated concentrates to the non-heated concentrates that "with that [virtually guaranteed infection] as the worst scenario, anything that was potentially better than that would be preferably used, whether it was proven to be better or just possibly better. I think ethically that would be the material you would want to use".[1924] Professor Thomas equated the use of a product which was just possibly safer as imposing an ethical duty on clinicians to try to use it. There was an ethical failure on the part of the Scottish clinicians and the SNBTS to seek a supply in 1985. In his Penrose evidence, Professor Ludlam was keen to point out that when he heard about the 8Y product,

---

[1919] PRSE0003273_0004
[1920] Penrose Inquiry transcript for 14/10/11 (day 55); 144 (18) to 155 (7) (Professor Colvin); [PRSE0006055_0144 to 0155]
[1921] Penrose Inquiry transcript for 7/12/11 (day 74); 89 (11 to 14) (Professor Colvin); [PRSE0006074_0089]
[1922] PRSE0003439
[1923] Penrose Inquiry transcript for 11/10/11 (day 52); 89 (21) to 90 (1) (Professor Thomas); [PRSE0006052_0089 to 0090]
[1924] Penrose Inquiry transcript for 11/10/11 (day 52); 158 (22) to 159 (1) (Professor Thomas); [PRSE0006052_0158 to 0159]

he was thinking that it might be **safer** against NANBH than the then available Scottish concentrate, rather than **safe**.[1925] This is precisely the abasis upon which steps being taken to procure a supply for probably uninfected Scottish patients. That it appeared safer, to whatever degree, should have at least started the process. As is shown below, the response when the process was started was swift and welcoming. It can reasonably be inferred that this would always have been the case.

4.281 There is a more general point to be made here. The need for conclusive proof before there was an obligation to act was a theme which ran throughout the evidence heard on behalf of the government and the medical community in this and the Penrose Inquiry. In the latter, significant reliance was placed on "Koch's postulates" as being the touchtone by which scientific proof of viral infectivity could be deemed to have been proven and hence any obligation to take action could be thought possibly to have arisen. The governmental "conclusive proof" line in relation to the possibility of a viral aetiology for AIDS is a manifestation of this approach. It was convenient for the government to adopt this line taken by the medics as it absolved them from any responsibility to act as well. Despite representing a position to both inquiries of the need for conclusive proof before accepting a responsibility to act, in his Penrose evidence, Professor Ludlam accepted that in clinical medicine one required to make many scientific assumptions.[1926] This was why Koch's postulates did not feature in the contemporary discussion about the appropriate response to the emerging information about AIDS.[1927] It was more than clear that action was necessary to protect recipients of blood products. In a commentary on the AIDS crisis in 2007, Dr Evatt pointed out that the crisis shows how when faced with incomplete scientific data experts tend to resort to existing paradigms rather than accepting

---

[1925] Penrose Inquiry transcript for 13/10/11 (day 54); 100 (14 to 20) (Professor Ludlam); [PRSE0006054_0100]
[1926] Penrose Inquiry transcript for 04/05/11 (day 19);11 (24) to 12 (2) (Professor Ludlam); [PRSE0006019_0011 to 0012]
[1927] Penrose Inquiry transcript for 04/05/11 (day 19); 12 (3 to 6) (Professor Ludlam); [PRSE0006019_0012]

new hypotheses.[1928] This manifested itself by a reliance on scientific principles of proof as opposed to the need to move quickly in the interests of patient safety.

4.282 There are three aspects to this which merit the Inquiry's attention at this juncture in our analysis. The first is that this approach, clearly taken at the time by certain members of the medical profession (including the UKHCDO and its members) was clearly misguided when applied to the subject matter with which they were dealing. The diseases with which the debate was concerned were known to be diseases which had significant prodromal periods. Further, patients who received pooled products were "canaries" who would be likely to be exposed to any viruses which entered the system early in the life cycle of any virally transmitted disease. A cautious and reactive approach was necessary. The "conclusive proof" approach was the opposite of this. It was or ought to have been known that it misguided and unsafe. By definition, this line of thinking would result in any action being taken after the event. The conclusive proof upon which those in charge were waiting was the proof that something had happened. It involved a complete lack of regard for the need to think forward and preventative. Secondly, that the line was stuck to so rigidly after the event is one of the main factors which have led to the cover-up of what really happened. The "conclusive proof" mantra was the scientific protection build in by the medical profession to the system. Without it, the actions and thinking of those in charge would be exposed for its inadequacy. Its general acceptance within the medical profession and the protection which is logically provided against criticism were a major part of the problem. It meant that nobody could ever be criticised and so there was never any imperative to act. It also explains why, despite clear evidence of is unreasonableness and lack of patient safety basis, he contrary, the mantra has been so jealously protected by medical profession in investigations and inquiries over the years. The removal of this illegitimate protective layer is to expose the inadequacy of the effort. It is the supposed protective shield but it is also the reason for the inadequacy. The jealous need to guard it is what lies behind the "party lines" which are formulated based on it and is the basis of the unreliability of much of the clinicians' evidence. If you

[1928] PRSE0002607_0003

remove the assumption that it was reasonable not to act until there was no reason not to, you remove an effective immunity. In is in this light that the reasons given for inaction need to be assessed. They are often simply reasons which (judged by the standard of conclusive proof) justify not acting. By that standard, any factor, however immaterial, means that the justification for action cannot be deemed to have been proven conclusively. If, however, one removes that protective standard, the immateriality of the factors prayed in aid of inaction mean that the justification falls away. Thirdly, it is important to note that this approach did not fall away after the horrors of the HIV infection experience which became apparent in 1984. No lessons were learned. Patient safety was not priorities. She current analysis shows, the same attitude prevailed for the rest of the decade and indeed until 1991, when tests continued not to be used until they could be conclusively (or near conclusively) proven to work. The mantra was a clear example of the best being the enemy of the good. However, it was more than that. It was the protection which the medical profession (or certain part of it) had bestowed upon itself as a total protection from criticism. The profession could only be criticised when something was conclusively proven. The profession determined when that was. By definition, in this sphere that was always going to be too late for the patients. That is was integral to its thinking is indicated by the fact that it was jealously defended even before this Inquiry, many decades later.

4.283 The approach of Professor Thomas in this area is instructive, as has been submitted. However, it is also important to note that (and others like him, such as Professor Lever who also gave evidence to the Penrose Inquiry) come from outwith this system. Professor Thomas is a hepatologist as opposed to a haemophilia clinician. His CV showed, however that h was not only an independent but also a well-informed expert. He had had a distinguished career and that he was a founding editor of the Journal of Viral Hepatitis.[1929] He had a long list of academic distinctions and also appeared able to talk in his evidence to Penrose about different aspects of haemophilia care.[1930] His CV also demonstrated

[1929] PRSE0002631_0003

[1930] See his evidence on home treatment in Penrose Inquiry transcript for 11/10/11 (day 52); 92 (Professor Thomas); [PRSE0006052_0092]

that he had a general knowledge of medicine and that he had practised acute case receipt.[1931] He had involvement with haemophilia patients due to their infections with HIV and hepatitis (B and C) and also wrote papers in conjunction with haemophilia clinicians, like Dr Kernoff (see above). Importantly, he was not part of the UKHCDO "club" and was not privy to the "party lines".

4.284 In this specific context, it was claimed in evidence that it was not until 1988 or perhaps until 1993 that it could be shown that 8Y was free from NANB hepatitis. That may be so by the standards of conclusive scientific proof. However, the evidence was available much earlier for the correct test, based on the best interests of patients to be met for a supply of 8Y for virgin or minimally treated Scottish patients. In his statement to the Penrose Inquiry, Professor Van Aken confirmed that "An interim review of the clinical trial with 8Y in March 1986 showed that it was likely that the product was free of NABNH."[1932] The evidence on fact shows that sufficient evidence was available to take action long before that.

Exchange of information

4.285 Information about the emerging data on 8Y was communicated to people at the PFC by the BPL. Dr Foster explained that in his experience there was a very free exchange of information about products in the not for profit sector, in particular between the BPL and the PFC.[1933] That nobody at PFC thought to act on this information in the interests of virgin and minimally treated patients in Scotland was an error.

4.286 As for the clinicians, Professor Ludlam gave evidence to the Penrose Inquiry to the effect that he first became aware of the development of the 8Y product at some point in 1985 and that he received information about it at the UKHCDO meetings

---

[1931] PRSE0002631_0006
[1932] PRSE0001090_0004
[1933] Penrose Inquiry transcript for 10/05/11 (day 22); 93 (23) to 94 (1) (Dr Peter Foster)

which he attended.[1934] Professor Ludlam could not remember what evidence had been made available to him about the early indications of NANB safety in the 8Y product.[1935] It is submitted that this is an example of Professor Ludlam conveniently forgetting the detail when the written evidence did not suit the defence of his position. He attended 5 directors meetings between the launch of 8Y and the spring of 1986, at which time he could have discussed the clinical trial progress with those involved, such as Dr Rizza and Dr Colvin or even Dr Craske.[1936] In his Penrose statement, Professor Colvin alluded to discussion amongst haemophilia directors about infectivity issues and other product risks as well as to the results of trials being known and shared before publication.[1937] Dr Perry expressed the view to Penrose that the emerging data about the apparent safety of 8Y would have been discussed at the UKHCDO meetings.[1938] That may explain why action was not taken by the PFC staff. The information which they had should at least have been passed along to the directors. Professor Thomas pointed in his Penrose evidence out that information would be exchanged between haemophilia centre directors around a year before it would be published in a journal.[1939] Professor Lowe did not recall seeing the launch letter or any information about the emergence of 8Y being given to him by his centre director at the time, Professor Forbes.[1940] Both Professors Ludlam and Forbes were reference centres directors. It seems hard to believe that they would not have been privy to this information as it related to a highly significant development in the safety of a key product used for the treatment of haemophilia A patients in the UK. If they knew, they should have acted. If they die not, they should have sought information out or the ULKHCDO system should have provided it to them. There was a wilful

---

[1934] Penrose Inquiry transcript for 14/10/11 (day 55); 91(15 to 22) (Professor Ludlam); [PRSE0006055_0091]
[1935] Penrose Inquiry transcript for 13/10/11 (day 54); 107 (10) (Professor Ludlam); [PRSE0006054_0107]
[1936] PRSE0004271 - 30 September 1985 (21st meeting of the Reference Centre Directors); PRSE0001638 - 21 October 1985 (16th meeting of the UK Haemophilia Centre Directors); PRSE0001281 - 9 January 1986 (22nd meeting of the Reference Centre Directors); PRSE0001688 - 17 March 1986 (17th meeting of the UK Haemophilia Centre Directors); and PRSE0004338 - 14 April 1986 (23rd meeting of the Reference Centre Directors)
[1937] Penrose Inquiry reference PEN.017.1674 @ 1675, para 3.2
[1938] Penrose Inquiry transcript for 7/12/11 (day 74); 12 (16 to 18) (Dr Perry); [PRSE0006074_0012]
[1939] Penrose Inquiry transcript for 11/10/11 (day 52); 43 (25) and 44(24) (Professor Thomas); [PRSE0006052_0043; 0044]
[1940] Penrose Inquiry transcript for 11/10/11 (day 52); 43 (21 to 24) (Professor Thomas); [PRSE0006052_0043]

blindness which was a disservice to Scottish patients. It can be explained by the culture of conclusive proof.

Availability of a safe factor VIII concentrate over this period

4.287 No steps were taken to procure a supply of English 8Y for Scotland before the aftermath of the infection of Mr Wright in Edinburgh in May 1986.[1941] It is unclear why no steps were taken to have Scottish patients put forward for the clinical trial as Scottish patients had been used in BPL trials before.[1942] Dr Perry was of the view that by the time a request was made in the summer of 1986, he would "probably" be able to get some, given the small requirement.[1943] Dr Perry said in his evidence that once it was suggested that a supply of 8Y might be procured from England by Professor Ludlam via Dr Boulton, he and Dr Bouton considered it to be a feasible proposition which was well worth exploring.[1944] Despite the short supply of 8Y in England, that did not seem to them to prohibit the likelihood of a small supply being made available to Scotland for probably uninfected patients, especially as such a request might provide BPL with interesting data on how these rare patients reacted to the product.[1945] This should have been done before that. The possibility of a product swap was also not considered and that possibility is also addressed elsewhere in this submission. Professor Ludlam gave evidence at Penrose to the effect that if he had had a supply of 8Y available in May 1986, he would have used it on the untreated patient at that time.[1946] Professor Colvin gave evidence to the same effect.[1947]

[1941] Penrose Inquiry transcript for 7/12/11 (day 74); 13 (9 to 11) (Dr Perry) [PRSE0006074_0013]
[1942] PRSE0000040 (his note of UKHCDO meeting of 17 October 1983). In this regard. A Glasgow patient appears to have been involved in a clinical trial. NB - the vaccinia data was referred as a possible indicator of non-infectivity and see para 106 of Dr Perry witness statement @ WITN69200001 regarding the use of "model viruses" to determine infectivity. This could have been done regarding 8Y.
[1943] Penrose Inquiry transcript for 7/12/11 (day 74); 26 (9 to 14) (Dr Perry) [PRSE0006074_0026]
[1944] Penrose Inquiry transcript for 7/12/11 (day 74); 22 (2 to 4) (Dr Perry) [PRSE0006074_0022]
[1945] Penrose Inquiry transcript for 7/12/11 (day 74); 21 (11 to 15) (Dr Perry) [PRSE0006074_0021]
[1946] Penrose Inquiry transcript for 13/10/11 (day 54); 131 (3 to 18) (Professor Ludlam); [PRSE0006054_0131]
[1947] Penrose Inquiry transcript for 7/12/11 (day 74); 96 (2 to 7) (Professor Colvin); [PRSE0006074_0096]

4.288 In the aftermath of the infection of Mr Wright in May 1986, Professor Ludlam instigated the procurement of a supply of 8Y which was chieved quickly. Dr Boulton wrote to Professor Cash that Professor Ludlam had indicated that he would be happy to treat patients such as the virgin patient infected in Edinburgh with a concentrate produced by SNBTS which had been subjected to a similar heat treatment regime to the then available English 8Y product.[1948] This of course indicated that it was well known by that point that 8Y was safe or at least more likely to be safe for NANBH than NY. In a letter to Dr Perry of the same date, Dr Boulton suggested that Professor Ludlam was a bit "ruthful with his own staff" as he thought that the patient could have received 8Y or "an equivalent product".[1949] This is a clear indication (a) that Dr Ludlam thought that the infection should not have occurred and (b) that 8Y could and should have been available for such situations. The Inquiry is aware of another infection which occurred in the case of a previously untreated patient in Edinburgh in 1986.[1950] He thought it should have been foreseen at the start of 1986 at the latest that this would happen at some point, this infection and the then then available evidence that 8Y seemed safer meant that there was an obligation to procure a supply of 8Y or at least institute a safer system in Edinburgh and indeed Scotland-wide. In his evidence Dr Boulton said that he thought that Dr Ludlam thought that the patient should have been given 8Y and not NY.[1951] He thought it likely that the subsequent request for a supply of 8Y had been triggered by the May 1986 infection of Mr Wright.[1952]

4.289 By letter dated 2 July 1986, Dr Perry informed Dr Boulton that it was anticipated that trial versions of the Scottish factor VIII concentrate heated to same degree as English 8Y would be available before stocks of the previous product were exhausted but that that could not yet be announced as a policy.[1953] By letter dated 7 July 1986, Dr Perry stated:

[1948] PRSE0002000
[1949] PRSE0003845
[1950] HSOC0011756
[1951] IBI transcript for 04/02/22; 122 to 123 (Dr Frank Boulton)
[1952] IBI transcript for 04/02/22; 127 (Dr Frank Boulton)
[1953] PRSE0003030

"While there will be no PFC product virucidally comparable to 8Y until September '86, after that time it would be my intention to supply the Phase III product to "virgins" since we hope to demonstrate by that time that it is virucidally equivalent thus removing the need to go South"[1954]

4.290 In letter from Mr Pettet of BPL to Dr Perry dated 24 July 1986, Mr Pettet appeared to want to make it clear to Dr Perry what the possible risks of the products were. He raised one point and one point only, concerning the lack of HIV screening of the plasma. The product had of course been heated well beyond the extent of the PFC NY product, for which safety from HIV transmission had been claimed by SNBTS since December 1984. No issue was raised about possible NANB infectivity from the product.[1955] There was no reluctance on the part of BPL to supply some 8Y to Scotland when it was asked for. No supply issue was raised. Dr Boulton said that BPL had been very willing to help out and that the reluctance to ask had been due to a reluctance to accept that the Scottish system was failing. It is submitted that this misplaced sense of professional pride was not in the best interests of Scottish patients.[1956] There was no suggestion on his part that the relative safety of 8Y was not known before May 1986.

4.291 At the time when a supply was made available, Dr Perry did not think that participation in a clinical trial was being made a mandatory condition of the supply from BPL.[1957] Though follow up information from the reaction of probably uninfected patients to the product would have been useful (and indeed possible), there is no reason to think that an earlier supply would have had any such mandatory condition attached to it either. When the supply was actually produced, Mr Pettet at BPL pointed out to Dr Perry in the letter dated 24 July 1986 that he could provide 8Y set aside for trial purposes but also suggested that some

---

[1954] PRSE0003814
[1955] PRSE0003693_0002
[1956] IBI transcript for 04/02/22; 127 to 128 (Dr Frank Boulton)
[1957] Penrose Inquiry transcript for 7/12/11 (day 74); 34 (8 to 9) (Dr Perry); [PRSE0006074_0034]

can be put aside for patients who did not meet the criteria for the trial.[1958] Dr Perry was clear that the product was there to be used freely in the treatment of probably uninfected patients in Scotland.[1959] This evidence made clear that it could be used freely, though no steps were taken to make it known nationally that the product was available for this purpose (see below). By the latter part of 1985 the product was available for routine use in England and not just as part of a clinical trial (as Dr Perry pointed out in his evidence[1960]). The 50 vials which were eventually procured were not provided with a requirement that they be administered only as part of a clinical trial.[1961] Given that by the latter part of 1985 the product was available for routine use in England and not just as part of a clinical trial, it is likely that a request for an amount to meet the requirements of virgin and minimally treated patients in Scotland would have been likely to have been fulfilled at any point from late 1985 onwards. Relatively small quantities of 8Y would have been needed to cater for the eventuality of probably uninfected patients requiring treatment with a concentrate in Scotland in the time period between 1985 and the introduction of Z8 in April 1987. No analysis appears to have been done by the SNBTS or the haemophilia centre directors as to the likely demand from the small group of patients for whom the treatment would have been potentially life-saving. This was the result of the *ad hoc* nature of the request.

4.292 As noted above, 50 vials were procured in the aftermath of the infection of Mr Wright in Edinburgh in May 1986. A request for this amount, apparently for Edinburgh patents only, was made by Dr Boulton to Dr Perry by letter dated 7 July 1986.[1962] The 50 vials is described as amount which would be enough for initial treatment of a presenting virgin patient. He anticipated in the letter that if more were needed they could call it in from Oxford over the next 24 hours. He indicated that Professor Ludlam had no untreated patients on his books at that time. This letter is clearly the genesis of why an amount was procured. It was procured in

---

[1958] PRSE0003693
[1959] Penrose Inquiry transcript for 7/12/11 (day 74); 41 to 42 (Dr Perry); [PRSE0006074_0041 to 0042]
[1960] Penrose Inquiry transcript for 7/12/11 (day 74); 49 (15 to 17) (Dr Perry); [PRSE0006074_0049]
[1961] Penrose Inquiry transcript for 7/12/11 (day 74); 50 (9 to 12) (Dr Perry); [PRSE0006074_0050]
[1962] PRSE0004097

that amount for the reasons set out by Dr Boulton, not because anyone was of the view that more would be impossible to obtain. Indeed, this was an attempt by a former English haemophilia centre director to open the door to a supply on the basis that more could be requested if necessary. It is likely that an earlier supply, in greater quantities, would have been forthcoming, if requested. It should be borne in mind that Dr Ludlam's claimed treatment philosophy (not observed in Mr Wright's case, it is submitted) that a concentrate should only have been used over this period if its use was unavoidable. Patients in this group could usually be treated with DDAVP (as per the theoretical Glasgow policy and the UKHCDO December 1984 guidance for mild and vWD patients) or cryoprecipitate. It was only in unavoidable cases that 8Y would have been needed. It is notable that the infection of the Edinburgh patient had not prompted any realisation on the part of any of those involved in this process (Dr Ludlam, Dr Boulton or Dr Perry) that a patient in need of such treatment could equally arise in any centre other than Edinburgh or indeed in hospitals beyond the centres. There was no dissemination of the availability of this procured supply or the fact that the door had been opened to a possible further supply beyond Edinburgh. No thought appears to have been given to those who we know attended in such a group over this period in other centres who may also have benefitted from an 8Y supply for situations in which concentrate therapy was unavoidable.

4.293 Dr Perry gave clear evidence at Penrose to the effect that it was the responsibility of the haemophilia clinicians to instigate this process. He said that it could not have been part of the role of SNBTS/the PFC in his view actively to promote a potentially better product from outwith the SNBTS.[1963] It was not normally the case that non-SNBTS products were procured through SNBTS/PFC but in the case of the 8Y supply, that was what happened due to the specific request for assistance made by Professor Ludlam.[1964] He gave evidence to the effect that, in the early 1980s, the haemophilia doctors had strongly rejected the proposal that the PFC should

[1963] Penrose Inquiry transcript for 7/12/11 (day 74); 39 (22) to 40 (1) (Dr Perry); [PRSE0006074_0039 to 0040]
[1964] Penrose Inquiry transcript for 7/12/11 (day 74); 37 to 39 (Dr Perry); [PRSE0006074_0037 to 0039]

be responsible for the procurement of all products for use in Scotland, given their specific interest as a manufacturer.[1965]

4.294 In the letter from Dr Boulton to Dr Perry dated 27 June 1986 it was reported that Professor Ludlam thought that the patient infected in May 1986 (Mr Wright) should have got 8Y or some equivalent. That Professor Ludlam was ruthful with his staff, or "a bit sad" as he described it in evidence at Penrose[1966] was, because he had regretted not acting upon the data available earlier that year, which he himself accepted indicated that 8Y might not be hepatitis free but that it might be less infective than the then available SNBTS concentrate which was highly likely to transmit NANB hepatitis[1967]. He knew that it was his responsibility and the responsibility of other directors to have acted upon the information and to instigate such an action, which he later did. In light of that, the fact that he instigated an approach for a supply of a non-SNBTS through Dr Boulton via the SNBTS suggests that he did so in order to distance himself from the request. It was clearly instigated by him. At Penrose, he claimed that there he made the request through that channel as he thought that it would be the best way to get a supply of the product.[1968] He thought it unlikely that he would be able to secure such a supply, though by this time he had been a reference centre director for around 6 years. His personal control over the supply of all products is clear. He later procured a further supply of 8Y himself. This evidence seems unreliable and seeks to hide his true motive. It is reasonable that it would have been the haemophilia clinicians who would have been expected to instigate such a process as they would have been most likely to recognise the need for such a product for particular patients. The principal responsibility for this failure must lie with the directors. However, the system described by Dr Perry was also deficient in that it is clear from the material available to the Inquiry that both at PFC and within the SNBTS more generally, there was knowledge of the clinical trials going on with the 8Y product in England. Further, the development of the Z8 product, obviously known

---

[1965] Penrose Inquiry transcript for 7/12/11 (day 74); 54 (15 to 25) (Dr Perry); [PRSE0006074_0054]
[1966] Penrose Inquiry transcript for 13/10/11 (day 54); 120 (3 to 4) (Professor Ludlam); [PRSE0006054_0120]
[1967] Penrose Inquiry transcript for 13/10/11 (day 54); 119 (14 to 23) (Professor Ludlam); [PRSE0006054_0119]
[1968] Penrose Inquiry transcript for 13/10/11 (day 54); 130 (18 to 23) (Professor Ludlam); [PRSE0006054_0130]

about at the PFC played a part in the need for the supply to be accessed (see below and as the correspondence between Dr Perry and Dr Boulton demonstrates). A more reactive, cautious, cohesive and patient-orientated system with clear information sharing mechanisms would have been reasonable and would have assisted. This was a particularly the case as another mild patient in the RIE was infected on first infusion early in 1986.[1969] This could and should have prompted investigation into a safer supply of 8Y ad also safer systems of treatment of uninfected patients. A further supply of 8Y from Newcastle.[1970] This would tend to suggest that the supply was not as difficult to obtain as has been suggested by some.

4.295 There is no evidence that the possibility of swapping a quantity of the then current SNBTS factor VIII concentrate for a small quantity of English 8Y was considered. The available supply of 8Y in England was not sufficient to meet the treatment of all English patients.[1971] The Inquiry has, however, heard evidence that the English and Scottish manufacturing centres worked in close co-operation with one another and there were precedents for "mutual assistance".[1972] The HIV safe NY could have been offered and supplied to England (as unheated PFC factor VIII had been in 1984 at a time of surplus[1973]) for the treatment of those who were already infected with NANBH, ie more severe patients. In return, a supply of 8Y could have been used for those whom it could save, is the probably uninfected group.

Availability of Z8

[1969] HSOC0011756

[1970] PRSE0001806 – 24 July 1987, procurement of another 30 vials from Newcastle by the Edinburgh centre; see also May 1988 - PRSE0004751– Letter about 8Y supplies from Ludlam to Boulton

[1971] Penrose Inquiry transcript for 13/10/11 (day 54); 130 (6 to 7) (Professor Ludlam); [PRSE0006054_0130]

[1972] Penrose Inquiry transcript for 7/12/11 (day 74); 66 (7 to 17) (Dr Perry); [PRSE0006074_0066]

[1973] CBLA0001850 – 8 June 1984. Perry to Pettit on agreement reached by Dr cash and Dr Lane to supply England with excess Scottish stocks of factor VIII and CBLA0001882 (September 1984) – turns out to be 2.135 million units for the quarter or around 8,320 vials

4.296 In his Penrose evidence, Dr Perry clarified that the intention was that that the SNBTS product (Z8) would be used from that time for both virgin and minimally treated patients.[1974] An "eleventh hour problem" was encountered with freeze drying the new product in around August 1986.[1975] By 22 December 1986, Z8 (dry heated at 80°C for 72 hours) was issued to Edinburgh for clinical trial.[1976] We would submit that it is likely, as was anecdotally described by Professor Colvin at Penrose, that in rare situations, small supplies of new products might be made available.[1977] This should have been done as a matter of urgency and supplies for clinical trial been made available for virgin and minimally treated patients around Scotland. 8Y should have been secured for such patients while Z8 was being finalised.

4.297 As far back as May 1983 in a memo from John Watt to Dr Foster referring to overriding concern leading to experimentation with heat treatment to that point having been to try to eradicate hepatitis from SNBTS products, the strategy to that point had been to benefit mild and moderate haemophiliacs in the foreseeable future as severe patients would already be infected.[1978] The plan at that time had been that 30% of the concentrate produced would be heat treated as this was the amount of the total which the mild and moderate group would need. A safe Scottish factor VIII concentrate did not actually become generally available until April 1997. In a document entitled 'The Development of Hepatitis-Safe Factor VIII Concentrates by the Scottish National Blood Transfusion Service" (by Peter Foster dated 9 February 1999), it was pointed out that Scotland was believed to be the first country in the world to be able to provide sufficient hepatitis safe factor VIII for all of its patients with haemophilia A.[1979] It would appear that at some point over this period, the focus of the PFC changed from being on producing a safe product for a minority of the patients (predominantly virgin and minimally treated patients) for whom it was likely to be of help to producing a quantity of product

---

[1974] Penrose Inquiry transcript for 7/12/11 (day 74); 24 (15 to 19) (Dr Perry); [PRSE0006074_0024]
[1975] PRSE0002591
[1976] PRSE0004776
[1977] Penrose Inquiry transcript for 7/12/11 (day 74); 98 (11) to 99 (2) (Professor Colvin); [PRSE0006074_0098 to 0099]
[1978] PRSE0001111
[1979] PRSE0000131_0003

sufficient to meet the needs of all haemophilia A patients. Though a genera release was a laudable ambition, it failed to appreciate (as had been sent out in 1983) that a limited supply would meet the most pressing need.

4.298 The haemophilia directors were in close contact with one another. They met regularly at conferences, meetings of the reference centres directors and the regular directors group. They had regular access to and contact with Dr Craske, who attended the directors' meetings and was part of the hepatitis working party of the UKHCDO. They had regular contact with English directors whose patient were being tested as part of the clinical trial. Information could have been shared about its progress in the interests of patient safety. Staff at the PFC (including Dr Perry and Dr Foster) boasted about their close working relationships with the staff at BPL, in particular with Dr Smith who had worked at the PFC previously and who was at the forefront of the 8Y development project. The impression given by all of the relevant witnesses at the inquiry was one of cohesion across the NHS. This system failed. All or any of these individuals could have access information about the apparent safety of 8Y. Arrangements could and should have been put in place to allow a small supply for to meet the needs of untreated or minimally treated patients in Scotland. These patients were the priority over those in England and elsewhere in the UK who had been treated with concentrates before (a) continue to be treated mostly with commercial concentrates anyway over this period and (b) were probably already infected with HCV, irrespective of their treatment regimes. As the systemic issues evident from Mr Wright's case and the lack of clear thinking when supplies of 8Y were eventually secured about the patients whom it could help show, nobody thought about the need to protect these patients as a priority. The UKHCDO guidelines for treatment remained those which had been promulgated in December 1984 and which were related primarily to the protection from the threat of AIDS. The opportunities to procure a safe supply were missed. Even when a supply was procured, it was not made available widely enough. The pool of patients whom it could have protected was never clearly defined. It could and should have been.

4.299 A supply of 8Y could and should have been procured. Patient could have been made part of the 8Y clinical trial or the product could have been made available in

the relatively small quantities which would have been necessary to provide treatment . Such treatment (according to Professor Ludlam) would only have been administered where absolutely necessary. A supply could and should have been procured in 1985 or at least early 1986 for these purposes. When it transpired that the PFC had a stock surplus in 1984, supplies of NHS factor VIII concentrate manufactured there were made in England. Practical arrangements existed already for the cross-border supply of these products.

4.300 As stated above, the failure to seek to extend information about the availability of a supply 8Y and the potential for further supplies to be sought for appropriate cases throughout Scotland was an error. Professor Ludlam felt that it was the responsibility of Dr Perry to disseminate throughout Scotland that the product was available.[1980] This sems unreasonable in light of the directors' clear personal responsibilities for product selection and use, the fact that it had been he and not Dr Perry who had instigated the 8Y request and the fact that this was in essence an assertion that the director of the PFC should have been responsible for the promotion of a non-PFC product (a role not fulfilled by the PFC staff at any other time). Dr Perry was clear that he took no steps to advertise the availability of the 8Y to centres outwith Edinburgh, or any other hospital for that matter and that he thought that Professor Ludlam would be best placed to spread that news to his colleagues.[1981] This seems entirely reasonable. As a result, Professor Lowe (for example) had no awareness of the availability of the 8Y product for use in Glasgow at any time, and certainly not in 1986.[1982]

4.301 Even within the Edinburgh centre, Professor Ludlam had no specific recollection of even telling his own staff about what it would be used for but thought that he would have done. [1983] This seems to be a wholly unreliable assertion, given the background of the infection in May 1986 and the efforts which had been put in to secure the supply. Therefore, no better system for the protection of patients like

---

[1980] Penrose Inquiry transcript for 14/10/11 (day 55); 64(5 to6) (Professor Ludlam); [PRSE0006055_0064]
[1981] Penrose Inquiry transcript for 7/12/11 (day 74); 42 to 44 (Dr Perry); [PRSE0006074_0042 to 0044]
[1982] Penrose Inquiry transcript for 11/10/11 (day 52); 46 (5 to 6) (Professor Thomas); [PRSE0006052_0046]
[1983] Penrose Inquiry transcript for 14/10/11 (day 55); 64(23 to 24) (Professor Ludlam); [PRSE0006055_0064]

Mr Wright even appears to have existed after his infection. Lessons continued not to be learned.

4.302 In the event, the first 20 vials of 8Y were used on a patient who was allergic to the SNBTS factor VIII concentrate.[1984] It is unclear of this patient was previously untreated but it seems logically impossible that he could have been. He must have previously been treated with the SNBTS product for the allergy to have become apparent. Thus, the first 40% of the supply was used for a patient who was probably already infected. A further supply was obtained by Dr Ludlam from Newcastle. Dr Perry told the Inquiry that the other 30 vials were entered into the PFC stock system and they were eventually distributed to Professor Ludlam in Edinburgh.[1985] Professor Ludlam also implied that the further 30 vials were also used in Edinburgh but he was not sure what they were used for. Professor Lowe gave evidence (under reference to the Inquiry's tables relating to product use) that no 8Y was used in the GRI.[1986]

Patients exposed to NANBH in Scotland over this period

4.303 An investigation into the failure of the SNBTS to have a factor VIII concentrate heat treated so as to inactivate the threat of NANBH over the period when 8Y was available was later instigated by then health minister Susan Deacon. That investigation is analysed in more detail in the section of this submission relating to the governmental response to the disaster below. As part of that investigation, on 1 September 1999, Dr Aileen Keel (SHHD) asked Professor Ludlam and Professor Lowe to report on numbers of patients who received first time treatment between 1 September 1985 (when 8Y became routinely available in England) and 30 June 1987.[1987] This equates roughly with the period with which this topic is concerned. These figures eventually were reported in 2000.[1988] The number of people treated

---

[1984] Penrose Inquiry transcript for 13/10/11 (day 54); 142 (1 to 12) (Professor Ludlam); [PRSE0006054_0142]
[1985] Penrose Inquiry transcript for 7/12/11 (day 74); 62 (10 to 23) (Dr Perry); [PRSE0006074_0062]
[1986] Penrose Inquiry transcript for 13/10/11 (day 54); 40 (16) to 41(1) (Professor Lowe); [PRSE0006054_0040 to 0041]
[1987] PRSE0000978
[1988] Penrose Inquiry preliminary report, para 9.326

for the first time in Scotland with a blood product during the period from 1 September 1985 to 30 June 1987 was 18 in the East of Scotland and 13 in the West of Scotland. In the east of Scotland, eight were treated with cryoprecipitate (of whom four were known to be HCV negative and four whose HCV status was unknown) and 10 were treated with SNBTS Factor VIII or IX (of whom four were HCV positive, one HCV negative and the HCV status of five unknown). In the west of Scotland, two were treated with SNBTS Factor IX and were HCV negative, one was treated with SNBTS Factor VIII and Cryoprecipitate was known to be HCV positive, one was treated with a commercial Hepatitis C safe product and the remainder (nine) were treated with Cryoprecipitate of whom three were known to be HCV positive. Evidence about the ways in which these patients were treated, their infection routes and the timing of their infections is clearly incomplete. In his oral evidence to the Penrose Inquiry, Professor Lowe added to the figure for 13 for the west of Scotland by indicating that he thought that 3 were from the GRI (adult patients) and 10 were children being treated for the first time over this period at Yorkhill.[1989]

4.304 Further evidence about the patients first exposed to treatment over this period is also available in correspondence from Dr Cacchia, former director of the Dundee centre.[1990] He identified 29 patients treated (we assume for the first time) between September 1985 and December 1987. The paper reported 6 known HCV positive patients, who come from all across Scotland. 4 of them were treated with PFC factor VIII concentrates and two with cryoprecipitate only. No information is available about the treatment histories of the 9 patients who are reported to have tested negative for HCV. For 14 of the patients no information was available at all. The evidence about the ways in which these patients were treated, their infection routes and its timing are incomplete. The up to date position of these patients is not known. Equally, the period only runs from September 1985 and not the start of the year, when we would suggest that (although 8Y could not have been made available) patient could either not have been treated or could have been treated

[1989] Penrose Inquiry transcript for 13/10/11 (day 54); 60 (8 to 19) (Professor Lowe); [PRSE0006054_0060]
[1990] PRSE0000295 (17 March 2000)

with DDAVP or cryoprecipitate instead of PFC factor VIII concentrate. The figures also do not include patients who were minimally treated and thus (on available ALT evidence and/ or epidemiological deduction) may not have been infected but became exposed to risk over this period. These numbers are thus likely to represent an underestimate of those infected and/ or unnecessarily exposed to risk over this period.

Conclusion

4.305 We represent two patients who were infected with NANB hepatitis transmitted on first infusion with an SNBTS concentrate over this period. We submit that both of their infections could and should have been avoided, had earlier and safer measures been put in place to recognise the need for treatment other than Scottish factor VIII concentrates to be given to those patients unless it was unavoidable. The patients identified above are potentially all ones whose infections could have been prevented by (a) 8Y being requested earlier and (b) more careful consideration being given to avoiding treatment with Scottish factor VIII concentrate As far as (a) is concerned, later studies confirmed that the product was indeed non-infective for NANB hepatitis.[1991] Scotland went on to develop its own product heated under the same regime (80 degrees for 72 hours), namely Z8.

4.306 As far as (b) is concerned, there is the evidence of the Thomas paper detailed above in which everyone treated with only cryoprecipitate avoided infection. All got less than 70 units. The Inquiry has evidence from Dr Hay report in the C5 section which suggests that an uninfected patient might have been likely to become infected after an infusion of around 100 units of cryoprecipitate anyway.[1992] In his evidence, Professor Lowe told us that each bag of cryoprecipitate is from a single donor but one required to pool together 20 bags

[1991] PRSE0000044 and PRSE0001077]
[1992] PRSE0003616_0022/ 0023

for the average adult.[1993] Professor Ludlam told the Inquiry that the average adult dose was from 20 donors.[1994] The amount of product which would be required would vary from case to case. Professor Ludlam expressed the view in evidence that one would be infected with NANB hepatitis after exposure to between 100 to 200 donors based on an incidence of around 1 percent.[1995] On this basis it would take 5 days of treatment to become infected.[1996]

4.307 There will be likely to be emergency clinical situations in which the infusion of a concentrate is clinically unavoidable. There will be situations where even the administration of cryoprecipitate in sufficient quantities would have resulted in infection with NANB hepatitis. However, such situations would require a sufficient amount of that product to have been administered for the value of the small pool production system to be lost and the likelihood to become that the patient would be infected. Given that virgin and minimally treated patients would be likely to be at the milder end of the haemophiliac population and consequently have higher resting factor VIII levels, it would be likely, in our submission, that they would require lesser amounts of cryoprecipitate than others to achieve haemostasis. Evidence was given by Professor Lowe to the effect that the objective in the administration of treatment would be to get the levels up to "30, 40, 50 per cent which is approaching the levels required to achieve normal haemostasis".[1997] This would be more readily achievable, the higher the resting factor level. Other virgin patients are likely to include children, for whom smaller amounts of product would be likely to be required to achieve haemostasis anyway. In our submission, a significant number of infections could and should have been avoided over this period.

4.308 In particular, on the evidence available of which we are aware the earliest virgin infection within this period occurred in May 1986. It is, in our submission, it is likely that had proper measures (as detailed above) been taken in response to the fact

---

[1993] Penrose Inquiry transcript for 13/10/11 (day 54); 65 (18 to 19) (Professor Lowe); [PRSE0006054_0065]
[1994] Penrose Inquiry transcript for 13/10/11 (day 54); 136 (8) (Professor Ludlam); [PRSE0006054_0136]
[1995] Penrose Inquiry transcript for 13/10/11 (day 54); 133 (5 to 7) (Professor Ludlam); [PRSE0006054_0133]
[1996] Penrose Inquiry transcript for 13/10/11 (day 54); 136 (10 to 14) (Professor Ludlam); [PRSE0006054_0136]
[1997] Penrose Inquiry transcript for 13/10/11 (day 54); 26 (12 to 14) (Professor Lowe); [PRSE0006054_0026]

of that infection, further infections over this period could and should have been avoided.

Conclusions

4.309 There was a failure to ensure that clinical decisions about the treatment of virgin or minimally treated patients (mild or moderate) were taken by those with the greatest knowledge of the risks inherent in the alternatives. Early warning systems designed to achieve the involvement of those with greatest knowledge at the earliest stage possible in such decision making did not exist, though they would have been relatively easy to institute given the small numbers of such patients likely to present for treatment. Such strategies as did exist, such as the standing instruction in Glasgow aimed at treating mild patients with DDAVP, seem to have been ineffective.

4.310 There was a complete lack of government involvement in providing any assistance, facilities or guidance at this time. This was not a matter which appears to have been discussed as an issue arising in haemophilia care with SHHD, despite his knowledge of the risks of viral transmission associated with the use of factor concentrates in the treatment of bleeding disorder patients. Lord Glenarthur on arriving in the Scottish office as health minister in charge of SHHD in 1986 appears to have taken no role in this area. This is despite the fact that he had been the minister responsible for blood and blood products who had been at the front line of the DoH's handling of the AIDS crisis as a junior minister at that time.[1998] In his evidence, he seemed completely oblivious of this issue. There was a complete failure of system (medical and governmental) to recognise the risks which existed after the advent of an HIV-safe factor VIII concentrate in Scotland in December 1984.

[1998] IBI transcript for 23/07/21; 155 to 156 (Lord Glenarthur)

4.311 Focus on the provision of a factor VIII concentrate for general use by the whole haemophilia A population (a consistent boast by the SNBTS/ PFC) indicates a lack of appreciation that, by this time, the primary focus should have been on producing a volume of a virally attenuated product which could assist the groups most in need, namely mild and moderate patients. No consideration appears to have been given to reducing the exposure of more severe patients either. The issue of what information was shared with patients over this period is expanded upon below.

4.312 The medical profession should have procured a supply of 8Y for patients who could have been saved from inevitable infection and whose treatment with a factor concentrate as unavoidable. It was or ought to have been known that it was safe, increasingly so as this period progressed. Access to a supply was achieved easily when it was requested, both through the SNBTS/ PFC route and through the haemophilia centres. Informal product swaps to meet local treatment priorities were not unknown – Dr Ludlam had been swapping products with Dr Mayne in the early part of the decade. If this has been clearly identified as a treatment policy, this could have been achieved. If the government had made itself aware of the issue, or been so advised (which it was not), assistance at government level could have assisted with that process, had that assistance been necessary or useful.

4.313 There should have had clear guidance in primary care and in admitting hospital departments about the need to get expert input into the treatment decisions for these patients. No effective system of this nature existed anywhere in Scotland.

4.314 The continuing focus on concentrates even after the horrors of the HIV infections from domestic products from December 1984 showed that the prevailing attitude towards the treatment patient continued to pay inadequate attention to the need for safety.

4.315 In the section below relating to research a submission is made about the effect of the lack of candour between clinicians and patients about the precise circumstances of their infections and the reasonable suspicion which resulted, when patients found out about their value as previously untreated patients, as to the propriety in the doctors' motivations in treating them. These two factors combined to leave patients with the reasonable and honest belief that they may

have been treated with products which carried unnecessary risk of infection due to the fact that the clinicians responsible for their care was more interested in ascertaining the valued results of their reaction to the product in terms of its infectivity with disease than revising them with the best treatment available based on their informed consent, in light of the risks and benefits of all reasonable alternatives. It is submitted that those from the previously untreated or minimally treated groups who were infected in Scotland in this period are perfectly entitled to have held this suspicion. Their infection with NANBH as a result of their treatment over this period would not have happened elsewhere in the UK and should not have happened due to the availability of less risky treatments. The failure of the system to identify their particular risk and treat them accordingly was a failure of system. The fact that they appear not to have received a clear explanation of the circumstances of their infections for many years compounded the harm they suffered and gave rise to reasonable suspicions and the motivations of their doctors. They were unnecessarily harmed and that harm was unnecessarily compounded.

5. Information provided to patients and parents about the risks of treatment

General

5.1 This section of the submission is intended to assist the Inquiry in its requirement specifically to consider the issue of consent, pursuant to Term of Reference 6. Issues relating to information sharing with patients in particular periods are addressed in specific detail below. The ethical obligations and the duty to promote patient autonomy at the time and now in this regard are set out above. They are of particular practical significance in the current day NHS, in particular in light of the Supreme Court decision in *Montgomery.*

5.2 The lack of information provided to patients about the risks inherent in their treatment is symptomatic of what is often described as a "paternalistic" approach to medicine. At the outset, we do not agree that this term appropriately describes the attitude of decision being made for the patients. "Paternalistic" implies a fatherly, loving, supportive attitude of a trusted advisor motivated only by the interests of the patient. We do not agree that this euphemism is an appropriate adjective to describe much of the attitude which has been demonstrated by evidence heard by the inquiry. Emphasise that also heard evidence of good treatment – serves only to illustrate that this was not impossible but a choice, inappropriately and at times unethically made by the treating doctors.

5.3 It is also clear that what information should be provided about the advantages and risks of products required to be measured against the timing of the proposed treatment. Even in the most general of terms, the risks of different treatment varied over time, as did the benefits. These were variable factors depending on various moveable factors such as the purity of the product, the availability or imminent availability of safer products, as well as factors relating to the patient such as their age, type and severity of bleeding disorder, attitude to risk and many other factors. The variability of the risk/ benefit profile at different times and the variability of factors relating to the individual mean (a) that it was essential that the advice and position on consent was reviewed regularly, in light of developing information about risk and (b) it was essential that for the consent to be informed, the patient and/ or their representative required to be involved in the decision-making process. Though these considerations applied also to proposed treatment by way of blood or blood component transfusion (as is addressed below) the chronic nature of bleeding disorders merely increased the need for patient participation and the need for a strong partnership-based working relationship between the clinician (or more accurately the team of clinicians) and the patient/ patient representative.

5.4 The evidence available to the Inquiry shows that (as was the case in other areas) the inclination of the part of medics not to provide information to patients or their representatives about the risk inherent in treatment had become a matter of culture, endemic in a system which appeared to pay little regard to the

fundamental right of the patient to autonomy in his or medical treatment. What was termed "paternalistic" was deemed to be in the patients' best interests, the "doctors knows best" attitude confusing knowledge and learning with rights to invade the body of another person. This cultural philosophy led to an attitude that certain practices about which the Inquiry had heard volumes of evidence were acceptable, such as the practice of assuming that when a patient held out his arm to give blood for one purpose, such as the monitoring of factor levels, the doctors had the right to do what he or she wanted with it. The very act of participating in the medical treatment process was deemed to be a surrendering of autonomy. This was the fundamental error of the profession. Just because this approach was widespread did not and does not make it a reasonable one. The fact that things had become common practice was confused with that practice being morally or ethically acceptable. Because doctors did not, in fact, not respect the autonomy of patients was not a justification for their inference with that fundamental human right. That the approach to patient autonomy had become institutionally divorced from this human right is demonstrated in early material available to the Inquiry. The investigation of the Rosenheim group into the dangers posed by HBV, in particular in the setting of hospital renal units is discussed in some detail above. At one meeting of the advisory group in 1971, an analysis was undertaken of the risks posed by the virus in such settings. Various preliminary information about the risk, including the public health risks, the implications of testing and preventative measures were discussed. The meeting was attended by senior government advisors as well as key members of the transfusion community at the time. Though the risks were clearly characterised as serious, the meeting records that the general view of the physician members of the group that patients should not be informed about the risks.[1999] The culture at the time was that patients need not be bothered about such matters. Government had no contrary view. Like so many issues with which the Inquiry is concerned, this context is important. As with the practice of the collection of blood, the backdrop to the infections in the 1970s and 1980s is instructive in providing information about systems which had become

[1999] DHSC0000114_0006 (11 January 1971)

institutionally fixed and not challenged, such as the practices relating to donor exclusion. Similarly, knowledge about risks in this period required detailed consideration of the context. In the area of patient autonomy also, the context is important. At the start of the 1970s, as this minute shows, patient engagement in decision making was institutionally absent. That this was the case was absolutely wrong.

5.5 The evidence available to the Inquiry is to the effect that little if anything had changed by the time of their infections with which this Inquiry is concerned in the 1980s and into the early 1990s. By way of example, an analysis is presented above about the particular considerations which applied in the period between 1985 and 1987 when no HCV-safe factor VIII concentrate was available in Scotland. The Inquiry has no evidence that any specific information was given to virgin or minimally treated patients over that period about the particular risks inherent in treatment for their bleeding disorders, in particular about the high probability that they would be infected with a potentially lethal disease if treated with SNBTS factor VIII concentrate. The Inquiry has no evidence that these patients were involved in treatment decisions, despite the almost inevitably severe consequences of certain decisions being taken. In his evidence to the Penrose Inquiry, Professor Thomas expressed the view that patients would have to be told at that time about (a) the fact that of treated with a concentrate they would probably develop NANB hepatitis and might go on to develop cirrhosis[2000] and (b) the different treatments which might be available to them, especially in the case of mild patients[2001]. Then current UKHCDO guidance (considered in more detail above) contained no suggestion that patients should be given this information. In response to questioning about information given to patients or parents about first infusions, Professor Ludlam pointed out that they would have given leaflets to patients after they had received their treatment. Even if this were true (and there is no evidence other than his assertion that it is), he was forced to accept this

[2000] Penrose Inquiry transcript for 11/10/11 (day 52); 141 (23) to 142 (2) (Professor Thomas); [PRSE0006052_0141 to 0142]
[2001] Penrose Inquiry transcript for 11/10/11 (day 52); 141 (12 to 17) (Professor Thomas); [PRSE0006052_0141]

measure was *post hoc*.[2002] Despite the clear foreseeability of the risk to these patients, no system of advice about risks, benefits or reasonable alternatives or patient participation in decisions about their treatment appears to have existed.

5.6 Elements of the decision-making and treatment regimes of the Scottish haemophilia centres which have been discussed in detail above were not conducive to the proper functioning of a consent-based system of care. These included the culture of paternalism which is referred and the culture of treatment decisions being made by a single centre director as opposed to on a more corporate basis within the centres. Consultants (for example Dr Willoughby and his successor Dr Hann) were stretched very thin and relied on junior staff to see patients regularly, making regular dialogue between the patient and the decision-maker about treatment based on developments in risk and benefit hard to achieve. Many (like Dr Ludlam, Dr Forbes and Dr Lowe) also had significant laboratory and research commitments, as well as commitments to national committees and other bodies and conferences, which kept them away from patients. This system led to patients being allocated with treatment regimes fixed by their consultant-director whom they did not see. This was not a system which was conducive to an ability to advise and adapt treatment regimes according to the rapidly changing parameters of the period (both with regard to risk and product development), far less effective dialogue and patient involvement in deciding upon those regimes. The movement towards home treatment and, in places, prophylaxis further diminished the opportunities for up to date, patient orientated advice and decision-making. The control exercised by the five national centres over large geographical areas meant that regimes were fixed but not delivered in the same place across much of Scotland. As is discussed above, in places product availability was a matter largely beyond the knowledge and control of the patients. Reference is made to the analysis above of factors over which patients appeared to have no control but which had an effect on the treatment which they had – for example, the constant strain placed on the blood collection services by Dr Ludlam's unquenchable concentrate expansion policy, the limited

[2002] Penrose Inquiry transcript for 13/10/11 (day 54); 163 (21 to 23) (Professor Ludlam); [PRSE0006054_0163]

expertise available in centres like Dundee, the commitment to Armour products at Yorkhill and the haphazard nature of product availability at the GRI, as described by Professor Forbes.

Evidence about information about risks of hepatitis – the bleeding disorder community

5.7 The consistent position of patients or their families was that the patients were not informed of the risks of infection from the products they were receiving for their bleeding disorders across Scotland.[2003] It is unclear whether there is any real intention on the part of the medical profession to seek to refuse these claims, which have been made in respect of all risks of infection by almost every witness who has passed comment on the subject. If so, it should be observed that there was rarely if ever any evidence of consent to treatment being recorded in notes.

5.8 However, in response to these universal claims, in very general terms, Professor Lowe gave evidence to the Penrose Inquiry to the effect that it was very much part of the unit policy at the GRI to discuss the risks of NANBH with the patients, though this evidence was related to the period discussed above between 1985 and 1987 when HCV safe factor VIII concentrated were not available in Scotland.[2004] Even in emergency situations, he was of the view that it would be a bad doctor who did

---

[2003] Eg see WITN2665001, para 8 (first statement of Linda Grigor, widow of co-infected Edinburgh cohort patient); WITN2677001, paras 5 and 8 (first statement of Agnes McNeish, widow of co-infected Edinburgh cohort patient in which she references the practice of Dr Ludlam to make sure Edinburgh patients were kept on PFC factor VIII if they left Edinburgh, as US products came from drug addicts, a comparative assurance of safety); WITN2203001, para 6 (first statement of WITN2203 – Edinburgh); WITN2233001, paras 5 and 6 (first statement of Steven Newby, whose parents were taken to court to ensure his continued use of blood products in the late 1980s, on the advice of Dr Ludlam and contrary to their religious beliefs); WITN2317001 @ para 8 (first statement of WITN2317 - Edinburgh); WITN2306001 @ para 5 (first statement of Hugh MacInnes – Inverness); WITN2083001 @ para 5 (first written statement of William Barry - Dundee); WITN2091001 @ para 6 (first written statement of WITN2091, not an anonymous witness but identity protected to protect others – widow of haemophilia B patient treated over many years in Dundee with plasma and factor IX concentrate); WITN4183001, paras 4 and 5 (first statement of Joseph Monaghan – no advice given of risk to factor VIII concentrate treatment in young child who was a mild haemophilia A patient at GRI in 1984); WITN2119001 @ para 7 (first statement of John Dickson - Yorkhill); WITN2149001 @ para 7 (first statement of WITN2149 – no information about risks or alternative to parents at all, including of risks associated with the use of US concentrates heavily involved in home prophylactic regime);

[2004] Penrose Inquiry transcript for 13/10/11 (day 54); 24 (9 to 12) (Professor Lowe); [PRSE0006054_0024]

not discuss with the patients the pros and cons of the different treatment options with an untreated or minimally treated patient.[2005] This was a clear recognition that is was a duty incumbent upon doctors, expect where to do so was not possible or clearly not in the interests of the patient, to discuss the risks of treatment with the patient or, where appropriate, the patient's representative. The evidence as to whether this happened on the evidence is discussed below.

5.9 In Edinburgh, the long history of reliance on locally produced cryoprecipitate under the treatment regime of Dr Howard Davies lasted until his departure in 1979. His replacement by Dr Christopher Ludlam led to a significant change in treatment regimes, as is examined in detail above, involving a huge expansion of reliance on factor concentrates (initially based on an expansion in the use of commercial concentrates) and home treatment. The consistent position of patients or their families was that the patients were not informed of the risks of infection from the products they were receiving in Edinburgh.[2006] Dr Brian McClelland described that the bleeding disorder patients treated by Dr Ludlam as "jealously guarded" by him.[2007] This indicated that he wished to exert a degree of control over them but also that they relied on him and him alone for information about the risks of the products. Particular themes which emerged as to the standard approach taken by Dr Ludlam and his staff included that patients were

---

[2005] Penrose Inquiry transcript for 13/10/11 (day 54); 31 (22 to 23) (Professor Lowe); [PRSE0006054_0031]

[2006] Eg see WITN2665001, para 8 (first statement of Linda Grigor, widow of co-infected Edinburgh cohort patient); WITN2677001, paras 5 and 8 (first statement of Agnes McNeish, widow of co-infected Edinburgh cohort patient in which she references the practice of Dr Ludlam to make sure Edinburgh patients were kept on PFC factor VIII if they left Edinburgh, as US products came from drug addicts, a comparative assurance of safety); WITN2203001, para 6 (first statement of WITN2203 – Edinburgh); WITN2233001, paras 5 and 6 (first statement of Steven Newby, whose parents were taken to court to ensure his continued use of blood products in the late 1980s, on the advice of Dr Ludlam and contrary to their religious beliefs); WITN2317001 @ para 8 (first statement of WITN2317 - Edinburgh); WITN2306001 @ para 5 (first statement of Hugh MacInnes – Inverness); WITN2083001 @ para 5 (first written statement of William Barry - Dundee); WITN2091001 @ para 6 (first written statement of WITN2091, not an anonymous witness but identity protected to protect others – widow of haemophilia B patient treated over many years in Dundee with plasma and factor IX concentrate); WITN4183001, paras 4 and 5 (first statement of Joseph Monaghan – no advice given of risk to factor VIII concentrate treatment in young child who was a mild haemophilia A patient at GRI in 1984); WITN2119001 @ para 7 (first statement of John Dickson - Yorkhill); WITN2149001 @ para 7 (first statement of WITN2149 – no information about risks or alternative to parents at all, including of risks associated with the use of US concentrates heavily involved in home prophylactic regime);

[2007] IBI transcript for 27/01/22; 134 (Brian McClelland)

told that the products were **safe** as they were made from voluntarily donated blood from Scotland with the result that patients would not be exposed to risks of which they had heard emerging abroad.[2008] One patient described how he was restrained as a child to receive his factor treatments in the Edinburgh unit in the 1970s and early 1980s, which he described as assaults. The restraints themselves caused further bleeding which then required further treatment.[2009] This resistance was based on a fear of infection as well as religious objection to being given the treatment, which he was forced to do.

5.10 The fact that in the period after the arrival of Dr Ludlam at the Edinburgh centre there was a propensity to treat with concentrates without questioning sufficiently whether that treatment was necessary or appropriate given its infection risks is also seen in evidence of those suffering from haemophilia B. One patient who was GRO-D GRO-D[1] No explanation of any alternatives is notes either, which in a mild patient (whose haemophilia was predictable as it ran in his family) he could have been treated differently, with FFP to minimise the infection risk.

5.11 The Inquiry has heard an overwhelming body of evidence from patients who were treated for bleeding disorders in Scotland, from representatives of deceased patient and from parents of such parents or their representatives that information about the benefits of certain treatment regimes was generally provided to patients or parents (as appropriate) but that information about the risks inherent in the products being proposed for use was routinely not so provided. This was unethical, even at that time (as is set out above).

5.12 Professor Ludlam attempted in his evidence to balance irreconcilable positions relating to the right of the patient to take an active part on choosing his treatment.

[2008] WITN2203001, para 4 (first statement of WITN2203)
[2009] WITN2233001, paras 14 and 39 (first statement of Steven Newby)
[2010] GRO-D
[2011] GRO-D

On the one hand, it is submitted that the standards of the time required that the patient have the right to give informed consent to treatment. This is analysed above but the materials below vouch this proposition.[2012]

5.13 Professor Ludlam accepted the ethical advantages of this position by agreeing that but claimed that that modern medical practice has benefitted greatly from listening to patients and their families[2013] but by attaching the caveat that there existed a right in the clinicians to decide when it was "appropriate" for the patients to have that right.[2014] By caveating his position as he did, he seemed to suggest that it was up the clinician to decide when it was "appropriate" for the patient to be involved in decision making and hence attempted to place a caveat on the patient's right to autonomy. This was, in our submission, a flaw in his position which was inconsistent with the ethical requirements of the day. The normative standard was that the patient had the right to know expect where to know would be harmful to him. The fact is that the evidence clearly shows that patients did not, in his unit, have the opportunity to give informed consent to their treatment. His norm was that patients did not know. He had decided that they would have the aggressive treatment regimes which he instituted. He presided over the vulture whereby doctors simply reached for a factor concentrate, whereby in most cases it was simply the medicine which was prescribed for the condition of haemophilia. By abrogating to himself an inappropriately wide right to determine when it was appropriate for the patient to be involved in choosing his treatment, Professor Ludlam had set up a system which did not accord with the contemporary standards. He also referred to risk reduction measure in this regard including collaboration with patient and groups and societies. As is submitted above, this was not an acceptable proxy for the patient's individual right to choose. He

---

[2012] 1 October 1981 – the Declaration of Lisbon - right to refuse or accept treatment based on adequate information); BMAL0000085 (1970); BMAL0000082 (1972); BMAL0000086 (1974); BMAL0000085 (1980), para 12 *"It has **long been accepted**, and is well understood within the profession, that a doctor should treat a patient only on the basis of the patient's informed consent."*

[2013] Para 550 of first witness statement of Professor Ludlam at WITN3428001

[2014] Para 170(c) of first witness statement of Professor Ludlam at WITN3428001

provided no written evidence to support any claim that patients or societies received information about the risks or benefits of treatment or reasonable alternatives to factor concentrates or programmes in which they were used, either generic or individual. No such information was provided to support any claim that patients were provided with any information about the risks of hepatitis or AIDS, the likelihood of them being transmitted or the possible consequences of they were. No information was provided to support any contention that Edinburgh patients knew about the immune function studies, their purpose or had a right to exercise any control over that process from 1983. No such material was provided from any centre in Scotland over the relevant period. In Edinburgh, the evidence available to the Inquiry is that patients were generally told in the unit which Professor Ludlam was in charge that the products were local and safe and so safe to be taken in any quantities. The fact was that Professor Ludlam also had HIV positive patients under his care before many of his haemophiliac patients became infected. In addition to the late husband of Mrs U, it seems that he also had a female patient who was infected with HIV from a transfusion.[2015]

5.14 The 1 May 1988 GMC guidance on AIDS stressed the importance of honesty at root of doctor/ patient relationship.[2016] This had always been at the root of that relationship. There was simply no such honesty and so this relationship was undermined from the start. By the time of the Pandora's box letter of June 1987 about giving patients the choice on having a patient information leaflet[2017], Professor Ludlam seemed to want patients to be given the information they had not routinely been given before. In one letter he highlighted the importance of patients being given leaflet for new product and having APBI cover for its use.[2018] Similarly, he said in 1987 that "Disquiet and suspicion arises when patients feel they are not being fully informed".[2019] This can be contrasted with his routine

---

[2015] see WITN4096001, statement of Alison Richardson at para 13

[2016] PRSE0003932

[2017] PRSE0000866

[2018] PRSE0000184 – letter from Ludlam to McIntyre in July 1987

[2019] LOTH0000010_028 (6 July 1987) – letter to SHHD on the same subject

position earlier than that. At that time, he continued to perform and publish research on patient without their knowledge. His attitude to clinical trial compensation (addressed below) was based on self-exoneration. This was also his motivation in connection with the litigation around the same time. He as keen in 1989 to avoid the possibility of litigation against you and others and hance was keen to see an early settlement of the actions. He recognised that patients were reluctant to take actions (which you proposed should be settled) as they had an ongoing requirement to dependent on the haemophilia doctors.[2020] By that point you had been instructed as an expert witness for the DoH.[2021]

5.15 Professor Ludlam was on the UKHCDO hepatitis working party and was thus privy to all of the emerging information about AIDS from Dr Craske.[2022] He had attended the Immuno meeting at Heathrow in January 1983.[2023] Thus, he had since that time been aware of the information presented by Dr Craske including the clinical definition of the syndrome, 45% mortality, the fact that all cases in US have prolonged treatment with factor VIII concentrate and that no specific batch was involved, that it had also been associated with blood transfusions, had an incubation period 6 months to 2 years, that there were one or 2 cases in UK and the contents NEJM articles discussed. Nothing in his presentation had suggested any cause other than infectious agent or agents. He later expressed the view that it had been reasonable to assume in mid 1983 that AIDS caused by transmissible agent[2024] yet none of this was communicated to the patients. He was aware of the limitations of steps being taken to prevent transmission. He had attended a meeting of haemophilia and blood transfusion working group in March 1983 at which AIDS was discussed – you are in attendance. He knew that the transfusion directors were loathe to ask questions to which exception could be taken by

---

[2020] LOTH0000069_021 (29 November 1989) - Letter from C. A. Ludlam, The Royal Infirmary of Edinburgh to Dr. Robin Cook, House of Commons

[2021] LOTH0000069_022

[2022] HCDO0000273_079 (11 May 1982) - Working hypothesis that the AIDS had been transmitted in the incubation period via factor VIII or IX and that assume that there will be more cases in the severe haemophiliac population

[2023] PRSE0002647

[2024] PRSE0000332 – Ludlam report to the HIV litigation, page 23

potential donors but it was **hoped** that homosexuals would not donate blood.[2025] He had attended the meeting of the hepatitis working party of the UKHCDO meeting of 14 September 1983, where the Fletcher paper was discussed which revealed 100% transmission of NANBH from commercial or NHS concentrates No information about the cumulative risks or alternative treatments was communicated.[2026]

5.16 In her evidence to the Penrose Inquiry Dr Vivienne Nathanson stated that:

"While some doctors and some practices worked in ways which would fit with current day expectations, this was far from always the case. It is fair to say that the change from an essentially paternalistic, doctor-knows-best culture to one which the patient is at the centre of medical practice and his/her empowerment an essential element of the relationship between patient and doctor, has evolved at different rates in the practice of different doctors. The earlier the time frame under consideration the commoner an essentially paternalistic approach would have been. Changes have occurred following clear expositions of good ethics, and supported by case law, education, and in particular training in communication skills to enable doctors to communicate with patients and their relatives in a sensitive and nuanced manner". [2027]

5.17 There is simply no reason why ethical practice could have justified the approach which was described and clearly the basis of so much of the way that doctors approached warning patients of the risks from hepatitis of their treatment with blood or blood products over the period with which the Inquiry is concerned. The progression of the availability of information about the risks of transmission of

---

[2025] PRSE0000728 – 22 March 1983

[2026] PRSE0000879

[2027] PRSE0003970_0001 (statement of Dr Vivienne Nathanson to the Penrose inquiry)

hepatitis (in the form of HBV and later NANBH) is described elsewhere in this submission. Patients and/ or their representatives ought to have been aware of the risks and been involved in decision making, updated as that knowledge developed.[2028] The lack of such information being provided to them create a dehumanising effect. In addition, the requirement to make clear notes of the risks described would have strengthened the obligation to provide the advice in the first place. Advice required to be in terms which patients and/ or their representatives understood to enable them to make informed decisions about what was happening to them.

Evidence about information about risks of HIV/ AIDS – the bleeding disorder community

5.18 The clear and consistent evidence available to the Inquiry from the infected and affected community across Scotland was that patients who were being treated for bleeding disorders in the first half of the 1980s received no or inadequate information about the risk that they may be exposed to the agents which was causative of AIDS from their treatment. the information which was or should have been available to their clinicians in this regard from late 1982 and early 1983 at the latest and increasingly so between 1983 and 1984 is discussed in detail above. As is discussed elsewhere in this submission, patients in Edinburgh and Glasgow were (unknown to them) involved in published studies about the possibility they would or may already have contracted AIDS. The work leading to the 1983 publication by Ludlam et al in The Lancet about immune function in haemophiliacs was internally referred to as the "AIDS study". The possibility that at least some of the Glasgow patients' immune deficiencies may be attributable to having already been infected/ already having AIDS was expressly acknowledged in the paper. The leaders of the profession in Scotland were located in these two reference centres. In fact, multiple patients at Yorkhill were already infected by 1983 and the first

[2028] Penrose Inquiry transcript for 13/01/11 (day 84); 2 (10 to 14) (Dr Vivienne Nathanson); [PRSE0006084_002]

infection from domestic concentrate had occurred in 1982. The clear evidence heard by the Inquiry is that patients and their parents were completely unaware of the risk.

5.19 It follows from the fact that the risks of transmission of the agent causative of AIDS was not discussed with bleeding disorder patients or their representatives that reasonable alternatives were not discussed. What these reasonable alternatives might have been are discussed elsewhere in this submission but they would have included adaptations to lifestyle to minimise the risks of bleeds, minimising the amount of concentrate to which the patients was exposed, postponement of elective surgery, greater use of cryoprecipitate and in appropriate cases DDAVP. The risk of transmission from blood products (domestic and imported, respectively) as well as the likely difficultly of detection of the causative agent due to the known lengthy prodromal phase and the likelihood that if AIDS were contracted it would prove fatal all required to be discussed openly and honestly with patients. These alternatives and risks were clearly not generally discussed. As such patients could not have given their informed consent to any treatment.

Role of the PFC

5.20 Dr Perry prepared a paper for the Penrose Inquiry outlining the content of package inserts included with PFC products. No specific warning of the risk of infection from AIDS/ HIV from SNBTS products was included until 1985.[2029] From April 1985 the leaflet issued with the NY product stated that it was heat treated but could not be assumed to be "non- infective". There was no specific reference to AIDS or HIV until heat-treated DEFIX was issued routinely in September 1985. He indicated that the information provided in product leaflets, labels and packaging was primarily designed and intended for prescribing doctors. Patients were not the primary audience for the information intended. In his view discussion with

[2029] PRSE0001324

patients of the treatment options and the associated risks is exclusively the responsibility of treating doctors.

5.21 Whilst it must be correct that prescribing doctors were primarily responsible for the discussion of the risks of the products with their patients given that it was only they who had knowledge of the particular medical circumstances and characteristics of indeed access to the patient/ the patient's representative, the logic of the PFC seems flawed. In the first instance, even if the products were being supplied to inform doctors, given that the products carried a known risk (even after heat treatment) that information should have been clearly communicated for that purpose. Many doctors, in particular those outside the main treating centres or more junior doctors would have benefited from clear information to this effect. Further, that the information was only intended for doctors was a flaw in the system in itself. A large part of the purpose of the increase in the availability of concentrates was to allow more patient autonomy via home treatment. Bleeding disorders and chronic conditions. Patients and their representatives required to be highly involved in and attuned to the purposes of their treatment and hence its risk and benefits. The failure on the part of the manufacturers to instigate a mechanism whereby necessary information about risk could be communicated directly to them was simply a symptom of the system of medical "paternalism" which deprived patients of informed choice. By thinking that they required to communicate with the doctor only, the PFC was in effect depriving the patient of a role in that essential conversation. The system of Crown Immunity had resulted in there being no sanction and so not incentive to consider matters such as this proactively and in the interests of patients. Though the primarily responsibility did lay with clinicians, the PFC's failings in this regard also contributed to failures in accurate and full information disclosure to patients and/ or their representatives.

6. Commentary on patients infected and the avoidability of their infections

The "need" for blood products

6.1 It has been argued that without blood products bleeding disorder patients would have suffered significant morbidity or would have died. The evidence relating to that propositi, in particular that of Professor Charles Hay is discussed above. The evidence to this effect is weak and historic. The information upon which the argument is based is convenient to the position of the doctors, who wish to persuade the Inquiry that they had no choice but to administer products as they did. The evidence in fact shows that it as cryoprecipitate that changed the morbidity and mortality expectations and not concentrates, as evidenced by Edinburgh patients who were treated with mostly cryoprecipitate up to 1980 and the survived.

6.2 In any event, the evidence shows that there was no or little effective re-assessment of the balance between perceived mortality and morbidity advantages and risk of disease in light of emerging information about transmissibility and the mortality and morbidity risks of disease or even in light of changing pool sizes. It was not apparent that clinicians even now what the pool sizes were. In effect, the argument that these were emergency/ necessary and thus non-elective treatments, where normal considerations of ethical rules around patient choice do not apply is inappropriate and misguided.

6.3 This approach negates the element of patent personal choice, so fundamental to any ethical system of medicine. It was an abrogation of the clinician's responsibility to give advice and to let the patient choose, based on a false assertion that there was no choice. It gave no consideration to the amounts of products administered and whether an appropriate balance was struck between dangers and the use of concentrates in larger quantities. It took no account of the need to review treatment in light of emerging information about benefit and risk. It took no account of the differences between patients with different severity of disease and different priorities and views. It suggests they are all the same. It was a misguided approach which removed their humanity.

6.4 The knock-on effect which this false attitude to treatment had on the safety of collection systems means that it cannot be said that reliance on cryoprecipitate alone would have resulted in infections anyway. The reason why cryoprecipitate infections (and blood transfusion infections) occurred was that unsafe collection practices continued to be adopted when they did not need to be due to the demand for plasma to make concentrates in such large volumes, apparently based on a false assumption about its necessity at all and in such large amounts. It cannot be safely said what infections could have been avoided by an alternative course. Patients have been robbed of the right to know that. In any event, it hugely increased viral load and hence mortality and morbidity from disease.

6.5 It is a reasonable epidemiological assumption that volume of product also caused increased risk due to increased viral exposure, viral load and virus for the body to fight against. It caused things like the effects of alcohol on the liver to be magnified unnecessarily. Thus, the proliferation of the assumption that concentrates were a necessary, miracle cure which spread from this starting point about them being the saviour of the "crippled boys" led to overuse, both in the sense of being used at all in the treatment of patients for whom safer alternatives would have been appropriate and in the sense of use in the more with unchecked and hence dangerous abandon.

Mild and moderate patients

6.6 For mild and moderate patients, treatment with factor concentrates could and should have been avoided based on proper informed consent based on the limited need for treatment in their cases. Dr Walford gave evidence the Inquiry, based on her considerable experience of the risks of NANBH and HIV that for mild and moderate patients the disadvantages of large-pooled concentrates outweighed

the advantages.[2030] For such patients, their infections caused by concentrates ought not to have occurred.

6.7 For more severe patients, as submitted elsewhere in this submission, there was a need to minimise the risks of infection by limiting exposure to concentrates to the minimum necessary, until the products could have been rendered safe by heat treatment. This would have been achievable by the greater use of cryoprecipitate (frozen or freeze dried) and lifestyle advice, as well as informed consent based on the risks and alternatives. This approach would have voided the viral load for such patients avoided HIV infection.

6.8 One moderate patient who was born in 1961 and based in the Dundee area did not receive any treatment until 1990, when his haemophilia A was discovered.[2031] He was a witness in the Inquiry due to the fact that at the time of that treatment he was exposed to the risk of vCJD. His case, however, goes to show that moderate patients like him could survive without treatment (or even detection of their haemophilia) over the period during which products were infective for HBV, HCV or HIV.

7. TESTING AND RESEARCH

a) The role of research on the bleeding disorder community in Scotland – general

7.1 This section of the submission covers numerous aspects of the Terms of Reference, in particular 1, 4, 6, 7, and 9. The evidence heard by the Inquiry has demonstrated the importance of those in the bleeding disorder community to medical research into diseases, due to the fact that they were at risk of being exposed to them if being treated with pooled products. Due to the value of gauging the effects of disease in uninfected patients, the Inquiry has heard evidence of the ever increasing use of more and more mild patients in the research and its implications

[2030] IBI transcript for 21/07/21; 198 (Diana Walford)
[2031] WITN2297001 @ paras 1 to 5 (first written statement of GRO-B

for the clinical necessity of treatment being administered in clinical trials. The importance of previously untreated patients or PuPs, often children has been shown to be significant.

7.2 The importance of research in the relationship between patients with chronic bleeding disorders and their clinicians cannot be over-stated. On finding out about research of which they previously had no knowledge, the relationship of doctor and patient was further undermined.

7.3 There is evidence about the lack of involvement of the patients in research. This is despite the fact that to be ethical, patients require to be involved in research and to continue to be to be willing participants. It undermines the value of the research that patients were not willing participants in it. The Inquiry should take note of the importance of the fact that, for those treating bleeding disorders in Scotland there was a motivation for the research which they were undertaking to be done in a clandestine fashion. The reasons why this was necessary were:

(a) That the divulgence of the nature of the information which was being compiled and analysed as a result of a research study would, by its nature make the patient intimately aware of the risks inherent in the products, of which the patients (or their parents as appropriate) had generally never been made aware. The fact that tests were being conducted for the possible signs of liver and the results analysed and possibly published as of general medical value would inevitably make the patient aware of the risk that the product he was receiving might damage or had damaged his liver, a fact of which he in many cases was unaware;

(b) The value of the information which was provided would have made it immediately apparent that there was an inherent conflict in the dual role of the treating clinicians.

7.4 This analysis also explains the logical necessity for it to be generally accepted that the treatment was in all cases "necessary". If the treatment was always necessary, any ancillary medical knowledge which would flow from the analysis of information resulting from its administration either to the patient, the patient group or medical science more widely, might be argued to be justifiable. If it was necessary to administer the treatment and such information is created as a result,

why not make use of it for these purposes? If, however, as is argued elsewhere in these submissions the treatment was not necessary (at all or at least not necessary in a particular way or a particular quantity) or did not accord with the patient's view of what was necessary, the information which is gleaned and analysed as a result of its administration is not some fortunate by-product of an otherwise necessary treatment. Where there was a choice about the treatment, the value of the information gleaned from its administration becomes a factor in the analysis of the motivation of the doctor in deeming it to be necessary in the first place.

7.5 The Inquiry has heard evidence from certain clinicians that certain activities which they or others were undertaking was not research. The reason why this line of argument has emerged is an example of the *ex post facto* justification for the failure on the part of these clinicians to obtain the fully informed consent of the subjects of the study to their participation in it. The argument is that this was not "research" and hence consent was not required. This, the Inquiry requires to consider the definition of research in order to resolve the apparent dispute about whether the exercise of compiling and analysing information about those with bleeding disorders in Scotland was "research" or something else. Professor Ludlam, in particular, suggested that the (analysed in detail elsewhere on this submission) was not research but an observational study, or something of that nature. It is submitted not only that this analysis is inaccurate but that it is a deliberate *ex post facto* construct adopted by clinicians like Professor Ludlam to attempt to justify failures in past practice on his part and on the part of others. This matter was settled by a simple answer given on the subject by evidence of the expert group on ethics. In answers given by members of the ethics group, it was confirmed that to be published work would require to contain original knowledge. That was by definition research, if the work was published.[2032] This anything that was published was research. This answer is to be preferred to the approach taken by the likes of Professor Ludlam both as the answer came from an independent group but also because it clearly and logically fitted in with the reasons why ethical rules around such work exist. When there is a possibility that

[2032] IBI transcript for 27/01/21; 119 to 120 (Professor Farsides and Professor Savulescu)

information which is being gathered will be used for a research purpose other than the care of the patient, there is a risk that the care of the patient will be compromised by measures taken more in the interest of the research objective (even sub-consciously) than the pure interests of the patient. Given that risk, it is imperative that the patient be fully informed and consent to taking that risk. The patient's safety and care require to be paramount. The patient has rights in information arising from his or her medical care. The advancement of medical knowledge (the clear objective of the publication of information derived from a patient or analysis of it) is also a laudable objective. So that the latter is never able to gain priority over the former, a wide interpretation of what is considered to be research is necessary and rules require to be observed and properly enforced when information from a patient may be published to a third party for reasons not directly considered with his or her care. It is thus entirely logical, reasonable and important that any publication of any such material in any form for a purpose not directly related to the care of the patient must be deemed to be research must be covered by struct rules to protect the primacy of the patient's care and rights. It is submitted elsewhere that there is clear evidence available to the Inquiry that the research objectives of the care of certain haemophilia patients had actually become the priority of those in charge of their care, rather than merely posing the risk that they might.

Ethics committees – ethical control

7.6 The protection of the primacy of the patient also required that there be effective systems in place to ensure that research was monitored and controlled in accordance with ethical norms and the best interests of those patients. That required not only that clinicians observe ethical rules designed for that purpose (which they often did not) but that there be an effective system to ensure that they did. In this regard, there was no effective system of regulation and compliance.

7.7 The Inquiry has available to it copious evidence relating to the role of local ethics committees as being like licensing. Local committees signed things off without any real protections or investigation. Dr Ludlam did not make an ethical application for his 1983 immune function research. In later research on AIDS, it seems that his applications were signed off. These required patient consent, which was not obtained. There appears to have been no sanction for this failure. The committee simply did not check. There appears to have been a certain circulatory element to the system of ethical control, much like the licensing system. Grant giving bodies for research such as the MRC seem to have relied on the existence of ethical consent when considering the award of grants, assuming that such ethical consent was properly given and considered and that the submission upon which that had been granted would be adhered to/ regulated. The Inquiry also has evidence about local ethical consent having been granted for a national study on vCJD. It seems far from satisfactory that local consents from close colleagues can justify such major projects, in. particular where adherence to any conditions was not policed.

b) Evidence of testing being carried out on patients with bleeding disorders without their knowledge or consent

7.8 The Inquiry has access to a significant amount of evidence which shows that patients with bleeding disorders regularly gave blood. The evidence shows that it was generally understood that the giving of blood was necessary in order that the medical profession could monitor the position with their bleeding disorder. Factor levels needed to be regularly tested for that purpose. Generally, that was a matter to which consent was given. Their haematologists were there to treat their bleeding disorders. They required and were entitled to information relating to those disorders in order to provide advice and treatment. The corollary of the general failure of these doctors to provide anything more than the most general of advice about diseases which might be associated with treatment was that it became logically impossible for those doctors to seek the patients' consent in the

monitoring of the presence or severity of those diseases. To have done so would immediately have alerted the patient to the fact that the risk of the disease had not been explained properly – why would diseases need to be monitored of there was no real risk of them being transmitted?

7.9 The evidence shows that patients were in fact regularly monitored for the presence of diseases which might be transmitted by the treatment, as is discussed below. Due to the failure to discuss the risks it became commonplace for these tests to be carried out without the knowledge of the patient. The corollary of that was that a culture developed of samples being taken retained which really had nothing to do with the patients. These were kept in deep freezes in laboratories. The processes which were undertaken with them in those laboratories became activities which were generally removed from and not discussed with the patients. The lack of patient consent to the taking of these samples for these purposes created a culture whereby there would be no need to involve the patient in any decision-making about the use of those samples. it did not appear to cross the minds of the doctors who were using these samples that the tissue was the property of the patient. This, in turn, created a culture whereby these samples became, in effect, the property of the laboratory in the minds of those working with them, dehumanised substances, as if surrendered to science to be used at the whim of the scientist. This culture led to a system whereby the value of these samples became an important means by which science could use (freely given by patients who assumed that doing so was for the management of the bleeding disorder for which they were receiving treatment). Campaigners from the bleeding disorder community have described themselves as "useful material". They have done so in order to illustrate the extent to which they rightly feel dehumanised by this process. They reasonably interpret the way that they have been treated as being the guinea pigs of a medical profession, who think that they should be grateful, having (on the profession's erroneous interpretation) been saved from an early death or a life as a "cripple", the use of their material without their knowledge or consent being the price which they should pay for what they have received. The dynamics of this relationship were clearly far from being in the interests of these patients.

7.10 Generally, patients were not advised when giving blood samples what they were to be used for beyond the monitoring of their bleeding disorders or that they might be used for studies being carried out or to be carried out in the future.[2033] Consent was not obtained from patients before the results of studies were published.[2034] As a result of the lack of information some patients felt that they had been treated like guinea pigs or lab rats. It has been suggested in certain evidence to which the Inquiry has access that "blanket consent" had been obtained in relation to stored samples and hence in relation to studies which took place using them. This was simply inadequate. It represents a patient giving carte blanche to matters which he could not possibly understand and completely undermines the whole point of consent being taken at all.

Viral hepatitis

7.11 There was a value in developing knowledge about infectious diseases which was clearly recognised by government. There were potential commercial gains to be made in such work, including the development of tests and vaccines. Though the wellbeing of patients and the prevention of disease must also have been legitimate parts of the objective of government and medics involved in research, such advancements in knowledge, though generally of benefit to society as a whole, was by nature of less use to patients involved in the research who, by definition, had already been exposed to the disease. For them the risk of disease which could be mitigated by testing, vaccines or treatment had already materialised. They were providers of information, unwitting medical pioneers in the supply of knowledge which might help other, not necessarily themselves.

7.12 An a hoc meeting which took place in February 1979 led to the MRC setting up a Working Party on Post-Transfusion Hepatitis which met for the first time on 14

[2033] Penrose Inquiry transcript for 17/06/11 (day 35); 78 (8) (Professor Ludlam); [PRSE0006035_0078]
[2034] Penrose Inquiry transcript for 17/06/11 (day 35); 79 (9) (Professor Ludlam); [PRSE0006035_0079]

February 1980.[2035] Government advisor Dr Walford was a member. The group had been formed at the request of the MRC by the DHSS.[2036] The value of research into hepatitis was recognised at that time by government due to the emerging knowledge of the severity of the disease which was still transmitted by transfusion despite the use of HBV testing. The group was set up under the auspices of the MRC, which was also the group which had been involved in the formation of the UKHCDO. There was a value to the government of learning more about this disease. Space allocated for the storage of infected sera for the development of vaccines/ research into products which could be used in the prevention of viral hepatitis.[2037] It is of interest that Dr McClelland's proposal for a multi-centre study into the problem of post transfusion NANB hepatitis (see minute at page 2) deferred at this and the subsequent meeting of the group.[2038] This is the TTV study which would have been of use in analysing how surrogate testing might serve to reduce NANBH transmission, as referred to above.

7.13 There was, at least by the early 1980s, an increasing understanding of the value of haemophiliacs in the study of disease. Given the previous exposure of many to the viruses casing hepatitis in their treatment previously, this meant a move towards untreated or minimally treated patients who had a value in providing information about infectivity of the products but also the nature of the disease transmitted as the pre-transfusion non-infected state could be compared with the post-infection state to give information about the nature of the disease uncomplicated by previous exposure to viruses. The value of previously untreated patients (PuPs) for the purposes of research was clear. The emergence of their value for the testing of new heat-treated products created a greater value in PuPs and the identification maintenance and exploitation of their scientific "virginity". It is important to note that previously untreated patient is an expression which, in the context of haemophilia treatment, really only applied to hepatitis. A better expression would be 'previously uninfected" or "likely not to be infected". This is

---

[2035] PRSE0002983
[2036] Ibid, page 1
[2037] Ibid, para 5
[2038] See meeting of 25 June 1981, PRSE0004843 at page 3

important as (a) it shows that those treating the disease already recognised their patients as almost universally infected with hepatitis, at least and (b) in the context of HIV for example previously treated patients also had a value for research (like the frequently treated Edinburgh cohort) as they were thought to be likely to be uninfected. What was clear was that in the early 1980s (at the latest) the value of classification of patients based on their research value became prominent in major hospitals.

7.14 As is explored above, The minutes of UKHCDO centre directors meeting on 13 September 1982 refers to interesting results from the Craske study pointing to involving mildly affected or seldomly transfused patients at that time.[2039] A separate note of the same meeting records the Oxford data as showing that the risk of contracting hepatitis from large pool NHS concentrates was unexpectedly high.[2040] This led to the Fletcher et al paper.

7.15 The UKHCDO Hepatitis Working Party report for the year 1982/83[2041] referred to this Oxford study, started in 1981, of hepatitis in infrequently treated haemophilia patients. It was noted that the study appeared to demonstrate that the risk of contracting NANB Hepatitis from Factor VIII concentrates was 100% on first exposure, whether of NHS or commercial origin. It was noted that the problem of AIDS had overshadowed these developments – as noted above they appear not to have been viewed as predicting a cumulative risk despite the known immuno-suppressant effects of AIDS which would render the ability fight the NANBH infection less. The availability of commercial heat-treated products was also discussed. Directors required to consider the ethical problem of exposing persons with mild haemophilia to heat treated commercial material.[2042] The ethical problem was expressed as follows:

"Since the only way of ensuring the susceptibility to non-A, non-B viruses is by using patients who have not previously received factor VIII or IX concentrate, a choice

---

[2039] PRSE0004807_0010
[2040] PRSE0002638_0002
[2041] PRSE0001160 (dated 28 September 1983)
[2042] PRSE0001160_0002

will have to be made between using heat treated products from commercial sources, which might carry a small risk of AIDS transmission, or using NHS concentrate which appears to carry a 100% chance of transmitting non-A, non-B hepatitis." [2043]

7.16 In the context of the AIDS risk (or even just the hepatitis risk) PuPs should not have been receiving concentrates at all, rather than the dilemma of which concentrate (the inevitably harmful or the possibly no longer inevitably harmful) to use being the focus. By this point, a culture had developed of using haemophiliacs to gain information, either about disease or about products or both. In Scotland, this had always been the case. Patients had been tested for disease by using ALT as an indirect marker for hepatitis for years, without their knowledge. The results of that had been shared with PFC as part of the SNBTS. Now what being contemplated was a similar process – testing patients for disease with the added purpose of checking the effectiveness of possible viral inactivation measures. Patients were generally not involved or aware – never, on the evidence active participants in decision making. They were openly being discussed for their value to research. The possibility of withholding commercial treatment was openly being disused to preserve a patient's "virginity" for testing heat treated domestic products. "Virgin" patients were now being actively considered for treatment for research purposes. Any clinical trial undertaken by the State at this stage would not have provided any compensation for any adverse consequences. Many witnesses have given evidence to the effect that they were treated as "lab rats" or "guinea pigs". By that, they meant that they believe based on having been kept in the dark about the risk and hence the need to consider disease monitoring or inactivation of disease and having reconstructed based on information gained in retrospect (often by their own researches) that it it is hard to resist the conclusion that by the early 1980s (based on a process which had been evolving for years) haemophilia patients had stopped being looked at as patients in need of care for their chronic

[2043] PRSE0001160_0005

condition and had started to be looked at as a commodity to provide information about disease or heated products, which would have considerable commercial value. In that, they are right.

AIDS

7.17 The evidence available to the Inquiry was that patients in Scotland were tested for HIV infection in 1984 without their consent. For example, samples from certain patients were set to Dr Tedder by Professor Ludlam in 1984 and tested without their knowledge or consent. Similar testing took place on Glasgow patients, at both the GRI and Yorkhill and in the other centres. Lord Clarke gave evidence about legal advice he received some years later (while Secretary of State) in relation to anonymous testing for HIV which made clear that all testing should be carried out only with the 'express consent' of the patient.[2044] At that time, Lord Clarke stated that the ethical position was assessed "from a layman's point of view".[2045] Whatever the legal ramifications, this should be taken by the Inquiry to mean that it was perfectly clear to the DoH that the testing for HIV without consent had always been unethical. We submit that it was. The legal advice appears to have been taken in the context of the government possibly making a public statement about HIV testing in around 1988. It appears that no such legal advice had been sought by any branch of government regarding the legality of non-consensual testing for anti-HTLV III in 1984/ 85 and indeed other such testing for NANBH (ALT) in previous years.

7.18 Very nearly as soon as the AIDS threat to the UK was realised, the attention turned to research. By the middle of 1983, the DHSS had asked the CBLA to set up the Central Committee for Research and Development in Blood Transfusion, which was to advise on research about AIDS. [2046] Medical research was an area in which

---

[2044] para 22.7 of Lord Clarke statement at WITN0758012
[2045] see para 22.22 of Lord Clarke statement at WITN0758012
[2046] PRSE0002741 (Minutes of Central Committee for Research and Development in Blood Transfusion, 21 June 1983, first meeting).

the DoH appeared to take considerable interest over this period. For example. in her statement to the Inquiry, Diana Walford referred to medical research being undertaken into infectious diseases at the Centre for Applied Microbiology and Research (CAMR) at Porton Down.[2047]. 'Collaboration' between BPL and Porton Down was envisaged in around 1983 as well.[2048] The fact that the DoH was involved in this research showed that there was a keen interest in developing knowledge about new infectious diseases and this new disease, in particular. There were considerable financial gains to bae had for the State if they could acquire knowledge about the disease as early as possible. This made groups such as the haemophiliac "canaries" of considerable interest. This is precisely the type of situation in which the ethical rules impose rules to protect the patient, ie where there is a string incentive to advance medical knowledge in an urgent situation, where the interest of the subject/ patient could early become less then the paramount priority. Rather than taking an active role in seeking to avoid that risk materialising, it seems that government took an active part in promoting it. The Expert Advisory Group on AIDS not formed until January 1985[2049] though this was suggested by Dr Galbraith in May 1983.[2050] By way of contrast, an MRC Working Party on AIDS was formed in 1983.[2051] The priority was given to research into AIDS not to seeing to it that the government was advised on how to prevent it. Dr Walford accepted that she was aware of the importance of the data provided by Dr Craske on haemophiliac studies for the government's understanding of post transfusion hepatitis).[2052]

7.19 The AIDS research undertaken in Glasgow and Edinburgh is considered in detail below. As regards patient knowledge of and consent to the research, Professor Forbes stated in his evidence to the Penrose Inquiry that a decision was made to collect samples from patients with a view to storing them until a test for HTLV-III

[2047] Para 114.2 of statement of Diana Walford (WITN4461001)
[2048] PRSE0001972 (Minutes of Central Committee for Research and Development in Blood Transfusion, 28 February 1984) – see page 3 (passage marked for "cover up").
[2049] Para 5.1 of statement of Diana Walford (WITN4461001)
[2050] Para 97.2 of statement of Diana Walford (WITN4461001)
[2051] Page 35 of statement of Diana Walford (WITN4461001)
[2052] Para 44.7 of statement of Diana Walford (WITN4461001)

became available.[2053] He stated that the initial samples "were taken over a period of several years". Interestingly, this decision was made against the background of an admitted awareness that "the HTLV-III virus was transmitting the disease in our patients". Professor Forbes accepted that the disease was more likely to be transmitted by concentrates than by cryoprecipitate and that many patients stayed on cryoprecipitate for this reason, which was in accordance with the policy of the centre at the GRI for that reason.[2054] This may account for why there were statistically fewer HIV infections in Glasgow than in Edinburgh and Yorkhill, where large amounts of concentrates were used freely.

7.20 It is clear from Professor Forbes' evidence that patients did not give consent for their samples to be used in subsequent studies.[2055] Professor Forbes made it clear that by March 1983 most clinicians thought that AIDS would undoubtedly appear in time and they were starting to look at their patients rather differently to see if they had any features that might be an early warning of the condition.[2056] The very fact that these samples were being taken showed that there was a risk that they might already be infected.

7.21 Professor Ludlam gave evidence at the Penrose Inquiry about immune tests being carried out in and around the beginning of 1983 in Edinburgh, again as a result of a concern that patients might be exposed to the agent which caused AIDS – hence he called it the "AIDS study". He claimed that it was explained to patients that immune testing was being carried out on blood samples and that the new condition called AIDS might be spread by blood products. He asserted that this is what "must have happened".[2057] Professor Ludlam was not surprised that patients did not understand that they were being involved in an AIDS study, this kind of research at that time. He said that it is not always possible to convey information to people. He said "They may have forgotten what they had been told. We may not have told them. This was part of the monitoring of patients that was my

---

[2053] PRSE0004744_0002 at paragraph 6
[2054] PRSE0004744_0002 at paragraphs 5 and 6
[2055] PRSE0004744_0003 at paragraph 9
[2056] Penrose Inquiry transcript for 15/06/11 (day 33) (Professor Forbes); 99 (18) – (22); [PRSE0006033_0099]
[2057] Penrose Inquiry transcript for 17/06/11 (day 35); 7 to 86 (Professor Ludlam); [PRSE0006035_0007 to 0086]

responsibility".[2058] Any claim that patients were told about this research evidence should be rejected. It was based on a reconstruction of what Professor Ludlam might have wanted to have happened as opposed to any clear recollection of what was done. The evidence of those patients who were involved is that they were unaware that the study described as "AIDS study" was being performed. It seems reasonable to think that if a person was specifically told that blood was being taken from him with a view to carrying outa study of his immune system in relation to the new threat posed by AIDS he would remember and would have reacted with some alarm about the possibility. The likelihood that that would have been the reaction, it is submitted, in the absence of any clear warning having been given of the risks was part of the reason why patient were not informed. The underestimation of the risks of disease in the past and the culture of regular testing of blood samples without consent would have been exposed. Patients would rightly have been furious and Dr Ludlam's research would likely have been undermined. It submitted that it is likely that by and large patients were not specifically told that this study was being carried out and many were unaware of it. No explicit consent was obtained from patients.[2059]

7.22 Professor Ludlam was reluctant to accept that his study was research preferring to describe it as "monitoring" or an "audit".[2060] It is submitted that this work and its analysis and reporting must rightly be regarded as research. In his own evidence to Penrose, Professor Ludlam tried to distinguish between the testing on the immune function of the blood samples and immune testing on the skin. He claimed that he sought ethical approval for the latter as it was invasive, whereas the testing on the blood samples was not.[2061] It is submitted that this distinction is entirely artificial as these two tests were being used for the same purpose, namely measure measurement of immune function for possible publication. The real reason why ethical approval was sought for the skin testing was that the process

---

[2058] Penrose Inquiry transcript for 17/06/11 (day 35); 56 (14) to (25) (Professor Ludlam); [PRSE0006035_0056]
[2059] Penrose Inquiry transcript for 17/06/11 (day 35); 60 (14) – (24) (Professor Ludlam) [PRSE0006035_0060]
[2060] Penrose Inquiry transcript for 17/06/11 (day 35); 60 (Professor Ludlam); [PRSE0006035_0060]
[2061] Penrose Inquiry transcript for 17/06/11 (day 35); 66 (13) to 69(2) (Professor Ludlam); [PRSE0006035_0066 to 0069]

meant that the patient would necessarily have to become aware that the usual test was being done, whereas the clandestine blood testing cold take place without detection. In any event, it was not suggested that patients were made aware that other test was for the purpose of detecting whether the patients (a) might have signs of AIDS such as that detected in US haemophiliacs by 1983 (b) might have a form of pre-AIDS which rendered them more susceptible to infection or (c) were merely exhibiting immune function abnormalities (and hence susceptibility to being unable to fight off any disease) as a result of the antigenic content of the concentrates. The patients were in any event in ignorance of research which was simply trying to work out how the harm which was inevitably being caused to them by their treatment had been caused. Vivienne Nathanson said in her evidence to the Penrose inquiry that at the time she would have encouraged anyone asking her to regard it as research and thus requiring ethical approval. [2062]

Anti-HIV testing

7.23 In 1984, once more specific antibody tests became available, testing was undertaken on blood samples without specific consent being taken from patients or their representatives. Professor Forbes stated in his Penrose evidence that in Glasgow *"I don't think that we actually asked for the consent to be specifically tested but as in all these areas things tighten up and then consent was asked for and eventually written....By 1987 specific consent was asked for . Often before that it was not. It was a gradual process which came in."*[2063] In Edinburgh, Professor Ludlam made it clear that the patients whose samples were sent for testing in or about October 1984 were not told and did not give consent.[2064] There is no reason

---

[2062] Penrose Inquiry transcript for 23/06/2011 (day 37); 162 (18) – (22) (Vivienne Nathanson); [PRSE0006037_0162]

[2063] See PRSE0004744_0003 at paragraph 9; and Penrose Inquiry transcript for 5/05/2011 (day 20); 53 (15) (Dr Anna Pettigrew); [PRSE0006020_0053]

[2064] Penrose Inquiry transcript for 17/06/11 (day 35); 92 (11) – (15) (Professor Ludlam); [PRSE0006035_0092]

to think that the position was any different throughout Scotland, given the lead taken on these matters by the reference centres.

Testing for anti-HCV

7.24 The general availability of testing of blood donations for antibodies to HCV and the delays involved in the availability of that test are discussed elsewhere in this submission. It is important to note that by this time, the medical profession had generally claimed that lessons had been learned from the HIV crisis if the first half of the 1980s and that practice had become more patient orientated. The evidence available to the Inquiry suggests that bleeding disorder patients were tested for anti-HCV without their knowledge or consent and that there were delays in them being told of their diagnosis.

7.25 In this regard, there is a particular issue which arose in the centre in Dundee with regard to testing patients without their consent. He described the state of affairs as late as 1992 where HCV testing was being carried out on patients stored samples without informing them or obtaining their consent. Professor Cachia said he was "a bit horrified" in his evidence to the Penrose Inquiry when he discovered that this had happened.[2065] It appears from his evidence that testing prior to his arrival in 1992 had been undertaken without confident on stored sera within the virology department. The storage of these sera within that department appears to have removed any last vestige of patients having any role in the testing of the sera, the "ownership" for practical purposes having been completely removed from the clinical medics who were responsible for the patients' care and who had taken the blood in the first place. Patients had obviously been left in the dark about their diagnosis, possibly putting their family and other close contacts at risk, in particular after bleeding episodes. They may have been causing damage to their infected livers innocently through alcohol or poor diet.

[2065] Penrose Inquiry transcript for 12/01/2012 (day 83); 25 (7) to 28 (12) (Dr Philip Cacchia); [PRSE0006083_0025 to _0028]

7.26 In addition, there is also evidence before the Inquiry indicating that there were delays in terms of when patients were tested in Dundee, with some not being tested until late 1995.[2066] Penrose Inquiry witness "Colin" (who has since died) informed that Inquiry that he and his 3 brothers (who also had haemophilia) were not tested in. Dundee until 1995. He had been hospitalised for about ten days in 1994 during which time blood tests were done, but he was not tested for Hepatitis C. He continued to drink over this period, unaware that the damage he was causing to his liver might be exponentially more significant than in the uninfected. These examples illustrate the importance having protocols and guidelines in ensuring a consistent approach to the way in which patients are tested, counselled and treated. In this regard it although there were guidelines available for doctors dealing with patients who were identified by the look-back, there do not appear to have been any equivalent guidelines for those treating patients with haemophilia.

c) Research on patients with bleeding disorders in Scotland

7.27 The types of research in which haemophilia patients were involved and the value of that research to the State. There was:

(a) Research into the nature of the bleeding disorders themselves
(b) Research into the effectiveness of the products which were being given for the bleeding disorders
(c) Research into the diseases which were being spread by the products.

7.28 The fact that this was going on around the country suggests a wide systemic lack of regard for these principles. This was not a case of a limited number of individual clinicians transgressing but a nation-wide. Its apparent acceptance, despite (as it

[2066] Penrose Inquiry transcript for 13/12/11 (Day 77): 15(19) to 25(8) ("Colin") [PRSE0006077_0015 to _0025]

submitted elsewhere) the fact that these practices clearly crossed ethical boundaries, was the reason why it crept into all aspects of the care of patients with bleeding disorders. The fundamental importance of research in the set up of the Treloar's school is a clear example of this. This is a subject which will no doubt be the subject of more detailed submission from other groups, with a more direct connection with what happened at that school. From the Scottish perspective, the scale of disregard for the rules of ethics pertaining to research is an important consideration in understanding why bleeding disorder patients were treated as they were. The unregulated organisation which determined how their care was to operate had been set up to give primacy to research.[2067] Clinicians operating under its umbrella appear to have taken comfort in the *Bolam* type approach to medical care – as long as others were doing the same, they could not be criticised for allocating an unreasonable primacy to research over patient care, even to the extent of the organisation which they formed beings set up overtly for this purpose. To this day (as copious, oft rehearsed and co-ordinated evidence heard from the surviving protagonists in the field shows) the clinicians involved still see nothing wrong with his approach. Their inability to see beyond their "party lines" and their apparent conviction that they did thing wrong has led to a failure to recognise the patient perspective, to consider or show remorse or apology. That conviction was and is ill founded. These clinicians' commitment to it has vastly compounded the harms inflicted on their patients by them.

7.29 The whole treatment model of those with bleeding disorders in Scotland was non-voluntary research. The fact that based on the close relationship between the haemophilia clinicians in Scotland and the SNBTS/ PFC, patients were engaged in undeclared clinical trials all the time. Patients were constantly being monitored to assess the efficacy of the products and their safety and the result fed back to the State fractionator the SNBTS, whether in clinical trials or not.[2068] Though

---

[2067] See submission in this regard above

[2068] Clinical trials on heat treated products went ahead without compensation provision in 1983 - see mentions of heat treatment trials over this period - CBLA0001669 - Hepatitis Working Party Minutes (11th Meeting on 19 January 1983) refers to a heat treatment trial in 1983/1984. The Protocol for trials of hepatitis reduced factor was circulated following the meeting on 22 March 1983 is at CBLA0001693_003; CBLA0001737 - the Minutes of

compensation would normally be available for the adverse effects of clinical trials, this system in which products were constantly being monitored in patients provided for no compensation when things went wrong, as they have. The State should in these circumstances be found to have a moral duty to compensate.

7.30 Benefit to the State was obtained from the research. In their review article on the AIDS epidemic in Edinburgh Robertson and Richardson identify that at the time testing started to become a possibility for HTLV III, "infectious disease doctors became celebrities and scientists...emerged as businessmen with an economic interest in health".[2069] Information about patients with AIDS or infected with HIV was at premium. Sera would be required for tests, research and ultimately, possibly vaccines. The clamour by doctors to associate themselves with publications about the new disease is clear for all to see, including Professor Lowe who was a named author of the Glasgow AIDS studies though claimed in his evidence to have had little role in the work. The economic advantage to the State in an emerging health crisis accompanies by mass hysteria was self-evident. In such an environment, the advantages for the research reputations and professional standing of doctors with access to information about the disease was considerable, in particular those who could claim to have access to unique information which could provide information about the disease and its progression which might not be available elsewhere. Such information about the epidemiology of the disease would be indispensable to the development of economic interests as part of the response to the disease. Compliant "canaries" like haemophiliacs, an infected group who were used to giving blood for legitimate reasons such as monitoring their factor VIII or IX levels and who were infected became a uniquely complaint research group. Though this phenomenon may have become more publicly apparent at that time, this had been the position in the UK, at least in this community for some time. Haemophiliacs had been part of research studies into hepatitis B and indeed non A non B hepatitis for years. The Inquiry has

---

the 12th Meeting of the Hepatitis Working Party on 14th September 1983 - see quote about trials in Edinburgh at page 2 (CBLA0001737_002)

[2069] EXPG0000033_0002 (2007)

heard evidence of large quantities of blood being taken from them[2070] for the development at least of factor assays[2071] and potentially for the development of HBV tests and vaccines as well. This was why an issue arose about factor VIII deficient plasma which has been supplied by the centre to PFC from one "zero level patient" (an HIV infected haemophiliac). The problem was identified that most patients on their "donor panel" had had the implicated batch (0900) and were at risk of HIV transmission to those who received products made with their factor VIII deficient plasma.[2072]

7.31 The State had long been using information and material derived from these patients to its advantage in developing knowledge about a disease to its economic advantage, at least in the sense of it being able to save money on these products by now having to purchase them from industry, in the same way as the saving made on producing blood components and blood products from blood donations given freely by altruistic donors meant that the State derived an economic advantage from not having to buy them more expensively from the market. These economic advantages for the good of all were based both before and after the advent of AIDS on the backs of the patients, whose suffering had produced the material and the information from which products, advances and savings could be made. The economic advantage to the State of the benefits derived by it from the suffering of those infected by blood products in the UK has never been recognised. It ought to be. In addition, the reputational enhancement available to clinicians was considerable. The problem with his situation was that in order for the historic research value of the compliant patients to continue, they required to remain compliant. They required for the purposes of the research to be kept in the dark. They continued to be, as is discussed in more detail above.

[2070] Large quantities of blood (50 or 60 ml) were taken from haemophiliacs in Edinburgh – see IBI transcript for 04/07/19, pages 66 - 67 (Alice Mackie))

[2071] Factor deficient blood was taken from haemophiliacs at least for this purpose – see para 176 of Dr Boulton witness statement @ WITN3456002 and for the development of reagents (para 284)

[2072] PRSE0000107 – 15 January 1985, Boulton to Perry

Edinburgh research environment

7.32 The value of previously untreated patients in research about disease transmission is analysed elsewhere in this submission. Evidence available to the Inquiry suggests that the Edinburgh centre was one which was uniquely placed in Scotland to carry out research. In fact, it was one of the foremost reach centres for haemophilia patients in the country. The unit had longitudinal sera store to facilitate this research, as did the Royal Free in London.[2073]

7.33 GRO-D

GRO-D [2074] Though he had been under the care of the previous haemophilia director, the movement of the children to ward 23 in the RIE seems an unusual move in a city where there was a bespoke children's hospital. The research value of the children being treated in the same place as his laboratory may provide the answer. Evidence was heard from a patient of a slightly later vintage about how Dr Ludlam openly referred to these children as his "pups", a term which the witness thought to be one of affection but, as he later discovered, was in fact an acronym for previously untreated patients.[2075]

7.34 One patient recounted an episode in his evidence which was typical of the culture of suspicion and patient misinformation. Dr Ludlam asked him and his mother to sign a consent for to something which was not explained to them, which his mother refused to do, in large part as another patient GRO-A had warned then not to. The patient recounted that they were threatened by Dr Ludlam who said that if they did not sign that they would receive "American factor" and that he would thereby contract something. He was not even aware what American factor was.[2076] This was in 1983 (when he was still 16). This was the time when the immune function study was started in Edinburgh, which is discussed in detail

[2073] BART0000552_001
[2074] GRO-D
[2075] WITN2168001, para 21 (first statement of Myles Hutchison)
[2076] WITN2317001 @ para 17 (first statement of WITN2317)

elsewhere in this submission. It seems likely that this patient was part of the immune function study as he was subjected to skin testing which was a part of the testing regime involved in it. He was told that this was part of a HBV testing regime (which it was not) and that he did not have hepatitis (which they knew he did).[2077] This episode led to this particular patient leaving Dr Ludlam's care and seeking treatment in another hospital in the city.[2078]

(d) Research into hepatitis

7.35 The retrospective analysis of the timing of HIV infection in Scottish haemophiliacs was able to be undertaken as a result of the fact that blood samples from the haemophiliacs had been kept for all of them (largely of not exclusively without their knowledge or consent) as part of a research project into hepatitis B.[2079] These samples were kept in all Scottish haemophilia centres in this way from the 1970s. It was this known at that time that the haemophilia patients not only required to be tested in order for the progression of their viral hepatitis exposure to be monitored but also for those sample to be retained, indicating that it was known that some later retrospective analysis would be necessary of their inevitable exposure to emerging pathogens. Similar samples for donors were kept in the SEBTS according to Dr McClelland from around 1981 or 1982 so that when inevitable future pathogens emerged a retrospective analysis of their source could be undertaken.[2080] The inevitability of serious viral exposure seems to have been a part of the system of haemophilia care in Scotland from the 1970s. the sophistication of the sample storage systems indicate clearly the research significance of the haemophilia patients – as new viral transmitted disease emerged, as they inevitably would in haemophiliacs, the system was set up to be

---

[2077] WITN2317009 @ para 1 (second statement of WITN2317)
[2078] WITN2317001 @ para 37 (first statement of WITN2317)
[2079] Penrose Inquiry transcript for 30/03/11 (day 14); 17 to 19 (Professor Ludlam); [PRSE0006014_0017 to PRSE0006014_0019]
[2080] IBI transcript for 28/01/22; 167 (16) to 168 (10) (Dr Brian McClelland)

able to look back and derive maximum research benefit from them. This could hardly be characterised as in those patients interests in a system so clearly set up for retrospective analysis, ie at a point where the harm to them would already have been done.

7.36 For some significant period of time, the value of previously untreated patients had been recognised for research purposes as their reactions to products would give an invaluable insight in as to the effects of new products in clinical trials. At a meeting of the SNBTS Haemophilia & Blood Transfusion Working Group on 14 November 1983, Professor Cash reminded those in attendance about collection of data of liver function tests of virgin haemophiliacs. Dr Forbes responded that 'there were not enough virgin patients in Scotland' and he was writing up his experience of hepatitis in 12 mild cases treated with PFC factor VIII.[2081] Attention continued to be paid to previously untreated or "virgin" patients into the period examined above between December 1984 and April 1987 when an HCV factor VIII products was not available.[2082] Professor Colvin told the Penrose Inquiry that untreated patients were ones he would have been interested in for putting into a clinical trial.[2083] As is submitted above, the value of untreated patients to the long standing system of research into diseases into Scotland, coupled with the absence of clear as to explanation as to how they had become infected and whether their infections could have been avoided reasonably gave rise to the suspicion that treatment had been subordinated to research.

7.37 Dr Ludlam engaged in research into hepatitis in his haemophilia patients as soon as he arrived in Edinburgh. His zeal for research into disease was clearly a main motivating factor in him coming to the centre. In a 1981 article by him, a deterioration in the liver function of patients was reported in the 5 year follow up in those on home treatment and not amongst those using cryoprecipitate.[2084] Hepatitis indicator levels of Edinburgh haemophiliacs had been studied over many

---

[2081] PRSE0002581

[2082] See PRSE0003749 (24 March 1984); PRSE0000909 (25 April 1984); PRSE0004276 (April 1984); PRSE0003930_0003 (15 May 1985) and PRSE0001641 (1 July 1986)

[2083] Penrose Inquiry transcript for 7/12/11 (day 74); 92 (17 to 20) (Professor Colvin) [PRSE0006074_0092]

[2084] PRSE0000013 – 1981 article about hepatitis in haemophiliacs in Edinburgh

years back into the 1970s, having been in receipt of some concentrates since 1974. The article recommended that patients in hospital should continue to receive cryo. Despite this, the Ludlam concentrate juggernaut (involving, in 1981 a not insignificant amount of commercial factor VIII concentrate) had been launched. As is analysed elsewhere he decreased the proportion of cryoprecipitate used in treatment.

7.38 A 1983 article by Ludlam and others looked at 56 haemophiliacs over the period of the 1970s and found that there was still high risk of HBV infection despite introduction of testing for HBV on donors.[2085]

7.39 In May 1980, Dr Kernoff was looking for Dr Ludlam to get involved in a project monitoring the liver function and condition of patients in Edinburgh, possibly by biopsy.[2086] No biopsy research took place. That would, of course, have involved the patients requiring to know that the research was going on, as must have been the case for patients in, for example, the Preston group in Sheffield. Dr Ludlam was, however, contributing information relevant to chronic hepatitis to Dr Craske.[2087] From his arrival at the Edinburgh centre the research interest in his patients (as is stated here) stemmed from the fact that have mostly been treated with NHS products. This was to become an important feature of the later AIDS research and was a reason why Dr Ludlam was keen that patients not be treated with non-Scottish products if away from Edinburgh, even with bleeds. Dr Craske strongly urged him to avoid the use of commercial products as it was likely that patients would be exposed to a fresh type of non-A, non-B hepatitis. It was to be well known from the letter that in 1980 patients would be exposed to NANB hepatitis irrespective of how they were treated and that different products may expose patients to different strains of the disease. This was the basis of the need for the Edinburgh patients to be kept "pure" – they were a group with a unique

---

[2085] PRSE0002188 – abstract; PRSE0000135 – article

[2086] HCDO0000270_083 (14 May 1980) - Letter from P. Kernoff to C. Ludlam.

[2087] HCDO0000270_085 (16 May 1980) - Letter from J. Craske to C. Ludlam. Re the meeting of the Hepatitis Working Party and discussions between the Royal Free Hospital, Sheffield and Oxford about the best method of conducting investigations of the incidence and clinical features of chronic hepatitis in haemophiliacs.

research value as they had only been treated with Scottish products since the Davies regime. Dr Ludlam had been the one who had realised and set out their unique characteristics, describing them as "useful material" in April of that year which had eld to the responses from Dr Craske.[2088] The research by Dr Craske of PHL had been going on for some time. He was in attendance at a meeting in Scotland in 1977 to talk and ask to extent his study of overt hepatitis in haemophiliacs to Scotland and the PFC product. He said had done study between 1974 and 1976 on commercial products and now had agreement to study the BPL product. A decision on Scottish participation was deferred. The Scottish directors were already providing such information in separate study to Oxford.[2089] The offer to submit information was taken up by Dr Ludlam.

7.40 By June 1980, the Edinburgh patients were involved in a chronic hepatitis research project. Their conditions were considered serious enough to be contemplating risking doing biopsies on their livers but het the treatment causing these conditions (concentrates) was being massively increased, a move which had a research value, increased viral load, made donor selection more dangerous due to the need for plasma and later exposed the patients to the risk of AIDS.[2090]

7.41 By October 1982, a prospective study in relation to the incidence of acute and chronic hepatitis in haemophiliacs as a result of first exposure to Factor VIII and IX concentrate or cryoprecipitate was in contemplation involving Edinburgh patients.[2091] The tendency to expose patients who were uninfected to concentrates is s matter which has given rise to considerable suspicion about their involvement in research (see below). Around this time there was certainly a willingness to use concentrates here they ought to have been avoided, in particular in children. By April 1983, the two were corresponding about issues on the 'methods section' of a protocol for Hepatitis Reduced Factor VIII Concentrate,

---

[2088] IBI transcript for 01/12/20; 111 to 113 (Professor Ludlam); LOTH0000031_027 (28 April 1980)

[2089] DHSC0001767 – 30 May 1977

[2090] 13 June 1980 - HCDO0000270_081 - Letter from C. Ludlam to Dr Peter Kernoff

[2091] HCDO0000270_050 (25 October 1982) - Letter from C. Ludlam to J. Craske

which would have involved virgin patients.[2092] He suggested that patients with persistently elevated liver function results should not be required to be sent to local liver clinic. Thus, the focus having been on those who were exposed to last products (and hence viral load) for what they could tell Dr Ludlam about chronic disease, the focus turned to those who had been explored to few or none for what they could tell him about the efficacy of heat treatment on new products. It was all part of the same continuum of research. The development of heat treatment products had safety advantages but also significant commercial value. Research brought academic live Dr Ludlam significant renown. In all of this, it was the patients who were suffering the damage or taking the risk. They were doing do unknowingly.

7.42 By October 1983, his patients were involved in a clinical trial of a PFC heated concentrate.[2093] In such circumstances, it would have been impossible to evaluate the clinical need for the products in virgin patients. Given the risks, they should not have had them at all. From later correspondence, we know that no compensation arrangements were in place for the trial. For some reason, Professor Cash indicated that as the Medicines Division knew about the trial, there was no need for clinical trials exemption certificate.[2094] It is far from clear why this met the regulatory requirements, which were theoretical anyway due to Crown Immunity. It appears that the licensing authority said that products could be used without a CTX without compensation. Against this background, a patient had an adverse reaction.[2095] In early 1985, he wrote to Professor Cash expressing concerns about this practice trialling new SNBTS products without details as doing so would be unsafe to "volunteers". He referred to mutual co-operation between SNBTS and him which had existed since he returned to Edinburgh. It is submitted

---

[2092] HCDO0000270_045 (21 April 1983) - Letter from C. Ludlam to J. Craske

[2093] PRSE0001343 (13 October 1983) – Cash letter that Forbes has agreed to infuse the factor VIII (heat treated) into one of his patients and PRSE0000367 (31 October 1983) - letter from Watt to Edinburgh and Glasgow BTS with factor VIII (heat treated) for clinical trial

[2094] PRSE0003851 – Cash to Ludlam re trials (13 June 1983) on heat treated factor VIII (NY batch 761) (60 degrees at 10 hours and then 30 mins at 70 degrees, wet heated)

[2095] PRSE0001031 – reply in early 1984 indicating adverse reaction in one patient on the NY 761 concentrate

that what is meant is that he had agreed provide trial subjects and information in return for them providing him with lots of products. All of this was known to be harmful. The treatment system was clearly designed to obtain information about (a) the products and (b) disease, to be published in research.

7.43 There is clear evidence that later in the 1980s, Professor Ludlam was not prepared to proceed with clinical trials without having a clear agreement that patients who suffered as a result of their involvement would be compensated by the government. This related to the proposed clinical trials of the heat treated Z8 product. These were legitimate concerns, which he had been raising though had not resolved for years. In January 1987, Professor Cash indicated that time was being wasted in the introduction of Z8 by Dr Ludlam not being happy with compensation arrangements and running of stocks of NY.[2096] Dr Ludlam later undertook trials on 3rd March 1987 on Z8[2097], which also shows that earlier trials were done in Glasgow and Belfast, with compensation arrangements. His true motivation was to maintain his supply from the SNBTS but also to avoid any possible liability himself.[2098]

7.44 The basis upon which Dr Ludlam argued that such compensation should be paid was that patients were potentially being put at risk for the benefit of the advancement of the State's knowledge about the products, their efficacy, the extent to which they transmitted disease and the nature of the disease which they transmitted. It is respectfully submitted that Dr Ludlam was quite right to insist upon on compensation being made available in these circumstances. Any delay caused in the availability of the product as a result of the government's decision-making was unnecessary (as is analysed in more detail above). However, what is harder to reconcile is why this apparent this insistence that the State had an obligation to pay compensation in the event of harm being suffered due to

---

[2096] PRSE0001927 – January 1987 – Cash to Ludlam – Russian roulette letter

[2097] PRSE0002046

[2098] PRSE0002134 – January 1987 – Ludlam reply to Cash. Willing to participate if compensation and wishes indemnity from SHHD as he may be liable if products used without a licence on a named patient basis; PRSE0004080 – 9 June 1987 – personal letter from Cash to Ludlam about developing a more formal working relationship between SNBTS and him

exposure to products in the clinical trial differed in any way from the position which existed before that time. Indeed, Professor Ludlam claimed that he had been making this argument for years before the Z8 trial dispute. The State had been using haemophilia as a means of compiling information about the efficacy and infectivity of products and the nature of diseases which they transmitted for years and would continue to do so for years thereafter. The medical establishment and hence the State had gained significant information about pharmaceutical products which it produced and the nature and extent of disease from those products and would continue to do so for years to come (see below). In essence, the entire system of the treatment of patients with bleeding disorders in Scotland had been used by the State for these purposes for years. In these circumstances, the State has a moral obligation to pay compensation for the harms occasioned as a result of this treatment, as it eventually accepted that it did as part of the Z8 trial. The case for the strong moral duty which underpins the Sir Robert Francis compensation system is a logical one.

7.45 Medical research into the consequences of HCV infection in haemophiliacs continued (without patient knowledge or consent). GRO-D

GRO-D

(e) The Edinburgh cohort

Background

7.46 Those responsible for providing scientific advice on the issuing of grants for scientific research into the threat of HIV/ AIDS considered the bleeding disorder population to be a useful population for testing and understanding the nature of

2099 GRO-D

the disease.[2100] Those with bleeding disorders in the UK were an ideal research population for understanding the disease, rather than as individuals entitled to respect for their integrity and autonomy and deserving of receiving information about the risks which are recognised in the products with which they were being treated.

7.47 Against this background the "Edinburgh cohort" became "one of the most extensively studied group of HIV infected individuals in the world".[2101] In his evidence to both this Inquiry and the Penrose Inquiry, Professor Ludlam continued to insist on the fact that the work which was done on the cohort group was not research. In fact, it clearly was. The narrative outlined below makes it clear that the origins of the group has been connected to the need to understand why an AIDS-like syndrome appeared to be developing in haemophiliacs identified in the US as suffering from the disease. It was always intended that the results of the investigations into this group be published. The ethics expert group confirmed that anything that was published was research.[2102] In any event, it was considered important that information be provided to patients about the kind of information which was going to be collated about them and why.[2103] It is submitted that Professor Ludlam wished to try to have his research classified as an "observational study" or something of that nature in order to try to avoid the consequences of his failure to follow the appropriate and important ethical rules in connection with it, mostly related to the importance of the subjects of such a study being willing and informed participants in it. It should be emphasised at the outset that this is not always how Professor Ludlam has described this work. In response to a GMC complaint he described it as a "research project"[2104] Later, in response to another such complaint he described the work as a "special or research project" which had been set up in direct response to the AIDS threat.[2105]

[2100] PRSE0000389 - Minutes of the Medical Research Council Working Party on AIDS meeting on 10 October 1983
[2101] The Edinburgh Haemophiliac Cohort", MRC News, September 1990, no 48
[2102] IBI transcript for 27/01/2021; 106(1) to 107(4) (Professor Savulescu)
[2103] IBI transcript for 27/01/2021; 109(6) to 109(18) (Professor Kerridge)
[2104] WITN3365031_001_0042
[2105] WITN3365029_001_0191

7.48 As is submitted elsewhere, it was important for the continued involvement of the patients in this study that they should be kept in the dark about the dangers of the products they were receiving, or else some or all would refuse to continue to take the treatment and would therefore cease to represent a group of such research value. The very essence of a study of this nature was that it involved the patients being kept unaware of the dangers of the products which they were being prescribed to treat their bleeding disorders and the actual effects which were being monitored in the study. This approach was inherently unethical, as is described in detail below.

The AIDS study

7.49 The "AIDS study" is an integral part of the Scottish experience blood contamination disaster. The evidence relating to it requires to be analysed fully and carefully. It represents a failure of the NHS in Scotland properly to distinguish between the competing interests of the advancement of medical knowledge and the need for patient care to be prioritised at all times. It demonstrates the practical ramifications of not respecting the principal ethical rule related to research, namely the need to ensure patient understanding of and participation in the process of medical research at all times. It shows that where that fundamental rule is not respected and painstakingly ensured patients and their relationships with those responsible for their medical care are likely to be irreparably damaged.

7.50 The importance of information regarding opportunistic infections in the bleeding disorder community being collected and reported centrally was discussed at a meeting of the Scottish haemophilia directors as early as 21 January 1983.[2106] Any such information of unusual or opportunistic infections was to be collated and submitted centrally. Dr Ludlam and others had attended a meeting of the UKHCDO reference centre directors on 19th January 1983 at which Dr Craske had set out the

[2106] PRSE0001736_0007 (21 January 1983)

findings of the inverted CD4/ CD4 counts in the US haemophilia patients who had AIDS, based on the early US MMWR papers.[2107] This contributed to the occurrence of studies nationally of the white cell counts of UK haemophilia patients discussed below, involving multiple centres, with the Edinburgh centre having the special value described below by Dr Ludlam in response to the Gordon letter based on their unique local treatment histories. Dr Craske was keen to know about reports of opportunistic infections in haemophiliacs and the cell mediated immunity of severe haemophiliacs. It was deemed essential to standardise tests if different laboratories were performing tests for CMI in the same project, thus confirming that the Edinburgh study was part of a larger research project being co-ordinated across many centres as opposed to being something which was part of the regular treatment of Edinburgh haemophiliacs to which they could be deemed to have given any consent previously. In Edinburgh the tests would be carried out by Dr Steel at the MRC unit at the Western General Hospital, ie not the hospital where the haemophilia unit was based.[2108] In his evidence to the Penrose Inquiry, Professor Ludlam admitted that not all of the patients knew about the study.[2109] His evidence to that Inquiry about what had been said to the patients was confused and evasive. He claimed that there may have been an informal arrangement for telling patients and did not answer when asked whether junior or nursing staff had been told to tell patients. He described the process as a low-grade part of their general monitoring.[2110] In fact, the monitoring was new and arise from the possibility that the patients may have or be exposed to a fatal disease. He deliberately tried to downplay the significance in that evidence so as not to have to face the reality – that patients were at risk of a fatal disease and he did not tell them.

7.51 The value of such information in this high-risk population was clearly understood at a national level. Despite this, little if anything appears to have been done to

---

[2107] HCDO0000411 (19 January 1983)

[2108] Penrose Inquiry transcript for 17/06/2011 (day 35); 34 to 35 (Professor Ludlam) [PRSE0006035_0034 to _0035]

[2109] Penrose Inquiry transcript for 17/06/2011 (day 35); 54 (Professor Ludlam) [PRSE0006035_0054]

[2110] Penrose Inquiry transcript for 17/06/2011 (day 35); 55 (Professor Ludlam) [PRSE0006035_0055]

minimise the risk to those patients. Their value as unwitting research subjects, though willing patients had become apparent in connection with hepatitis throughout the 1970s and into the early 1980s. The same value would be derived from them in connection with the new disease, AIDS. All Scottish centres, including Glasgow were to contribute any information to the UK study of the new disease.[2111]

7.52 On 30th April 1983, a letter was published in The Lancet by Dr Gordon which sought collaboration in AIDS studies in haemophiliacs.[2112] Dr Gordon was part of the National Institute of Health (North America) Working Group on Acquired Immune Deficiency Syndrome at that time. He was seeking collaboration on to medical research. Professor Ludlam had started his research on the Edinburgh patients by that point and was able to publish the preliminary results of these patients on whom the new white cell testing had been carried out.[2113] Ultimately this testing was to prove to be one of the important research values of the group which became infected, namely that white cell abnormalities which existed pre-infection could be compared with the post infection white cell readings, giving an impression of what level of dysfunction was caused by the treatment for the haemophilia alone and what had been caused by the virus. Thus, there was an important link between the pre-infection and post-infection research to the value of the whole project. Of the course, the patients, remained unaware that these tests were being carried out, far less that data emanating from them relating to a potentially fatal disease was being disseminated internationally.

7.53 The Edinburgh haemophilia patents being treated by Dr Ludlam represented a group who, in 1983, were thought to have been unlikely to have been infected due to the apparent safety of the donor pool in Scotland at that time and the fact that they (unusually) had been treated only with domestically produced products.[2114] It was in that response that Dr Ludlam referred to the "ubiquitous virus" which he contemplated was the reason why patients acquired immune dysfunction from

---

[2111] PRSE0002263_0002 (statement by Professor Prentice to the Penrose Inquiry)
[2112] CBLA0000059_031 (the Gordon letter)
[2113] PRSE0001303 (the Ludlam response)
[2114] PRSE0001303

factor concentrates, as opposed to a specific virus which caused AIDS. The fact that he was contemplating that there was such a virus clearly meant that he knew that there was a risk that the products were harmful as a result of this putative virus, yet he continued to allow his patients to be exposed to that risk. They were a group which appeared at that time to be of interest in the emerging knowledge about the disease. Analysis of their blood was being conducted without their knowledge as part of the immune function study. By November 1983, Dr Chernoff of the NHLBI had already been in Scotland to discuss the inclusion of the Edinburgh patients in a study, which was being discussed at an international WHO meeting related to AIDS.[2115]

7.54 Against this background, Dr Ludlam started a collaboration in March 1983 with Dr Steel (a colleague based at the Western General Hospital in Edinburgh) to carry out research into immune function in patients with haemophilia. US studies had shown immune abnormalities in asymptomatic homosexual men similar to but milder than immune abnormalities discovered homosexual men with clinical signs of AIDS. This led to US studies into the immune status of apparently well haemophiliacs being undertaken and showing similar immune abnormalities (T lymphocyte subset abnormalities involving a reduction in the number of T helper cells and a consequent derangement of the T helper and T suppressor cell ratio). It was possible that these immune function changes might have been related to the widespread prevalence of an AIDS virus in the US haemophiliac community, might have been due to some other side effect of Factor VIII concentrate treatment (such as antigenic or protein overload from the exposure to large amounts of the factor) or it might have been due to some previously undescribed feature of haemophilia. The purpose of the study was to look at immune function in haemophiliacs to see whether it was progressive and whether it might lead to AIDS. The study on the Edinburgh patients was published in the lancet in June 1984.[2116] This was a new study which had not been undertaken on the patients before. It was not part of the routine monitoring which they underwent on their

[2115] PRSE0003634
[2116] PRSE0001987 (30 June 1984)

bleeding disorders, which was the purpose for which they thought that their blood was taken on a regular basis by their clinicians. It involved their blood samples being looked at by staff in the virology department at the Western General, which was also an innovation. Despite this, the evidence of the patients is that they were not told about this new development. It is, of course, important to note that the reason why the patients were being so studied was the risk that they might have been infected with AIDS (which it was thought was unlikely) or that the results of the study may show that they were otherwise being harmed by the product which they were being prescribed (which they were). The Penrose tables of patients whom Professor Ludlam had been infected with HIV under his care show that (on retrospective testing) one patient was already infected at this time, who had been exposed to commercial concentrate having had a mixed treatment regime, namely patient E22, who had certainly been infected by 1 December 1981. AIDS had already arrived in Edinburgh. However, the patients who were to be infected putatively by the "implicated batch" and who were to go on to be the lesser cohort of infected patients who would continue to be studied without their knowledge for many years had not yet been infected, their seroconversions mostly happening at the earliest in the spring of 1984. Thus, if the patients had been aware of the background to the study being undertaken on them at that time, that it was an "AIDS" study and that it concerned the possibility that they had the virus which caused AIDS (which at least one patient in Edinburgh did at that time) or a "pre-AIDS" condition which created a vulnerability to AIDS or AIDS-like illness, patients would reasonably have inquired about this and demanded that their treatment regimes (which they had consistently been told were safe) be altered to minimise the risk. It is submitted that many of not all would have done exactly this. Thus, their infection could have been avoided. Patient ignorance was an essential part of the study. Patient ignorance caused their infections or at least cost them the opportunity (which they should have been afforded) to make choices for themselves as to how to avoid them materialising.

7.55 Evidence is available to the Inquiry from patients whose records survive of white cell testing happening as part of the study of immune function and reaction to

infection. The details of the entries are set out in the evidence of WITN2232, starting from the early part of 1983.[2117]

7.56 The study involved looking re the T cell position in 37 haemophilia A patients (26 of whom were severe based on a 2% factor VIII level), who had been treated with only SNBTS factor VIII concentrate or cryoprecipitate in the last 5 years (2 of whom had had only cryoprecipitate), 10 haemophilia B patients (3 of whom were severe based on a 2% factor IX level) who had been treated with SNBTS factor IX, whose results were compared with 22 healthy male controls and 6 severe haemophilia A patients who had been treated with a mix of SNBTS and commercial factor VIII concentrates. The haemophilia A patients showed a lower than normal T helper cell count, similar to the US cases when compared to controls. The haemophilia B patients did not show significant T cell derangement when compared to controls. The patients' liver function was also measured. 76% of the haemophilia A patients showed abnormally raised ALT levels. There was also evidence of raised immunoglobulin (IgA and IgG). 66% of the haemophilia B patients showed abnormally raised ALT levels, with no evidence of raised immunoglobulin (IgA and IgG). The study also indicated that 41 patients had shown evidence of antibodies to HBV (previous HBV infection), as per the regular tests undertaken on the patients in the clinic. The source plasma used in the preparation of the products which the subjects of the study had received had come from Scotland, where it was stated there had only been one reported case of AIDS. This was the basis of the Sumption that the immune changes were not due to AIDS or HTLV III infection. Though this proved to be correct, the known lengthy prodromal phase of AIDS made the assumption that there was not infection with the agent causative of AIDS illegitimate – this possibility is recognised on page 3 of the report. In fact, we know that by 1982, HIV had entered not only the Scottish population but the Scottish donor population. Despite this, the subjects of this study had so far avoided infection. The reduction in T helper cells in the SNBTS treated haemophilia patients was similar to that observed in the 6 controls who had been treated with mixed products, and AIDS patients, "pre-AIDS" patients and symptomless homosexuals

[2117] WITN2232035 @ para 2 (second written statement of WITN2232); and WITN2232036

from other studies. The changes in haemophilia B patients were less abnormal. It was noted that the SNBTS factor VIII concentrate was significantly less pure than its commercial equivalent, though the SNBTS factor IX concentrate was significantly purer.[2118]

7.57 Professor Ludlam explained in his evidence to the Penrose Inquiry that the study showed immune changes were taking place in a similar way in the Edinburgh patients as had been reported in American studies.[2119] It was thought by Dr Ludlam and his colleagues unlikely that the immune dysfunction was caused by AIDS because the majority had received only Scottish product (which was erroneously assumed to be free from AIDS at that time) and none had any symptoms or signs suggestive AIDS.[2120] It was factually correct to say based on evidence available to us now that these abnormalities had not been caused by AIDS or infection by an agent causative of AIDS as the patients had not yet been infected, retrospective testing revealing that most if not all became infected after the study was compiled, namely in the period between March and May 1984. The explanation postulated for the immune function irregularities was the effect of the protein in the concentrates, though the explanation remained unclear.[2121] It was thought that the presence of raised ALT and IgG in three quarters of the patients may be indicative of chronic liver disease.[2122] In this conclusion, the cleavage between research and the position of the patients was demonstrated. The theory which was postulated involved patients having been harmed by the concentrates, either due to protein overload and/ or a viral agent causing hepatitis within it. This was made clear by Professor Ludlam in response to a GMC complaint some years later.[2123] That theory recognised that the immune function had been compromised and that the patients had been exposed to a virus causing chronic hepatitis in most cases. Whether relate to AIDS or not, the patients had been found mostly to have a chronic disease affecting their livers and a reduced immune

---

[2118] PRSE0001987_0004
[2119] Penrose Inquiry transcript for 17/06/11 (day 38); 70 (5) – (14); [PRSE0006035_0070]
[2120] Exclusively SNBTS in the last five years see PRSE0001303
[2121] PRSE0001987_0004
[2122] Ibid.
[2123] WITN3365031_001_0042

ability to fight that infection. These were thought to have been caused by the concentrates which were therefore recognised as potentially very harmful. The patients were not told. No changes to their treatment regimes were instigated. It was postulated at the end of the that a patient's HLA status may affect how an individual's immune system reacted – ie there may be a genetic component. It was clear that there was an intention to continue to study these individuals.

7.58 It is important to note that the AIDS study research in Scotland was not conducted in isolation. Similar research was undertaken elsewhere in the UK in the early 1980s in an attempt to drawn information from haemophilia "canaries" about the emerging AIDS crisis. The Inquiry has heard evidence about a similar research project having been undertaken at the Royal Free Hospital in London, under the control of Dr Christine Lee.[2124] The Edinburgh AIDS study was therefore not an isolated project in the sense that it was a symptom of a wider NHS drive at that time for information about the emerging disease, which was championed over the immediate risks of the at risk patients who were its subjects.

7.59 Consideration is given elsewhere to the possibility that cryoprecipitate use either across the board or in a limited sense in response to the emergence of the AIDS threat could and should have been implemented. It is notable that evidence from other countries provided contemporaneous relevant information about the aetiology of AIDS and indeed of altered immune function patterns observed in haemophiliacs and homosexual AIDS patients in the US. In Finland, where severe haemophiliacs were treated with 8 volunteer donor cryoprecipitate and not factor concentrates, no such altered T cell patterns were noted in a study of half the country's severe haemophilia A patients.[2125] Though this research left open the question of whether the changes were caused by the aetiological agent of AIDS or the antigen overload theory, it seemed clear from this that whatever the cause of this altered, lowered immune function was that it would not occur with cryoprecipitate, only from concentrates. Lowered immune function of a similar

---

[2124] OXUH0002974_002 (17 October 1983) – reporting to Dr Craske of the up to date T cell readings of Royal London patients

[2125] RLIT0000119 (The Lancet, 25 February 1984)

nature to the US AIDS patients had been observed in the Edinburgh haemophiliacs, involving a lowered T helper cell number and T helper/ suppressor ratio. It was that immune function abnormality which exposed the US patients to opportunistic infections which could prove fatal, which the immune system would normally be able to combat. That same susceptibility existed in the Edinburgh patients, in particular as they had a potentially lethal virus in their systems and hence relied on normal immune function to combat it – it had been caused by concentrates and was not caused by cryoprecipitate. The cause (the concentrates) could have been removed or at least reduced. It was not.

7.60 A further relevant study was published in The Lancet in September 1984.[2126] It is not clear from the face of this paper but the Edinburgh patients positive HTLV-III results were part of the results. This is because in the subsequent paper on the Edinburgh cohort, under "Patients and Methods" it is described that tests were undertaken on stored sera of those patients as part of this study.[2127] Thus, the September 1984 paper is based in part on results from the Edinburgh patients resulting from the Tedder testing process described in evidence by Dr Tedder and Professor Ludlam. The samples which had been sent to Dr Tedder had been sent for the purposes of research study into HTLV III infection. The patients knew nothing about this and it was clearly research to which they should have consented. Indeed, that research was different from any previous study into immune function as it was clearly about testing for the presence of antibodies to HTLV III. This paper was published in September 1984. In evidence, it was claimed that the testing of the Edinburgh patient was not carried out and reported until October 1984. This interpretation of the papers suggests that this evidence cannot be accurate – the testing must have been carried out before the paper was published. Sera of haemophiliacs who formed part of the study had included sera which had been collected in 1982.[2128] This may have included stored samples sent to Dr Craske as part of the study. It also conceivable that samples were collected

---

[2126] PRSE0000197 (The Lancet, 1 September 1984)

[2127] PRSE0004177_0001 and footnote 5 (3 August 1985)

[2128] PRSE0000197_0002

from that time in light of the emerging knowledge of infection amongst haemophiliacs in the US. The paper (produced by a number of eminent scientist from a number of fields) stated that the likelihood that AIDS was caused by an infectious agent had been known for some years.[2129]

7.61 This study shows that by September 1984, an analysis of a wide range of patients who were at risk for AIDS showed that there was a close association between HTLV-III positivity on the tests (anti-LAV and anti-HTLV III) which had been carried out and the development of AIDS.[2130] All but one (30/31) of the AIDS patients studied was positive for the antibodies to HTLV-III which supported the theory that AIDS was caused by that virus.[2131] This showed that AIDS developed in patients with antibodies and that the antibodies did not represent a form of immunity, as with certain other conditions.

7.62 In a publication of March 1985, a report was written up of a glandular fever type illness in a boy under Dr Ludlam's care.[2132] By the time that this case was written up in 1985, it was the view of the authors that the rash and lymphadenopathy which had been experienced by the patient 5 weeks after a knew operation covered by SNBTS factor VIII concentrate were due to HTLV-III infection. However, the symptoms had been apparent at that time and had clearly our in the estimation of those caring for the boy. The As the boy was one of the Edinburgh cohort the operation (and hence the infection) must have occurred between March and May 1984. By 29 July 1985, it appears that Dr Tedder had recognised the appearance of a glandular fever type illness in the scute phase of HTLV-III infection.[2133] This was the 17 year old boy (14 in 1984) who was told about his infection in 1987, contrary to his parents' wishes by Dr Ludlam (an episode explored elsewhere in this submission). He had been known to have been positive and suffered an acute infection (lymphadenopathy) consistent with AIDS in 1984.

[2129] PRSE0000197_0001
[2130] PRSE0000197_0001
[2131] PRSE0000197_0003
[2132] PRSE0003481 (The Lancet, 9 March 1985)
[2133] MACK0001842_002 (29 July 1985 letter from Dr Cash to Dr Perry)

7.63 It was consistently claimed in evidence to the Inquiry that lessons were learned by the medical profession from the HIV crisis which were not understood and could not have been appreciated before that. It would appear from the evidence that this was certainly not the case with regard to the ongoing study of patients who had been infected with HIV from blood products in Edinburgh. The Edinburgh HIV cohort became one of the most studied groups in the world. Nurse Reynolds continued to be instructed to take blood from patients for research purposes but was instructed not to give patients any details. This was taken for immune function study as part of the ongoing cohort research.[2134] Any detail of the ongoing study was kept from the patients. They continued to trust those responsible for the care, as they had done before. That continued to give blood as requested. In fact, blood was being taken in addition to what was needed for their regular care for the ongoing study of their immune function. The State and the medical profession continued to derive significant ongoing benefit from the infection of these patients with a fatal disease, without their knowledge. It seems that nothing in this regard had been learned from the HIV crisis at all.

7.64 The value of study of the cohort group was that (a) assessment of their immune function had been carried out prior to seroconversion such that data existed of their pre-infection state, for comparison (b) the period of exposure was precise (all were infected in the period between March and May 1984) and (c) all members of the group were presumed to be infected from the same source(probably a single virus strain), mostly by the same batch if not all from UK derived products.

7.65 Despite the first stage of the (pre-infection) having revealed that patients were being harmed their concentrate therapy (as described above), the study continued. The study remained hidden from the patients. A further examination of the patients' immune function was carried out in the autumn of 1984.[2135] The

[2134] PRSE0001844 @ paras 27 to 29
[2135] PRSE0004177_0002 (5 August 1985)

timing of this examination is notable. In the autumn of 1984 a measurement and examination of immune function was undertaken. The glandular fever like illness with rash and lymphadenopathy in one of the infected cohort had been published been apparent in 1984 (see above). It had claimed that the illness was unexplained. Professor Ludlam and others like Dr Tedder had claimed that eh reason why the request for test to be undertaken in October 1984 had been to prove their theory that the immune function issues which had been detected from spring 1983 were not caused by HTLV-III infection. The temporal proximity of the updated immune function examination (autumn 1984) and the infective illness of the glandular fever patient suggest that this was not accurate. There was an ongoing and increasing body of evidence that something else was going on. It is suggested that the evidence given in this regard is not accurate – the testing was to investigate whether what was apparent was in fact the development of HTLV-III infection of which all involved knew that these patients were at risk. As is discussed below, the immune function study was being conducted on a wider cohort of patients then those who eventually became infected. However, for some reason Dr Ludlam knew which samples to send to Dr Tedder for testing. We know that those whom he had selected tested positive. There must have been something about their treatment which meant that they should be singled out to be sent for the precious testing to be carried out. We know that those who were positive had received more treatment with factor VIII generally. We know that all but one had received the implicated batch and that those who were infected used more of it than the patients with haemophilia A who did not seroconvert. We also know that those with the worst immune function were the ones who became infected. An immune function examination had taken place in the autumn of 1984 – this must have identified those with the most affected systems or indeed some significant change in their immune function which stood out. In some way Dr Ludlam was able to select those who were positive without having access to a test. This shows at the very least that he knew that there was something about their treatment, either the volume, their immune function and/ or the exposure to the implicated batch which made them into the preferred candidates for testing. Dr Ludlam and his colleagues knew from their previous study that those with the

worst immune function and those who had had the most concentrate treatment were the most at risk. He knew whose samples to send for testing as a result. He had knowingly allowed them to be exposed to danger which had now manifested itself as he had could have predicted.

7.66 The next stage of the AIDS study was reported in a Lancet article of 3 August 1985.[2136] By that time, the infections with HTLV-III had been discovered, the details of which discovery are examined elsewhere in this submission. Professor Ludlam's "shock" as he described it in his evidence about the infections appears quickly to have worn off and the research benefits of the infected group to have dawned on him. In that article, it was reported that "An important feature of our study is that the patients' lymphocyte subsets were measured during the spring of 1983 when all those who had received exclusively SNBTS factor VIII were negative for anti HTLV-III. We have thus been able to compare lymphocyte subset data before and after infection with HTLV-III. It is commonly assumed that the reduction in T-helper-cell numbers is a result of the HTLV-III virus being tropic for T-helper cells. Our finding in this study that T-helper-cell numbers and the helper/suppressor ratio did not change after infection supports our previous conclusion that the abnormal T-lymphocyte subsets are a result of intravenous infusion of factor viii concentrates per se, not HTLV-III infection. It is possible however that there will be progressive time-dependent fall in T-helper-cell numbers as a result of HTLV-III infection, but only long term follow up will reveal this". The significance of the availability of the pre-study data and the unique features of the group had made them candidates for long term study.

7.67 By this point the study group had become focussed on those who had become infected as opposed to the larger group who had been the subject of the study published in June 1984. Fifteen had seroconverted, all of whom had received one common batch of factor VIII concentrate (the "implicated batch") which was thought to be the cause of their infection. One further individuals had seroconverted who had not received that batch – a minimum of two batches were therefore infective. Eighteen other patients who had receive the implicated batch

---

[2136] PRSE0004177 (5 August 1985)

did not seroconvert. Recipients of the factor IX made from the same plasma as went into the implicated batch did not seroconvert. This further research showed that the probability of seroconversion was independently related to (a) the extent of the T cell suppression in advance (the weaker the immune system the more likely to seroconvert) (b) the amount of the implicated batch received (the more of the infected batch to which the patient was exposed the more likely the seroconversion) and (c) the amount of prior treatment received (the more of the infected batch to which the patient was exposed the more likely the seroconversion). These results demonstrate that the more concentrate a patient had had, the weaker his immune system had become. The more viral load he was exposed to, the more likely that weekend immune system was to be unable to resist the virus. The heavier the concentrate therapy, the more likely the patient was to be weakened. The patients had not (on retrospective testing of stored serum samples of which patients had no knowledge) been infected at the time of the previous paper, published in 1984 but conducted in spring 1983. All 16 of the infected patients had seroconverted in 1984. The implicated batch had been used in treatment between march and May 1984 and 18 patients who had receive this batch die not seroconvert.

7.68 All of the information contained in this paper would have been of use to patient in understanding how and when they had become infected. It would have demonstrated that their heavy treatment regimes with factor VIII concentrates had contributed to them seroconverting. It would have explained that their infections had come in 1984, at a time when the warning from the US about the dangers of AIDS were well known. It would have shown that with greater care in donor selection, possibly surrogate testing with anti-HBc or temporary changes to their treatment regimes to minimise concentrate exposure their infections could have been avoided. It would have shown that the protection which they had consistently been told would result from their treatment with domestic products was illusory. It would have shown that they had been misled and had contracted a fatal disease as a result. As is discussed elsewhere in this submission, this information was not shared with the patients. Indeed, a number of them die not know at the time of the publication of this report about their positive status that

they had even tested positive. These discoveries were said in the article to have resulted from the "continuing assessment of our haemophiliacs". Serum samples of a larger group of 34 haemophilia A patients, 8 haemophilia B patients and one severe vWD patient were being studied for their immune function in the aftermath of the previous paper in the Lancet, during late 1983 and early 1984. During 1984 the haemophilia A patients were in receipt of multiple batches of factor VIII concentrate – ie no batch dedication system was in place. None of the patients in the wider cohort were known to have any other risk factors for HTLV III other than the replacement therapy, which shows that the treatment was known to carry a risk of infection which had not been discussed with the patients.

7.69 That the research was not conducted in accordance with ethical rules or the local ethical consent upon which it was based (or not based on the case of the 1983/ 84 immune function research) in fact invalidated the scientific conclusions of the research. However, more importantly, it continued to compound the harm which had already been inflicted on the patients and their families and ultimately destroy any semblance of trust which those patients could reasonably have been expected to have in those upon whom they relied for treatment for their chronic bleeding disorders.

7.70 A publication relating to the ongoing research into the wider Edinburgh cohort appeared in The Lancet in February 1988.[2137] The study revealed that (unknown to those patients) significant information about the progression of their disease, antibody response and the relationship between the results of testing for both antibody and antigen and the progression of symptoms (if any) had been gleaned. By this time one of the 18 patients who had seroconverted from those who had been exposed to the implicated batch had left Edinburgh. It is clear from the paper that some information was available about him from the period after he had left but that it was not sufficient to be able to monitor him as fully as the others due to the lack of serum sample being available.[2138] Thus, the authors of the study were following a patient after he had left the care of the Edinburgh centre. It is

[2137] PRSE0000836 (The Lancet, 28 February 1988)
[2138] PRSE0000836_0002

worthy of note that the study was funded by the University of Edinburgh and supported by the MRC and the SHHD. The serum samples had been made available by the "hepatitis and AIDS reference laboratory" of Edinburgh.[2139] Access to samples and to information gleaned from them was clearly available nationally and in the circles of government. The patients remained unaware.

7.71 The research continued, unknown to the patients involved in the wider cohort. further publication appeared in The Lancet in 1988.[2140] In this publication, patients were identified by their years of birth, as is considered above. By this point the infected cohort group which had been exposed to the implicated batch had become 18, as opposed to the 15 thought to have been infected by that batch who had featured in the previous publication in 1985. The total number of patients being studied at this point (the wider Edinburgh cohort group) had been defined and including 32 patients, all of whom had been exposed to the implicated batch but only 18 of whom were infected. By 1988, there was still at least one member of the infected group was unaware of his infection. The non-infected members were being studied without their knowledge or consent, or even an awareness that they were in a group with some special significance (ie having been exposed to a batch of factor VIII concentrate known to have been infective). By this point, the T cell levels of the 18 who had seroconverted whilst those in the uninfected group of 14 remained normal. By this time 2 had died and 7 had shared to shows symptoms – all still unaware that they were part of this ongoing study of T cell levels. Genetic testing had also been carried out on these patients which had apparently explained the more rapid decline of these 9 patients than had been reported in other studies to symptomatic disease as being associated with the presence of a particular HLA haplotype pattern.

7.72 The Inquiry has evidence of patients at the Edinburgh centre being involved skin testing, which Professor Ludlam has conformed was part of the immune function study. One such patient was misinformed as to the nature of this testing, as is described elsewhere in this submission.[2141] Another described the mystery of

---

[2139] PRSE0000836_0006
[2140] PRSE0004673 (The Lancet, 28 May 1988)
[2141] WITN2317009 @ para 1 (second statement of WITN2317)

being subjected to multiple needles.[2142] He was clearly unaware of what the testing was for.

Family research

7.73 It is important to point out that the research into the haemophiliacs group which came to be known as the Edinburgh cohort was not restricted to the patients. The research facilitated by the misplaced trust which patients in the haemophilia centre had in Dr Ludlam also resulted in him boldly including their family members in his research. Evidence is available from both of the families of the living Edinburgh cohort members that their family members were asked to give blood which was used for research purposes. As had been the case with the cohort members themselves, this blood was taken without adequate explanation for the purpose for which it was taken. This was clearly unethical. The patients received no explanation as to the purpose for which their blood had been drawn or their rights with regard to involvement in/ withdrawal from the research project. They received no information about the findings or the publication of the research, either in a journal or more informally.

7.74 No clear explanation exists to this day of the purpose of this family research. The Inquiry has evidence from Alice Mackie that blood was taken from her and her mother-in-law by Dr Ludlam's unit. No clear explanation was given to these individuals about the purpose of the blood being taken – in these case snot by their own doctors. There was thought to be a genetic component to the susceptibility of individuals to seroconversion to AIDS. It may be (though it was never explained) that the blood taken from those relate to the patients was taken for a study of that element of the project. This does not, however, explain why blood was taken for research from Mrs Mackie who has not generically related to her husband, clearly. She was told that the research was "genetic" which she never

[2142] WITN2168001 (first statement of Myles Hutchison)

understood. Like the others involved, she gave her blood on the mistaken understanding that it was for the sole benefit of her husband, as any loving family member would. Like the patients themselves, whose trust in the department and Dr Ludlam had been exploited for the purposes of the research, their affection for their loved ones was similarly exploited for the same purpose. The only logical explanation for this element of the research must therefore have been to monitor whether she had become infected by her husband and what the immune function to reaction to such a secondary infection might be. Thus, it was known that she was at risk. Of course, it was not even known to the Mackies that Robert had become infected until January 1987. The only protection which Mrs Mackie had against this clearly known risk of unwitting infection by her husband with a fatal disease was the vaguely worded warding about contraception which had been imparted at and in the aftermath of the December 1984 meeting which the Mackies and others reasonably thought did not apply to them. It is also worthy of note that the Inquiry has evidence to the effect that another of Robert Mackie's extended family (his uncle) was part of a human genetic register in the RIE haemophilia unit.[2143]

7.75 GRO-D

GRO-D [4] This shows that the interests of the centre in trying to understand the consequences of infection stretched beyond the patients in the unit themselves. It also shows that there was a known transmission risk to family members which was allowed to exist. None of these individuals could have been aware of the risks as the patient and hence his relatives were not even aware of the fact that the patient himself was infected, until he was told in 1991.

7.76 The background to family research at around this time can be found in documents available to the Inquiry. In August 1985, Dr Forbes was looking for information about the HTLV III status of family and sexual contacts to gain information about

---

[2143] WITN3477001 @ para 23 (first statement of Carolyn McGimpsey); WITN3477012

[2144] GRO-D

the transmissibility of the disease on behalf of a UKHCDO committee.[2145] In octiber 1985, Peter Jones raised ethical issues with the proposed survey of haemophiliacs. In that correspondence Dr Ludlam was the one who was involved in drafting the form for the study.[2146] In October 1985, Dr Forbes discussed a study to assess the anti-HTLVIII status of household and sexual contacts of haemophilic patients.[2147] On Dr Ludlam's notepaper, a revised version of this research proposal suggested that it **may** be important participants are given information about the study and that it **might** be appropriate to seek local ethical approval (emphasis added). The ethical issues with the haemophilia patient studies had now spread to the family research. Family members were not even the directors' patients. This appeared to create no perception of ethical impediment.

Research records

7.77 It is clear from the analysis above that the State derived significant benefit from the infection of the cohort members. Both before and after their infections, their trust in the doctors and nurses who took their blood was misplaced. They willingly gave their blood to the medical staff on the assumption that what was being used for related to their treatment and served no other purpose. They were kept in the dark about what their blood samples were used for.

7.78 It is inconceivable that such a meticulous project could not have required detailed record keeping of the various measurements which were being undertaken by the research team. The projects became so large that Dr Ludlam employed a research

---

[2145] HCDO0000271_101 (1 August 1985) - Letter from C. Forbes (in capacity as the chair of the UKHCDO AIDS Committee) to centre directors. Regarding 'Haemophilia Centre Directors Anti-HTLVIII Survey of sexual contacts and household members

[2146] HCDO00000271_088 (22 October 1985) - Letter from Peter Jones to Dr C. Forbes. Re "sexual and household survey"

[2147] 07 October 1985 - HCDO0000019_023. Letter from C.D Forbes to a Director. Regarding "Survey of Anti-HTLVIII Status of Contacts of Haemophiliacs".

assistant, in the form of Dr Tucker. Such record keeping must have involved results of various measurements taken of the patients' blood and analysis of it. All of the information which would have been contained within those records emanated from the patients. It was not kept in their records, as it should have been. All of that information related to the charting of the progression of a likely fatal disease, which carried enormous social stigma. As no information about the research was given to the participants, no detail of the way in which the information was generated, stored, shared or otherwise processed could have been given to them either. It is understood that the Inquiry has made efforts to recover the research records and that none have been forthcoming. It is inevitable that such records must have existed. They must have been destroyed. That they did constituted a further serious breach of the patients' right to privacy and access to information being kept and used about them. This aspect of the criticism being levelled at the clinicians applies not only to Professor Ludlam but also to those in Glasgow who were also involved in carrying out research on similar patients in the west of Scotland.

(f) The Glasgow AIDS research

7.79 In Glasgow, research was carried out on the immune function of patients at risk of HTLV-III infection. In his evidence presented to the Penrose Inquiry, Professor Forbes explained that patients were already at risk of infection in his view. He claimed that they had become aware "very early on" that the disease was probably being transmitted through blood products, concentrates more than cryoprecipitate.[2148] He managed to get access to what he described as "early tests" from the research group under the control of Dr Melbye in Denmark. It is unclear whether this means that he was able to access the anti-LAV tests which were clearly available to the Melbye group. The access which they had to these tests, it

[2148] PRSE0004744_0002 @ paragraphs 5 to 6

is submitted, should have allowed earlier diagnosis of infection in the Glasgow group. This should have allowed detection of transmission to have been made earlier and steps taken to protect further transmission to other patients. Information about the fact of infection only appears to have been communicated to patients in Glasgow early in 1985, after the Edinburgh outbreak had come to light (see below). He accepted that they became aware of transmission as a result of "early testing on special samples" which was made available by Dr Melbye.[2149] His impression was unlike the position in Edinburgh, where Dr Ludlam remained convinced that his patients had not been and would not be infected due to the complete protection which he deduced was derived from the voluntary donor system in Scotland and his use of PFC factor concentrates.

7.80 The Glasgow research was first published early, in October 1983.[2150] The study involved 19 patients, there being no evidence that any of them were consented or knew about it. In the report, it is interestingly stated there was no reason to suggest that the disease was likely to be associated predominantly with US rather than domestic concentrates based on analysis of immune function. This meant that it was the view of the authors that they were open to the possibility that either or both had caused the immune function irregularities noted. The results showed a decrease in T helper cells and increase in T suppressor cells, the reversed ratio. It was noted that Scottish haemophiliacs showed similar results to their US counterparts, thought it was not known what product (commercial or domestic) had caused the infection). No action was taken. In the final paragraph, it was observed that whether these patients were in the prodromal stage of AIDS would become apparent clinically. It was thought the lymphocyte abnormalities which were shown might be the early stages of AIDS and so entertained the possibility that the results were indicative of infection. Despite this recognised the possibility that patients were infected and hence infectious with a fatal disease they were not told. The report of this research suggested gradual diminution of the patients' ability to resist infections or neoplasms (tumours) as a possible consequence of

[2149] PRSE0004744_0002 @ paragraph 7
[2150] PRSE0001121

repeated injection. Professor Forbes recalled in his Penrose evidence that he and his colleagues "guessed it probably was some kind of virus that we had never encountered before".[2151] Despite this, nobody was told and there is no evidence that anything as done to intervene in the treatment regimes. It was erroneously assumed in the article that these patients had been infected/ possibly infected by commercial products, given that from the date of the knowledge of AIDS in 1980 the commercial factor VII usage in Glasgow had been (a) 1980 – at least 7% (b) 1981 - 10.8% (c) 1982 – 1.3%, ie much more NHS concentrate had been used.

7.81 In a letter from Dr Froebel to Dr Perry re the updated study dated 29 October 1984, she confirmed that the study has been ongoing and included Dr Gallo.[2152] The positive results were known by October 1984. It should be noted that she reported 13 patients who appear to have tested positive here whereas the UKHCDO information which was used to generate the Penrose table 3.17 indicated only 12 patients infected in Glasgow. Also, that could not have included patients G3, or G9 – 11 who seroconverted later than October 1984. In October 1984 Dr Froebel was anticipating that the anti-HIV test would be commercially available in 2 – 3 months but it was not until October 1985.

7.82 This led to the Lancet study of Glasgow patients in December 1984, published jointly with the Danish (Melbye) group. The Danish group had access to test early in 1984.[2153] The Danish group reported positivity to a sensitive LAV assay, showing 16/22 22 tested clearly positive. With that test, the Scottish patients could have been tested earlier than they were. Professor Forbes thought that they did have access to that test, which means that the delay between testing and patients finding out in Glasgow was from earlier in 1984.[2154] The study indicated that the infections in Glasgow, based not on immune function but anti-HIV testing were by that time thought to be due to US concentrates transfused pre-1982.[2155] As the

---

[2151] Penrose Inquiry transcript for 28/04/11 (Day 17); 90 (Professor Forbes) [PRSE0006017_0090]
[2152] PRSE0000259

[2153] See PRSE0002859 (Lancet 7 July 1984)

[2154] PRSE0004744_0002

[2155] PRSE0001630

Penrose data shows this was erroneous as a number of the Glasgow infections were caused by SNBTS concentrates. Thus, in the meantime patients who had been infected were left potentially to infected other in the time between the studies. The study also shows that a Glasgow severe haemophilia A patient had died in October 1984 and had been showing symptoms of AIDS for 7 months, from March 1984.[2156] There is no evidence that the signs of that infection caused a change in treatment policy for others. Greater awareness that the symptoms could be AIDS (which were meant to be being monitored for reporting to Dr Craske) could have prevented the Edinburgh cohort and other infections. The symptoms and death of this patient also show that any suggestion that the implications of anti-HIV positivity were not well understood in 1984 is erroneous. A patient had already died.

7.83 The study also observes that by 1981, 9% of Danish homosexuals had anti-HTV III and that that was strongly associated with travel to the US. International travel spread the virus potentially into the donor population from at least 1981.[2157] The earlier assumptions that Europe was somehow immune from the spread of the disease were wishful thinking and irresponsible. Recommendation at the end of the article was irresponsible. It was to use concentrates from low risk donors for children and new patients. As was subsequently ascertained (and could have been at the time of the article), 2 of the positive patients had not had any commercial treatment. Others could have been infected from the UK treatment due to their mixed treatment. The Scottish donor pool was compromised. Yet, the authors still advocated the use of concentrates, even in children in whom it had been recommended to use cryo since at least February 1984. It is unknown who could have been considered in this context to be low risk donors. This had partly been caused by the fact that the donors were thought to be low risk and were not.

[2156] PRSE0002859_0002

[2157] PRSE0002859_0003

7.84 As in Edinburgh the immune function tests continued thereafter on infected patients.[2158] A study was undertaken of 29 severe haemophiliacs, 12 of them HIV positive.

7.85 It should be noted, in connection with this research, that Professor Gordon Lowe was asked about it (as one of the named authors) in his oral evidence to the Inquiry. He claimed to know little about it and stated that he had only played a minor part in the research, which he (unlike Professor Ludlam) did to claim to be anything other than research. In a situation where a named author has had the opportunity to explain the content of the papers and defend it, we submit that the Inquiry should not be slow to draw the adverse inference that this was yet another example of haemophiliacs being used for their research value and they are their families being kept in the dark about the risk that they may be infected, which caused unnecessary harm and lost an opportunity to make changes to the treatment regimes which could have prevented later infections.

(g) The role and potential of white cell research and other information in monitoring the emerging picture of damage

7.86 It was often said by clinicians involved in treatment that information about the threats from viral infection, such as HIV or HCV was not well understood and so it was not possible to advise patients properly as to what the downsides of infection might be. It is argued elsewhere in this submission that ample evidence was available which ought to have alerted clinicians to the risks, such that action as regards treatment was mandated. The white cell research undertaken in Edinburgh by Dr Ludlam and in other centres as a result of a combination of Gordon letter and the co-ordinated approach to assessing haemophiliacs from

---

[2158] PRSE0003671 – 18 October 1986 - Article by R Madhok, A Gracie, G Lowe, A Burnett, K Froebel, E Follett and C Forbes titled "Impaired cell mediated immunity in haemophilia in the absence of infection with human immunodeficiency virus". Published in the British Medical Journal Vol 293, pp. 978 – 980 (skin testing for immune function)

around 1982/83 was based on the possibility that they may have AIDS or have been exposed to the agent which caused AIDS is assessed above. In her evidence to the Inquiry, Dr Diana Walford stated that that of a patient who had only had a BPL concentrate had contracted AIDS, that would have "thrown us into the most terrible confusion".[2159] As is argued elsewhere in this submission, there seemed to be a blindness within the DoH as to (a) the possibility that patients in the UK may be infected with the agent causing AIDS generally (the focus being on incidence of AIDS as opposed to risk of infection with the agent causing it) and (b) the possibility that the agent causing AIDS had entered the UK donor population, such that it was now potentially being transmitted to the recipients of domestically produced blood or blood products.

7.87 It remains unclear what if any information was made available to Dr Walford or the DoH more generally about the research going on into the T cells of haemophiliacs in the UK in centres like the Royal Free, Edinburgh and Glasgow. In her evidence she was taken to a paper by Dr LK Fowler from within the department which advocated moving haemophiliacs into cryoprecipitate to minimise the risk from AIDS.[2160] She seemed to be under the impression at the time of her evidence that white cell derangement was also apparent in patients treated with cryo[2161], though not as bad as with concentrates, which does not seem to be borne out by the literature (see below). She talked about information about altered immune systems but there is no evidence that the detail of the picture emerging was shared with her. This information ought to have been shared with government, as should information available about T cell derangement which pre-dated the start of that research in 1982/3. The research being undertaken in Glasgow and in other centres where patients had been exposed to commercial concentrates was interpreted as possibly meaning that haemophiliacs' T cell derangement meant that they had been exposed to the caused AIDS. In many cases, retrospective testing shows that that was accurate. The Edinburgh research showed T cell derangement in patients who were wishfully thought not to have been exposed

[2159] IBI transcript for 21 July 2021; 50 (Dr Walford)
[2160] DHSC0002229_059
[2161] IBI transcript for 21 July 2021; 77 (Dr Walford)

to the risk of AIDS (which turned out to be true). A systematic assessment of this information (and indeed mor historic T cell derangement data in haemophiliacs) would have enabled the emerging picture to have been assessed as showing (a) that there was evidence of haemophiliacs showing signs of T cell derangement similar to the pattern seen in homosexuals with AIDS in the US and (b) that even of these derangements were not caused by the AIDS-causing agent, they showed that immune function was becoming harmed by concentrate use, which showed that concentrates were causing harm anyway. Such evidence ought to have been interpreted as showing that a temporary cessation or reduction in concentrate use should be ordered, at least in areas where this was possible, such as Scotland. The very fact that this research was going on indicated that the haemophilia clinicians thought that they considered their patients to be at risk of the kind of immunosuppressive agent which led to AIDS. In Edinburgh, the records indicated that it was called the "AIDS study". In addition to the information collated via the Edinburgh and Glasgow immune function studies, which are analysed above, the following pattern emerges from the evidence. This pattern could and should have been considered as part of the emerging picture of the cumulative harm being done to haemophiliacs by concentrate use.

7.88 A September 1984 article which was published in the Lancet called "Prevalence of antibody to human T-lymphotropic Virus Type III in AIDS and AIDS-risk patients in Britain" indicated that sera from haemophiliacs had been collected since 1982.[2162]

7.89 The US material about white cell dysregulation started to appear in the literature from early 1983. One article included tables depicting lymphocyte proliferation in haemophiliacs and controls in addition to natural-killer activity of peripheral-blood mononuclear cells.[2163] The article was written by Ratnoff & Ors, whose connection with Professor Forbes from his Penrose evidence is explored elsewhere. The article reported 3 cases of PCP in haemophiliacs, 2 of which had proven fatal and 2 of whom had oral candida, a symptom which emerged in the Cardiff patient under the care of Professor Bloom in the spring of 1983 and was reported to Professor

[2162] NHBT0000068_015 @ page 478

[2163] PRSE0004470 – 13 January 1983 - Article in The New England Journal of Medicine Volume 308 No. 2 - Impaired Cell-Mediated Immunity in Patients with Classic Hemophilia

Ludlam in connection with one his multi-transfused leukaemia patients (the late husband of witness Mrs U) around the same time. Immunological studies in the survivors showed (a) poor lymphocyte response to mitogens (a protein which induces white cell action/ mitosis) (b) absolute and relative reduced overall number of T helper cells (c) an increased ratio of T suppressor cells. It was noted that it had also been reported that this was new disease, whose characteristics were suggestive of transmissible agent.[2164] The article noted a similar pattern of cell mediated immune abnormalities which had been observed in haemophiliacs being given factor VIII concentrate but not those treated with cryoprecipitate, an indicator that that latter treatment was not associated with the white cell dysfuction. The pattern was not precisely the same, as it showed a reduced ratio of T helper to T suppressor cells but not the same level of overall drop in T cells. The article concluded by asking the the question of whether the immunosuppressant agent which caused AIDS was what is caused the immune abnormalities in the haemophiliacs. It was conceded that the position remained unclear. The possibility of the immune dysfunction being caused by HBV is rule out as they are not HBV positive on testing. It was postulated that the evidence was either indicative of an infective agent or a predisposition to harm on the part of the haemophiliacs due to immune function irregularity caused by concentrate exposure. The concentrates were thus being classed as actually harmful (transmitting infection) or potentially harmful (creating a predisposition to infection due to the harm being caused to the immune system, the body's ability to fight infection either way. Exposure to risk and predisposition to suffering its ill effects. This was the same pattern seen by Professor Ludlam in his 1983 study, though he (correctly as it happens) rules out option 1 as he not think that his patients could have been exposed to a transmissible agent. The remaining option was that they were being predisposed to harm, meaning that he continued allow them to be exposed to the agent creating his predisposition. Ultimately, they became infected in the spring of the following year. His scientific interest in the comparison appears not to have caused any alarm bells to ring, for the matter to

[2164] Under reference to Marx, "New disease baffled medical community" (Science, 1982)

be discussed with his patients any change in the treatment regime to be proposed, despite the fact that the concentrates were thought to be predisposing the patients to harm.

7.90 Another US article was published on the same date in the New England Journal of Medicine.[2165] It reported that homosexual AIDS patients had shown lymphopenia, decreased T4 helper cells, increased T8 suppressor cells, inverted ratio of T4 and T8 cells and that the three recently diagnosed haemophiliacs with AIDS defining illnesses also showed decreased numbers of T cells and inverted T4/ T8 ratio. None of the patients in the study treated with volunteer donor cryo and 57% of those treated with commercial factor VIII had abnormal T4/T8 ratios. This evidence was said to be consistent with possibility that AIDS linked to use of concentrates, though it was said that the population was too small to be sure and that it was not clear if this would be a transient change in ratios or a persistent one. The authors urged those treating patients with haemophilia to monitor for the stigmata of AIDS or immune function abnormalities.

7.91 A further US article was published in the Lancet on 5 March 1983.[2166] It referred to the article by to Kornfeld et al (1982) which postulated (amongst homosexual subjects) the (a) overall depression of lymphocyte and (b) the reversal of the normal T helper T suppressor cell ratio as the mechanism for allowing the opportunistic infections.[2167] 5 of 25 young haemophiliacs showed an inversed ratio of T helper and T suppressor cells.

7.92 A further US article reported a striking alteration in the normal T helper T suppressor cell ratio in 9 of 12 healthy haemophiliacs similar to that seen in 2 patients previously studied with PCP and homosexual men.[2168] The 3 who did not demonstrate that reversal were much less exposed to concentrates.

[2165] PRSE0001320 – 13 January 1983 - T-Lymphocyte Subpopulations in Patients with Classic Haemophilia Treated with Cryoprecipitate and Lyophilized Concentrates, Menitove, JE et al

[2166] PRSE0001330 (5 March 1983) – (US) - Article titled 'Altered distribution of T-lymphocyte subpopulations in children and adolescents with haemophoilia' Luban,NLC et al, The Lancet

[2167] "T-Lymphocyte Subpopulations in Homosexual Men" N Engl J Med 1982; 307:729-731 (attached to ARMO0000234 (internal memo within Armour dated 11 January 1983))

[2168] PRSE0003158 - Article titled 'T-Lymphocyte subpopulation abnormalities in apparently healthy patients with hemophilia' Goldsmith, JC et al, Annals of Internal Medicine (US)

7.93 Then followed the Gordon et al letter in in Lancet.[2169] It reported 3 haemophilia AIDS cases in Spain and listed 4 studies of abnormal T-lymphocyte distribution in haemophiliacs in US and the fact that there were 11 cases of AIDS in haemophiliacs in the US reported to CDC. It mooted the possibility of there being a transmissible agent which caused immunosuppression before full AIDS or an immunosuppressant state due to concentrates which predisposes patients to later infection.

7.94 An internal Armour memo enclosed an American Medical Association article entitled "What is the role of Factor VIII therapy in inducing helper suppressor ratio reversals in haemophiliacs".[2170] It referred to a San Diego conference at which it was showed that the severity of the imbalance in the T4/ T8 ratio was due to the number of doses of factor VIII received and that the reversal of the ratio was shown in those with factor VIII therapy and not those who had had no therapy or got factor IX. Though this reversal did not show that the concentrates caused AIDS, it dis show that the concentrates caused the reversal of the ratio as seen in AIDS patients.

7.95 During period when these results were emerging from the US linking a particular pattern of white cell dysfunction with homosexuals with AIDS and haemophiliac patients, copious work was going ion to investigate whether the same phenomenon was apparent in UK haemophilia patients. By 15 January 1983 (two days later), Jones et al reported T cell subset OKT 4 and 8 reversal in 11 of 16 patients in Newcastle, who were treated with large amounts of commercial concentrates. This white cell dysregulation was associated with the emergence of AIDS in the US, as follows:

> *"However, an immunosuppressive syndrome associated with T cell subset reversal has now been noted in a small population of multi-transfused, heterosexual haemophiliacs in New York (M Hilgartner, ponal communication).*

[2169] CBLA0000059_031 – 30 April 1983
[2170] ARMO0000281

The syndrome shows similarity with that affecting homosexual males in the United States and named acquired immune deficiency syndrome (AIDS)."[2171]

7.96 Grant applications were required to be filed for much of this work. Minutes of the meeting of the executive committee of the Haemophilia Society dated 14 June 1983 contained reference to numerous applications for funding into AIDS, including an application by Dr Kernoff (Royal Free) on the effects of blood products on immune function and by Dr Forbes (Glasgow) (long term study of cell function, complement function and clinical evaluation).[2172]

7.97 By 18 October 1983, the MRC Working Party on AIDS was looking at possible recommendations for grants on study of AIDS.[2173] The importance of studying those in the early stages of the disease was stressed. It was acknowledged that the blood products cases would enable the various different aetiological theories to be tested. T helper cell depletion was thought to provide the best clue as to pathogenesis. CD4 are T helper cells which assists the body's immune response to pathogens, CD8 cells secrete cytokines to mount an attack to pathogens. Data available from blood studies broadly represented what was happening in lymphoid tissue.[2174]

7.98 Interestingly, it was noted that the appearance of virus like particles on electron microscopy also to be monitored. [2175] It should be noted that the possibility that a virus could be identified by this method in the blood of infected individuals, even before a test for the virus was available was recognised in the evidence of Professor Tedder.[2176] He indicated that he was keen to use this technique to try to identify the virus responsible.[2177] This was the proposal which led him to describe having been told by the DoH to go away and "stop rocking the boat". Along with

---

[2171] DHSC0002351_004 (15 January 1983)
[2172] HSOC0029476_024 – minutes of the meeting of the executive committee of the Haemophilia Society dated 14 June 1983 - @ 0003/ 0004
[2173] PRSE0000389 – 18 October 1983 – MRC Working Party on AIDS
[2174] Ibid, page 3
[2175] Ibid, page 4
[2176] WITN3436003 @ paras 20 and 25, where he talks about Professor Dane pioneering the use of the electron microscope as a diagnostic tool, a technique in which he was trained
[2177] WITN3436003 @ paras 67

the emerging evidence from the white cell testing, there were thus further methods which could have allowed identification of the virus causing the condition which would have allowed it to be discovered that those who had been exposed to commercial concentrates already had evidence the virus, whereas those who had not, did not. This would have allowed steps to be taken to avoid their infections.

7.99 The MRC working party meeting further identified that the fact that the AIDS epidemic was lagging some 3 years behind the US in the UK was important, in that the pre-AIDS state in high risk groups could be identified. Thus, the priority certainly seemed to be on the importance of looking at the pre-AIDS state in high risk groups to understand how the infection changes the characteristics of the group, as opposed to the opportunity to avoid those infections occurring in high risk groups. It was noted that the UK system for haemophilia treatment would allow detailed study of the disease which had not been possible in the US due to their system of record keeping.[2178] Blood transfusion policy and the possibility of using "clean" donors panels was discussed as well as the close links between clinical and laboratory workers deemed important in immunology research. Under "possible genetic engineering", the possibility of producing concentrates products from those with "pre-AIDS" discussed.[2179] Avenues for communication between the MRC and DHSS were agreed at the meeting to make sure that projects not taken up by the MRC could be taken up by the DHSS. [2180] The meeting was attended by Dr Prentice of SHHD and Dr Walford of DHSS. Dr Galbraith sent apologies. Thus, the emphasis over this period appears to have been on looking at the research value of haemophiliacs and not on the possibility that what was being demonstrated could be used to prevent infection.

7.100 Research was undertaken at the Royal Free Hospital.[2181] In 1983 it showed low T4/ T8 rations in 27 of 41 of above average factor VIII usage patients who had mixed

---

[2178] Ibid, page 4
[2179] Ibid, page 5
[2180] Ibid, page 6
[2181] See OXUH0002974_001 (25 October 1983) - Letter from C. R. Rizza to Dr Christine A. Lee, The Royal Free Hospital, re: results of the differential white cells counts on patients; WITN0644065 "Plasma fractionation methods and T-cell subsets in haemophilia" (16 July 1983) (Lancet), Lee et al

factor VIII treatment. The article concluded that this may have a biological cause and should "not necessarily be regarded as being predictive of AIDS" but appears to entertain that possibility. The chance to act on these results as indicative of the possibility that US treatment had caused AIDS in UK patients to prevent further such infections was not taken. A further publication from 1984 provided further information on the Royal Free Group.[2182]

Patient records

7.101 The Inquiry also has access to patient records which show that white cell testing prior to the 1983 research was being carried out and that this could have given an indication (a) at an early stage that the concentrated were causing some T cell derangement in some patients, indicative of the fact that concentrate therapy was causing harm even pre-AIDS and (b) that some patients were showing signs of such derangement similar to the US homosexual AIDS patients from an early stage, such that action could have been taken in light of the risk that that was indicative of AIDS to prevent further exposure and infection. Records available to the Inquiry of such testing include:

a) TREL0000167_003 - 14 September 1980 – anonymised patient record, indicating that the patient's lymphocyte percentage was being monitored as part of routine bloods in 1980/ 81
b) TREL0000173_082 - 22 January 1982 - anonymised patient record. Dr Aronstam thanks Bloom for agreeing to put the patient on the European study. Part of the study was to include three monthly samples requiring lymphocyte separation. Inhibitor levels would need to be tested during the summer holidays.

[2182] CBLA0000059_038 (13 April 1984) – The New England Journal of Medicine article: "Abnormal T-Lymphocyte subsets in hemophilia: Relation to HLA proteins in plasma products", by Christine A. Lee et al

c) TREL0000108_006 – 2 January 1983 – anonymised patient record with immune function results, including normal OKT4/ 8 ratio at that time (1.3 above 1)

d) TREL0000276_065 - 26 January 1983 – anonymised patient record with immune function results, including normal OKT4/ 8 ratio at that time (1.3 above 1)

e) TREL0000143_058 – 14 June 1983 - anonymised patient letter recording that the patient had lost movement in his elbows and both shoulders due to his reluctance to treat himself adequately because of the 'current hysteria about AIDS'. Dr Aronstam also noted that lymph nodes have been found and the patient's T lymphocytes were showing the same sort of inverted ratio that characterises HIV. By this point this patient had become infected.

7.102 This research undertaken in this area was designed to try to work out (by using in effect a surrogate test for immune function abnormality as a marker for "infection" with or exposure to the causative agent of AIDS) whether haemophilia patients may already have been exposed to the agent which caused AIDS and/ or at risk of going on to develop AIDS. The government evidence available to the Inquiry indicated that there was a general confusion between incidence (numbers of AIDS patients) and risk (the calculation of the future possibility that patient will develop AIDS). This was a mistake, in light of the known latency period between "infection" or exposure and the development of AIDS. Focussing on the numbers of AIDS cases would inevitably not be an appropriate approach in light of the latency period, as by the time a significant number had developed AIDS, the opportunity to prevent exposure/ infection would already have passed. Lord Clarke's evidence was that even well into 1985 all he was being told about was the numbers of actual AIDS patients, not the likely number who had been exposed/ infected and so the likely number who would in time develop AIDS.

7.103 The research was an attempt on the part of the clinicians to gauge how many patients had already been already exposed to the causative agent of AIDS and so at risk of going on to develop AIDS at a time when further infections could have been prevented. The evidence of immune function abnormality was a relevant body of evidence of which Dr Walford should have been aware in her assessment

of the position in advising government as it was relevant to risk, not just incidence of AIDS. If she was not aware of this research or its results, that would represent a significant omission, in our view. If she was, she should have acted upon it to recognise that risk as manifesting itself in real time due to the immune dysfunction shown in the patients and take steps to order action be taken to prevent further transmission. The material above shows clearly that the priority was to use the haemophiliac population to learn about the disease not to do what could be done to prevent them from suffering the effects of it.

(h) Research elsewhere in Scotland

7.104 It has been suspected that the certain of the boys at Yorkhill may have been part of a research project as well. This is based on the fact that their treatment regimes were so contrary to the accepted standard practice in Scotland at the time as well as the fact that they were generally only exposed to one type of commercial concentrate (Armour Factorate) which would have allowed some assessment to be undertaken of the effects of that product. Th Inquiry has access to evidence about research being undertaken elsewhere involving the effects of Armour Factorate on children, notably in Birmingham where that product was also used in their treatment. It has been a reasonable inference that the boys at Yorkhill may have been involved in research as well. We would urge the Inquiry to look into this possibility further in an attempt to understand fully what happened there.

(i) Post mortem research

7.105 There is evidence available to the Inquiry to the effect that post mortem research was also carried on haemophiliacs who continued to offer value to the medical community, even after they had died. Harrowing evidence in this regard was heard

by one witness who gave oral evidence to the Inquiry as Mr AB.[2183] He was the father of twin sons who had both been infected with HIV as a result of their treatment at Yorkhill Hospital in Glasgow. In his evidence he explained the suspicion he had had that his sons had been used as "lab rats". It is submitted that this suspicion was justified by the fact that he had discovered that it was unusual for them to have been treated as they were in Scotland, especially as children, as they were on a prophylactic regime, using a large amounts of commercial concentrates. He was also aware that they had been given AZT treatment for AIDS which seemed experimental as the dosage they were given was wrong.[2184] When one of his sons was dying of AIDS at Ruchill Hospital, he described how he had initially been resistant to the possibility of a post mortem when asked about it by a doctor before his son died. He eventually agreed in the broadest of terms despite that resistance as his wife had been convinced that doing so may be of benefit to their other son. He had subsequently been unable to access the post mortem report (which was destroyed, he was told) but was horrified to learn that his son's brain had been examined post mortem, which is precisely what he had not wanted to happen – "he had suffered too much already".[2185] Records revealed that neuropathological examination of his brain had taken place at another hospital in Glasgow.[2186] In addition to the terrible trauma of losing his son to AIDS this had compounded the harm he and his wife had suffered immeasurably. He died of encephalopathy in 1992. During the course of the Inquiry, responses were sought from the doctors who had been responsible for this. These responses revealed the extent of the post mortem examination and the fact that the information from it, along with body parts had been circulated amongst various medical schools and researchers, indeed around the world.[2187] Given the initial resistance on Mr AB's part to having the post mortem examination done at all, the extent of this activity involving his son post mortem was indeed shocking. He had not known about that

---

[2183] WITN2239001
[2184] WITN2239001 @ para 38
[2185] WITN2239001 @ para 46
[2186] WITN2239006
[2187] WITN2239012, para 5 and para 10

until then and had certainly not agreed to it. He had, in fact, been reassured by the doctors that the post mortem would be minimally invasive. The consent form which he signed was consistent with this understanding of what was to happen.[2188] He has rightly suggested that clarity in what he was consenting to in written form was necessary in the distressing circumstances of his son's death.[2189] He has rightly called for the inquiry to recommend that the medical profession requires to be honest and transparent at all times.[2190]

7.106 The Inquiry is, of course, also aware of the research carried on under the auspices of the National CJD unit in Edinburgh, involving amongst others, Professor James Ironside. He was involved in a study which reported in the late 1990s which involved the examination of the brains of 33 haemophilia patients who had been infected with HIV. The purpose of the study was to assess the possibility of CJD infection from factor concentrates.[2191] The study involved deceased patients from London, Oxford and Edinburgh. They had "been consented" for another project involving AIDS but their brain tissue was used for this research as well., as well as their spleens subsequently being examined.[2192] In his evidence Professor Ironside discussed the possibility that relatives might be asked to consent to tissue being retained "for research purposes" without any further specification or notification of what that might be.[2193]

7.107 Further, the Inquiry is of course aware of the fact that blood samples are retained by haemophilia centres in Scotland, most notably Edinburgh. These are also kept of other patients infected from transfusion, such as in the case mentioned above of the husband of Mrs U.[2194] Thus, even after their death from diseases with which the State had infected them, haemophiliacs continued to be used for their value to medical research. Even in death, they were not given the human respect and

---

[2188] WITN2239012, para 7
[2189] WITN2239013, para 9
[2190] WITN2239012, para 16
[2191] HCDO0000133_024, "Retrospective neuropathological review of prion disease in UK haemophiliac patients."; IBI transcript for 17/05/22; from 22 (Professor Ironside)
[2192] Ibid, 24 to 25 and 121 to 122
[2193] Ibid, from 118
[2194] WITN0136001

dignity they had a right to expect. They continued to be looked as "useful material" or commodities.

(j) Suspicions about research

7.108 The evidence available to the Inquiry about actual research which was carried out in bleeding disorder patients in Scotland, for example the Edinburgh and Glasgow immune study groups, hepatitis research and the infected and wider Edinburgh cohort. The evidence available about these groups is analysed elsewhere in this submission. Beyond that, there are many witnesses who have given evidence to the Inquiry to the effect that they believe that they were involved in research. The fact that patients or their parents were not told about risks of the treatments which they were given (which is a near universal theme in the Inquiry's patient evidence from Scotland), in some cases that there were delays or inadequacies in sharing the fact of diagnosis, including the apparent total lack of any explanation as to how the infection had occurred or whether it could have been avoided, the common practice of testing without knowledge or consent (all common themes in the evidence which the Inquiry has heard about the infections in Scotland) have all contributed to the reasonable suspicion that this may have been the motivation for doctors to administer treatments for research purposes as opposed to in the patients' best interests. It is submitted that the inadequacies of consent procedures, the secrecy around testing, delays and inadequacies in these other areas render these suspicions entirely reasonable and natural consequences of the way that these patients were treated, in particular in the knowledge that published research was undertaken on fellow bleeding disorder patients. In addition, numerous patients gave evidence of large amounts of blood being taken from them without any clear explanation as to why.[2195] Though these patients were aware and understood the need for clotting tests to be undertaken to

[2195] Eg WITN2219001, para 21 (first statement of WITN2219 - GRI); WITN2190001 @ para 10 (first statement of Robert Mackie)

monitor their bleeding disorders, no consent could be deemed to have been given for testing or any other work with that blood beyond that. Patients have rightly become suspicious about what the blood was being used or tested for – possibilities include testing for the effects of viral exposure, for the purposes of studies or otherwise, the development of viral testing or vaccines etc. The Inquiry has been unable to ascertain whether research had indeed been undertaken on these groups. It seems to have been common practice to test for HBV and undertake surrogate tests for NANBH and measure liver function. This was for the purpose of monitoring the progression of disease and at least created the opportunity for the fruits of these investigations to be used for purpose other than the direct treatment of the individual patient. The fact that this happened without the details being discussed with the patients or their parents in most cases has inevitably and reasonably raised suspicions further.

7.109 These suspicious are all the more reasonable in certain groups, the circumstances of whose infections give extra objective reason for them. Previously untreated patients were clearly of potential value to medical research in that their reaction to first or early treatments would provide medical data about infectivity and infection which would be explained by the one or the few treatments and hence would be unmuddled by the consequences of past treatments. Many of these were children who have questioned whether the treatment which they have received (and possibly which might have been avoided, and thus their infections be avoided or at least the risk of them lessened). Such patients are even more justified in their concerns and suspicions in this regard which are well founded against this background. GRO-D

GRO-D

GRO-D He questioned the need for his treatment legitimately and this was a time when the infusion would have been highly to be infective (1983) and thus provide useful information about infection in a controlled environment. These suspicions were also held by the family of a child

---

2196 GRO-D

who had vWD who had first been treated in 1983 at the age of 2. He was treated with factor VIII concentrate after he was mis-diagnosed as having haemophilia A after a bleed in that year. He was infected as a result with HCV. He was later treated successfully with products other than factor VIII.[2197] He was also treated with cryoprecipitate which did arrest the bleed.[2198] He should have been treated with this in the first place. The unsatisfactory nature of the mis-diagnosis, the possibility that he could thus have been treated with other products (cryoprecipitate or FFP would have been likely to have had effect in such a patient), the timing of the treatment, the fact that he was a child PuP and the consequent value to medical research of him becoming infected have led to reasonable suspicions about why he was infected as a result of receiving factor VIII concentrate which he ought not to have received. It is of note that even if it had been thought that he was a haemophilia A patient, Dr Ludlam's policy ought to have been implemented that he should have received cryoprecipitate anyway as he was under 4. Dr Ludlam himself later provided an expert opinion to the effect that a child in the first few years of life could have been treated with cryoprecipitate for bleeds which would have been adequate treatment in another case which caused HIV in the first half of the 1980s.[2199] In the same litigation, an opinion was provided by Dr Savidge who described the use of concentrates in a child under 4 as negligent (due to the increased hepatitis and later HIV risk) This was because cryo was the product of choice for young children with haemophilia A in the 1970s and early 1980s, in his assessment.[2200] Therefore, this Edinburgh patient ought not to have been mis-diagnosed or infected. This is another example of the practice of reaching for a concentrate before asking pertinent questions about its infectivity, the culture which existed in Dr Ludlam's unit throughout this period. Another child with severe haemophilia A who was diagnosed in 1982 at

---

[2197] WITN2153001 @ para 3 (first statement of WITN2153)
[2198] WITN2153002
[2199] DHSC0043164_067_0009
[2200] DHSC0043164_067_0009

around 1 was only ever treated with factor concentrate, not cryoprecipitate in Edinburgh.[2201]

(k) Conclusions about research

7.110 The evidence of research carried on haemophiliacs in life and in death involved a serios violation of personal autonomy. It was unethical. The discovery that this happened has manifested itself in a serious compounding of the harm. The already fractured relationship between the infected (and their relatives) and the medical profession caused by the fact of infection has been seriously undermined further by these discoveries and the fact that it provides an explanation for why the health of the infected patients was not prioritised as it should have been. Untold psychological harm has resulted. The precise nature and extent of research activities is not known. The nature and extent of blood or tissue samples retained of those with bleeding disorders or those infected via blood transfusion to this day are also unknown. Despite the fact that research required the meticulous keeping of records, no such records have been produced. The fact that "personal" records did not require to be produced to the Penrose Inquiry is noted above and may account for the absence of some of these. No explanation as to what happened to them has been provided. Even when they have (such as in the case of the twin in Glasgow, examined above) they have not been forthcoming without significant effort. As is detailed below, the Inquiry should recommend mechanisms whereby the NHS in Scotland be required to provide full disclosure of the nature and extent of research activity involving the infected (or indeed the affected).

7.111 In Scotland, the treatment of those with bleeding disorders should rightly be characterised as always being research from the start. The close relationship between SNBTS, the haemophilia directors and PFC (unlike NBTS and BPL) meant that the monitoring of patients who willingly gave their blood for the monitoring

---

[2201] WITN2200001, paras 2 and 3 (first statement of WITN2200)

of their bleeding disorders was routinely used to generate information about the products and the disease which they transmitted.[2202] Much was made by Professor Ludlam in the latter half of the 1980s about the need for proper compensation to be available to patients who were involved in clinical trials of the SNBTS's new products. In essence, the integration within the SNBTS of the manufacturer of the products (PFC) meant that patients had always been involved in a form of trial of the products which they were being given. It seems hard to understand as a matter of logic why there should have been such a clamour for compensation for the ill effects of being given a trial product (z8) when that product had a prospect of being safe when there had been no such clamour for any payments to be made in respect of the ill effects resulting from the products previously transfused to patients when those previous products were known to have been harmful. The State was more culpable for the losses caused by the transfusion of the unheated products than it would be for a product it had tried to render safe. Compensation for the loss caused by those products is long overdue, as we argue below.

7.112 As we have submitted, there is a pressing need for clarification as to the extent of the involvement of patients in Scotland in research, defined in the broadest way possible (as basis for a recommendation that the compensation scheme should include an element to recognise the impact which unwitting involvement in research has had). This should be put in place urgently so that those who may not have many years left can know the answer to the question posed at the end of the evidence of one patient – "What were haemophiliacs for?"[2203] The answer, in a general sense, to which specific detail requires to be added, was given by Dr Ludlam to Dr Craske when he showed what he thought they were – "useful material. Amazingly, in his summary of the situation to the Inquiry, Professor Ludlam said the following:[2204]

[2202] Eg PRSE0003560 – Letter from McClelland to Watt in May 1983 re samples having been taken from Ludlam haemophiliac who has developed elevated liver enzymes.
[2203] IBI transcript for 9/07/21; 215 (Bruce Norval)
[2204] IBI transcript for 04/12/20; 153 (Professor Ludlam)

"I suppose I'm surprised by some of the comments that I've received from the Rule 9 requests; patients apparently not understanding their situation, which I found didn't quite accord with my reflections of the individuals. Now, that may reflect the passage of time for myself and for the patient. But I suppose it's emphasised to me the importance which can't, I suppose, be over-emphasised, of spending time, thinking through with the patient their situation, and I think perhaps checking out more that they more that they have understood what I think I have said to them."

7.113 This, it is submitted, shows a startling lack of insight. The complaints should not have come as a surprise to him. As his own testimony shows, they have been made many times in many fora, all without adequate explanation. His inadequate responses were mostly received shortly before he gave oral evidence. His surprise was dissembled. He is suggesting that the patients may have misremembered or misunderstood. Their positions are consistent, individually and collectively. The evidence shows that this was not at all a matter of the need to slight alterations to working practices with patients, as he suggested would be an appropriate reflection. This was, as the evidence, showed a problem with the entire culture which he created in the Edinburgh unit. There was no communication with patients at all. Staff were counselled not to communicate either. There was no room for misunderstanding as there was nothing to misunderstand. The culture paid no respect to patients or their autonomy. They were simply "useful material".

8. Information provided to patients/ parents about testing of patients for evidence of the adverse effects of treatment

8.1 As is explored in some detail above, testing was caried out on patients in the bleeding disorder community without their specific consent or that of their representatives. In particular, testing was carried out in connection with the risk of disease which was indicative of fact that their doctors considered that they were

at risk of contracting those diseases and hence suffering adverse consequences from their treatments. As discussed above, the risks which gave rise to the testing were not generally discussed with the patients or their representatives. At times, testing was carried out which was used to generate information which was used in research without the consent of the patients or their representatives. It was commonplace in Scotland for blood samples to be retained from patients with bleeding disorders without information being given to the patients or their representatives about why they were being so retained. Violation of personal autonomy. As is submitted above, this was unethical, whether judged by the standards of the time or of today. The clandestine testing of blood taken from bleeding disorder patients and its use in research the patient's knowledge or consent have significantly undermined the necessary trust between infected patients and their doctors. They reasonably gave rise to an apprehension on. The part of the infected and affected that they had been kept in the dark, that there were priorities which had perhaps taken precedence over their safety and that their complicity in achieving these other priorities had been achieved by secrecy and a betrayal of their trust. The Inquiry heard a good deal of evidence about patients on their representatives feeling like they/ their relatives has been treated like lab rats of guinea pigs. These unethical actions seriously compounded the harms inflicted upon the infected and affected communities. They undermined the essential trust of the infected and affected in the medical community which, by its failings, had become further reliant on the medical community for its ongoing care.

8.2 The evidence heard by the Inquiry constitutes a solid foundation for the inference to be drawn that the fact of not telling patients or their parents about the risks inherent in the products with which they or their children were being treated in the first place created a domino effect, whereby it became more and more difficult to share information candidly with patients. This effect was significantly compounded by the fact that research was also being undertaken on the patients without their knowledge.

Information provided about testing for infection with viral hepatitis

8.3 The reason why patients gave evidence about being shocked at their eventual diagnosis with HCV when antibody testing became available and they were eventually told was that they did not know that they were infected. This was in contrast to their doctors. Medical research at the time and clinical testing for heat treated concentrates when they became available (for example 8Y) worked as the medics had for years on the basis that NANBH could be diagnosed in the hospital using ALT elevation as a surrogate marker. Of course, this was a marker of the liver showing evidence of infection affecting it. The research such as the Fletcher at al paper mean that patients could be safely deemed likely to be infected if they had been exposed to factor concentrates of any origin, though they were generally kept in ignorance of that fact. One widow gave evidence to the Inquiry of her experience working in the haematology labs in the RIE in the 1970s. She described that there were lists of diagnosed HBV and NANBH patients available to ensure that special measures were taken when they blood was being handled.[2205] The staff at the hospital required to be protected. The patients did not know this so could not afford a similar level of protection of their loved ones, nor could they take lifestyle measures to minimise the risk of serious outcomes like stopping or minimising drinking alcohol or improving diet. That lady later found out that her husband's medical notes that his blood samples were marked as high-risk from at least 1986, 6 years before his HCV diagnosis.[2206] In one rare case, a patient who had been treated at Yorkhill and subsequently at the GRI was able to find some medical records of his treatment at the former. These records showed that his liver tests had indicated the presence of NANB from around the age of 11, in 1984.[2207] He was not informed of his HCV status for around another decade.

8.4 The presumptive diagnosis of NANBH was made in many cases, though patients were not informed. In one case medical records revealed in Edinburgh that a

---

[2205] WITN2674001, para 7 (first statement of Ann McInnes)
[2206] WITN2674001, para 15 (first statement of Ann McInnes)
[2207] WITN2245001, para 10 (first statement of WITN2245 – living Yorkhill and GRI patient infected with HCV)

moderate haemophiliac was diagnosed in February 1984 but was not told until his brother told him to go and seek a test (he also having just been diagnosed) in 1993.[2208] He also recalled having been given a bag of condoms in 1985 for no apparent reason, which stuck in his mind as he had only been 17 and had been embarrassed. This must have been due to his diagnosis (and also possible risk of HIV or HBV which are sexually transmissible) of which he would not become aware for another 8 years.[2209] The public health risks were known. Patients were not informed. That same patient had attended with unexplained illness in 1990. He was not told of his diagnosis at that time. He has become aware that he was being monitored for liver dysfunction at that time. As is explored elsewhere in this submission, the consequences of hepatitis infection in haemophiliacs was part of research by Dr Ludlam in Edinburgh. This patient reasonably believes he was the subject of such research, which involved testing and possible publication beyond his knowledge and without his consent.[2210]

8.5 The Inquiry heard considerable evidence about the fact that markers for viral hepatitis were checked consistently over the period with which the Inquiry is concerned, in particular monitoring of ALT levels to try to track the damage caused by treatment to the liver. The Inquiry also has evidence available to it about the correct approach to testing for anti-HCV in the period after that type of testing became available. In relation to whether or not patient consent was required, Professor Vivienne Nathanson referred to a 1988 BMA publication "Philosophy and Practice of Medical Ethics"[2211] which provided that "The basis of any discussion about consent is that a patient gives consent before any investigation and treatment proposed by the doctor. Doctors offer advice but the patient decides whether to accept it." She explained that the best practice standard at the time was that doctors treat patients only on the basis of consent in that the patient makes the decision and the doctors offer advice and guidance. She also confirmed that best practice advice at the time was that testing was considered to be

---

[2208] WITN2317001 @ para 12 (first statement of WITN2317)
[2209] WITN2317001 @ para 14 (first statement of WITN2317)
[2210] WITN2317001 @ paras 15 and 16 (first statement of WITN2317)
[2211] PRSE0003970_0003

treatment.[2212] In relation to whether or a doctor should have told a patient that they were being tested for Hepatitis C, Professor Nathanson indicated that this would depend upon whether or not there had been prior discussion with the patient such that they knew that they had Non-A Non-B hepatitis and the test was merely a confirmatory test for the specific virus, but that it would still have been preferable to tell them.[2213] It is submitted that the ethical principles which were applicable after anti-HCV testing became available were clearly necessary before it. A patient had a right to be in involved in decisions both testing and treatment.

8.6 In relation to pre-test counselling, Professor Nathanson said that best practice at the time would have required doctors to give patients information about what was then known about the disease and to obtain their agreement to the test, but that prolonged pre-test counselling along the lines of counselling given prior to HIV testing was not required. [2214]

8.7 Prior to testing, patients should have been informed that a test was going to be carried out and that the test was likely to be positive or before 1991, that the testing was being carried out as it was presumed that the patients would have been infected and the effects needed to be monitored. This would have ensured that patients were in a better position to come to terms with and understand the consequences of their diagnosis when it was eventually made. In addition, lifestyle and future treatment choices could and should have been discussed which could have had the result of minimising the effects of infection on the deterioration of the liver. The fact that patients were left in ignorance meant that they were denied the opportunity to make decisions which could and should have avoided the deterioration of their physical condition. In addition, the fact that patient were left in a state of ignorance significantly compounded the harm which they suffered when their infections were eventually discovered. There was an inevitable sense of violation that damage had been caused by those whom they trusted, who must

---

[2212] Penrose Inquiry transcript for 12/01/12 (Day 84): 23(25) to 25(19) (Professor Nathanson); [PRSE0006084_0023 to 0025]

[2213] Penrose Inquiry transcript for 13/01/12 (Day 84): 56(3-23) (Professor Nathanson); [PRSE0006084_0056]

[2214] Penrose Inquiry transcript for 13/01/12 (Day 84): 37(3) to 38(21) (Professor Nathanson); [PRSE0006084_0037 to 0038]

have been aware that there was a risk of harm as assessing the extent of that harm was the whole point of the testing in the first place.

8.8 The subject of testing patients who had received blood transfusions for possible infection with NANBH/ HCV is discussed in more detail in the HCV Lookback section of this submission below.

8.9 As regards the findings of testing, the corollary of the fact that patients were generally not informed about the fact that viral testing or testing for the effects of viral exposure was being done was that patients did not generally know about the details or implications what had been discovered. Insofar as hepatitis was discussed, the tenor of the evidence was that patients were reassured that it was nothing to worry about. The clinicians often referred to elevated liver function testes being taken to be evidence of transaminitis, which simply means elevation of liver enzymes. There is a circularity about this position and a lack of inquisitiveness. In response to what the elevated liver enzymes were taken to mean, answering transaminitis is merely repeating the result of the test and not its supposed cause. There was a clear sense of wilful blindness in the position of medics. ALT tests were done. If they were elevated nobody inquired too much as to what that might mean. As the patients did not generally know they were being tested they did not inquire. It did not have the hallmarks of the system designed to keep tabs on whether there was something to worry about or not.

Information provided about testing for infection with HTLV-III

8.10 Testing took place throughout Scotland of patients without their knowledge or consent, despite the fact that this was something which breached their personal autonomy and involved the possibility that they had been infected with a fatal disease. By 29 November 1984, at a meeting of Scottish Haemophilia Directors, SNBTS representatives and SSHD a discussion took place about the implications of

the positive tests.[2215] Dr Ludlam reported on the anti-HTLV positive results in 16 patients, whom he said had been treated exclusively with SNBTS Factor VIII concentrate. Dr Forbes described the results for the Glasgow patients and said that the Melbye study of infection in Glasgow and Denmark would soon be published in The Lancet. Dr Gibson reported that five out of 10 patients already tested at Yorkhill were HTLV-III antibody positive. A discussion took place whether patients and patients' relatives should be informed and perhaps subjected to needless worry. None of the patients or parents knew they had even been tested. Dr Bell of SHHD advised members that ministers had been informed and that SIO had been briefed. It was agreed that every effort should be made for patients to have the situation explained to them before the impending publicity. Despite that, in many cases, the secrecy about testing was about to turn into secrecy about the fact and meaning of the results. Both the testing and the lack of information given to patients or their parents about the results were unethical.

9. Information provided to patients/ parents about the fact and potential consequences of infection

9.1 As the analysis above shows, haemophilia patients were routinely exposed to HBV and the agents which caused NANBH, for which their ALT levels were monitored years. They were routinely kept in the dark about the risks, the testing and the results. No counselling was available as there was nothing of the patients to be counselled about. They were told that the products were safe and/ or that they were perfectly healthy. The fact oof viral exposure in these earlier years created the opportunity to pit in place systems for patient engagement in treatment and the management of information about risks either potential or realised. The bleeding disorder community was a knowledgeable one with whom interaction and engagement could have been managed productively and positively, despite the clear risks of the products. An opportunity to develop and indeed to perfect

[2215] PRSE0000153

the patient information experience in accordance with the doctor's ethical duty to respect patient autonomy (see above) had been missed. When HIV arrived, it arrived in an environment where patients were at risk of contracting a fatal, highly transmissible disease in which there were no developed systems for a partnership approach to the risks to be developed between doctor and patient. When those risks were realised, the deficient system reacted in a way which caused significant and entirely avoidable further harm.

Edinburgh

The issue

9.2 The Inquiry has heard evidence that there were failures on the part of Professor Ludlam to inform his infected patients of their anti-HIV positive status. The extent of his failure to inform the patients is not known, although presumably he must know the reality of the position. The limitations on the evidence heard by the inquiry emanated from a combination of (a) the fact that there are only two living members of the group known as the "Edinburgh cohort" and (b) in other cases, either medical records have been destroyed as the infected individual has died or the evidence about what precisely happened is otherwise unavailable.

The immediate context in which patients became involved

9.3 The context in which the AIDS study was commenced including the Gordon letter and the research being undertaken elsewhere in the UK into white cell dysfunction is analysed in detail above.

9.4 Dr Ludlam was sent a copy of a letter written by Dr Craske which related to these important matters.[2216] The letter is dated 23 October 1984 but the stamp and the handwritten annotations suggest that it was copied to him and Dr Perry, then acting director at the PFC on 13 November 1984. It can be assumed that though the letter related ostensibly to the infection of a BPL batch of factor VIII concentrate that the information became relevant to the Scottish recipients due to the emergence of the Edinburgh infections. The context of the letter was instructive about the way in which the position was unfolding in the rest of the UK. The opening page gives a narrative of the actions Dr Craske had been undertaking in the role of epidemiological assessor of the extent and implications of the outbreak. A known homosexual donor who had given blood had been found to be showing signs of AIDS and his diagnosis had been confirmed by the development of PCP. Serum samples had been taken from him in September and October of 1984 which had tested positive for ant-HTLV III. A search had been undertaken for batches of factor VIII to which his plasma had been added and at least one had been found (batch HL 3186). These events were euphemistically described by Dr Craske as "unfortunate". Importantly, in what appears to have been a separate line of inquiry, one of the batches of factor VIII which had been received by one of the "1983 AIDS cases" (ie the Cardiff and Bristol cases) had tested positive and had been responsible for the infection of a number of other recipients. One assumes that this was a batch of BPL factor VIII concentrate from the context – this is a latter about follow up of infective domestic concentrate and has been copied to Drs Ludlam and perry for their interest in that subject. This means that the assumptions made about the infection of those patients (ie that they were infected by the commercial products which they had received) was erroneous or at least that the possibility of domestic products being contaminated in or before 1983 appears to have been ignored. Had this possibility been at least considered (perhaps in light of the revelations in the Fletcher paper published in 1983 which confirmed the 100% infectivity of domestic and commercial concentrates, limiting the safety differences between the two) firmer action could have been taken to

[2216] HCDO0000273_066

prevent domestic transmission. All of this investigation had been undertaken before the letter was written in late October 1984. The implication is that suspicions must have been aroused some months earlier for the investigations to have been undertaken by that time. It seems odd in this context that Dr Craske wished to point out (as he did) that some patients who had received commercial factor VIII from the start of 1980 could have seroconverted as a result of that treatment, without qualifying that statement by saying that care needed to be taken not to assume that that was the case in the absence of historic sample analysis.[2217] His primary interest was in discovering infected domestic batches and following them up. This unqualified comment must have been unhelpful to that aim, given the assumption which is appears to lead to, ie that commercial infection was more likely, in particular as so many English and Welsh patients (to whose clinicians this letter was originally directed) will have received a mixture of treatment. This appears to be the genesis of the assumption that infections were caused by imported products, masking the infectivity of domestic batches. It is, of course, also instructive that he was telling clinicians that by this time, it was being accepted that imported concentrates could have been infective going back as far as the start of 1980. The importation of commercial products was thought to have been infecting UK patients for almost 4 years by this time.

9.5 In the letter, Dr Craske proposed certain possible alternative strategies about whether patients who were anti-HTLV III positive should be told. Though his ultimate conclusion appears self-evident, namely that the only ethical thing to do would be to tell the patients who were positive, for the reasons he lists[2218], it does seem unnecessary for him to have even canvassed any possible alternative. His ultimate view must be understood in the context of his statement that it would ultimately be for each individual haemophilia clinician to decide what to do.[2219] His analysis of the pros and cons therefore serves to open the door to the possibility of patients not being told and renders his own ultimate view somewhat irrelevant, though of course ethically accurate. That the alternative (not telling

[2217] HCDO0000273_066_0002, para 2
[2218] HCDO0000273_066_0005
[2219] HCDO0000273_066_0004

patients) was included in the analysis suggests that there was some room for that route being followed and serves as some important context to what happened next in Scotland (as analysed below) involving an incompetently planned and conducted group meeting, patients being given a false impression of the real state of affairs, certain patients going some time before finding out about their status and other being out unnecessarily at risk of infection. That interpretation is clear from the context of the Craske letter. There is no reason to think that Dr Craske (a laboratory virologist) would or should ever have a role in assessing the pros and cons of telling patients about their status. The only reason why he would have an interest would be in the material which could be provided to assist his laboratory research efforts into the nature, extent and aetiology of the disease. In that context, the letter (not primarily intended for Drs Ludlam and Perry but circulated to them when they were in a position to assist the research effort, was intended to put in their minds the research benefits or taking the unthinkable, unethical course of not telling the patients. That Dr Craske appears to have had a role in advising about whether patient should be told suggests that there was a co-ordinated national effort not only to co-ordinate the response to the disease but to promulgate the advantages of patients being kept in the dark in the realisation of the ultimate goals of those efforts.

9.6 That seed (of the possibility of patients not being told) needed to be sown but it was being sown into the mind of a willing recipient. Dr Ludlam was well aware of the research advantage of his newly infected patients, had been willing covertly to extract information about disease from them before in the hepatitis study and enrolled then into the white cells study reported in 1984 but, perhaps mostly importantly, he did not want to have to tell them. It would of course be difficult for any doctor to break this news but in this case there was good reason to be all the more anxious about how the news would be received. Dr Ludlam knew that he had consistently advised his patients that the products they were given were safe, as Robert Mackie sets out in his statement.[2220] That that must be true is borne out by Dr Ludlam's own published research. The 1984 pre-infection white cells

[2220] WITN2190001 @ para 16 (first statement of Robert Mackie)

study (about which he had not told the 32 patients involved) proceeded on the (albeit erroneous) assumption that the products given to the Edinburgh patients were safe. As with one of the two AIDS patients discovered in 1983 (referred to above and in the Craske letter, whose infections were assumed not to have been caused by domestic concentrates) he had assumed that the PFC concentrates were safe. Dr Ludlam had repeatedly told the patients the products were safe and they now had turned out not to be. The patients had trusted him and he was wrong. The revelation of that would be likely to lead to anger. An incentive not to tell them in a quasi-official letter, circulated to other clinicians in a similar position and providing some justification at least for the possibility of not telling the patients or at least not telling some of them was an incentive towards a possible course of which Dr Ludlam must already have been aware and must have been welcome. Telling the patients, in particular one in the form of Mr Mackie who had so consistently sought reassurances that the products were safe[2221], that they were not would bring down the elaborate web of deceit. It would come to light that the reassurances about safety had been untrue based on contemporary knowledge (at least for NANBH which by 1983 at least were known to be 100% infective), that the lack of discussion about the risks of AIDS or changing treatment programmes as a result had now been proven to be a mistake, that hepatitis research and an "AIDS study" had taken place and that all along the patients had been kept in the dark, apparently for the benefit of medical research and the benefit of Dr Ludlam's increasing professional reputation. This was undoubtedly some justification for Dr Ludlam to keep the truth hidden, apparently to avoid the inevitable confrontation but in reality exponentially to compound the harms his treatment and culture of secrecy had caused.

9.7 The Craske letter and its analysis merits some further consideration, in the following regards:

(a) The downsides of not telling the patient are clearly spelled out. Thus, no clinician (including Dr Ludlam) could claim to have taken the decision not to tell an infected patient without knowing what the consequences would be likely to be.

[2221] WITN2189001 @ para 11 (first written statement of Alice Mackie)

One would assume that any trained clinicians, far less a consultant would be assumed to have been aware of these but, for the avoidance of doubt Dr Craske had spelled them out;

(b) One element of the letter appears particularly significant. One of the factors upon which Professor Ludlam relied in his evidence to the Inquiry with regard to not telling patients was that the precise significance of a positive anti-HTLV III test was not known, in particular it was known known whether or to what extent such a positive test would lead to the development of the inevitably fatal disease of AIDS. The Craske letter is likely to be the source of that doubt. It states that the number of positive patients who eventually contracted AIDS was not known. It predicts that as 34% of symptomless haemophiliacs were positive for antibody, it was likely that a significant proportion would remain in good health, ie not develop AIDS). 21 patients were known to Dr Craske to have features of AIDS, which one assumes in this context means that 21 haemophiliacs had reached the stage of AIDS diagnosis. From this, he deduced that proportion of those who contracted HTLV-III infection who went on to contract AIDS would be in the order of 1/100 to 1/500 (between 0.2 and 1%).[2222] This analysis seems epidemiologically unsound for the following reasons:

- The basis for the small statistical risk of positive patients going on to develop AIDS is striking. None exists, as far as the evidence available to this Inquiry suggests;
- The analysis continues to confuse incidence of AIDS (21) over risk despite the fact that the letter also acknowledges a likely latency period for the development of symptoms of a mean of 4 years, the long term prognosis being unknown.[2223] On the apparently legitimate assumption that AIDS had not been in the donor pool in the UK for a long time, as well as the time lag between the collection of a positive donation and the administration of the factor VIII made from it, it should have been

[2222] HCDO0000273_066_0002, para 3
[2223] HCDO0000273_066_0002, para 4

assumed that it was not surprising that symptoms were not evidence ion more patients. It is entirely illegitimate scientifically to assume the opposite, in particular in light of the known fatal outcome of the assumption proved not to be accurate;

- In the analysis of the specific numbers of patients infected by the infected batch received by one of the 1983 AIDS cases, it had been presented on the previous page that 7 of 13 recipients tested antibody positive and only one had signs of AIDS. It had been suggested that this was because only a limited number of the bottles in the batch contained the virus. This of course turned out to be untrue (there being a genetic element to whether a patient exposed to an infected batch would or would not sero-convert) but even at that point seems to be completely baseless scientific speculation. Based on other handwriting, it appears that the manuscript comments made regarding that copy is in the handwriting of Professor Ludlam. It refers to speculation that this proposition means that there was only one virus per bottle and remarks that this deduction may result in "limiting dilution experiment". The precise significance of that comment is not clear but is suggestive of some experimentation relating to the number of viral practices in each bottle of factor VIII.

9.8 Once again, this unreliable and speculative evidence amounts to little more than an absence of conclusive proof that AIDS would follow on from a positive antibody test. Professor Ludlam's reliance on this element of the epidemiology both at the time and now should be rejected, being based on an unreasonable and non-patient focussed which requires proof before action being mandated. As is argued elsewhere in this submission, this was and is an unacceptable approach which gives no or at least inadequate weight to known risk. This letter appears to have included a number of unjustified, illogical headlines for the use of a clinician in a position where patients had tested antibody positive. The provision of this material in the context of a discussion about whether patients should be told is

instructive. The material gravitates towards not telling patients as it illegitimately underplays the risks.

9.9 The component parts of the rationale for the possibility of not telling the patient is unusual but instructive. The alternative course of not telling the patient has a clear research advantage – information could be gained without the patient needing to know or consent. The concept of "restricted follow up" is proposed by Dr Craske. For some reason a seemingly arbitrary period of 2 years is specified, over which time the patient would have samples taken but testing would not be carried out util symptoms developed or the director requested testing.[2224] The logic of this is far from clear. The suggestion seems to be that the director would deliberately put himself in a position of ignorance about the patient's HTLV III status for an arbitrary period of 2 years, though the research advantages would still be gained by the serum being collected. This would be despite the disadvantages – it being impossible to warn spouses, limit the risk of infection in the period of potential maximum infectivity.[2225] As it set out elsewhere in this submission, there was a long history in Edinburgh of secret monitoring of the progression of disease in the complaint Edinburgh patients. There was a clear research incentive to seeking to find information about the patients and the progression of their disease in this poorly understood period or certain of them at least by keeping them in the dark about their infections and continuing to observe them for the 2 year period, as the letter suggests. That this alternative is clearly based solely on the research advantages of not telling the patient is demonstrated by the arbitrariness of the two year period and the absence of any suggestion that if circumstances changes, the patient might be told before the expiry of that period. The only possibility contemplated is that the serum samples might be tested over that period, at the discretion of the director. There is no mention of the patient finding out at all, in any circumstances, on this scenario. That alternative was all about the research gain and nothing about the patient's welfare. In addition, a factor in deciding not to tell a patient is listed as being "the

[2224] HCDO0000273_066_0003, para (ii) and _0005, para 2
[2225] HCDO0000273_066_0005, para 2

amount of anxiety concerning AIDS there is already present in the centre".[2226] This would seem to suggest that a patient might not be told based on the anxiety of others, which is a clear offence to the principle of individual patient autonomy. Why would how someone else might react in the centre undermine an individual's right to know? In addition, the extent to which the patient is capable of understanding the situation is listed as a factor which might influence the decision.[2227] This is a factor which gives the doctor an illegitimate excuse not to perform his duty to tell the patient and to assume the rights of the decision maker. Only two of the Edinburgh patients were children. Even they and their parents were well used to being given difficult medical information about their haemophilia. It was the duty of the doctor to ensure that the information was conveyed in a way that the patient could understand and that support mechanism were available to deal with the consequences.

9.10 The letter contains certain epidemiological evidence about the risks that the positive patients posed to their families and the wider community. Subsequent decisions about whether and how patients should be told must have been taken by Dr Ludlam and others in light of this knowledge. Sexual transmissibility and the risk to sexual partners is confirmed.[2228] The advice is the patient has been informed of the positive test is that the patient should be told of the risk to his spouse from sexual contact.[2229] Of course the parenteral transmissibility of the virus is assumed in this entire assessment, putting close contacts of haemophiliacs beyond sexual partners at particular risk due to their propensity to bleed. Interestingly, even if the patient were told, no advice beyond the risk of sexual transmission to sexual partners or spouses appears to have been advanced by Dr Craske. The alternative of telling the patient (in which scenario the doctor is described as the "caring physician" implying that not to tell would be not to care) is listed as including the benefit of being able to advise about methods of contraception. Again, Dr Ludlam appears to have devised a half-way house in this

---

[2226] HCDO0000273_066_0004
[2227] HCDO0000273_066_0004
[2228] HCDO0000273_066_0002, para 5
[2229] HCDO0000273_066_0003

regard by telling people of these methods without telling them of the infection (se below). Of course, the fatal flaw of that approach (not contemplated as possible by Dr Craske) is that patients not told they were amongst the infected would not think that that advice necessarily applied to them.

9.11 Of fundamental importance to the assessment by Dr Craske is the advantage listed of telling the patient that "It also maintains a trusting relationship between the physician and his patient which is essential if difficult problems arising from HTLV-3 infection are to be surmounted".[2230] This is a clear warning of the inevitable consequences of not telling the patients honestly and clearly. It is a clear reason for why this was the fundamental responsibility of the clinician – not to do so would inevitably undermine the trust between the patient and the doctor, at time when trust was needed the most. The importance of this warning cannot be overstated. It was a portent of what was to come in the Edinburgh haemophilia community. It is all the more significant in light of the later comment that "any benefit or peace of mind for the patient will be temporary is other persons exposed develops [sic] AIDS. If the patient finds out that he has had this batch [the BPL batch], then the trust of the patient will be lost and the haemophilia director will be placed in a delicate situation".[2231] This demonstrates the inevitable consequences if any patient develops AIDS. The haemophilia community was a close one. Many patients had relatives in the centre due to the inherited nature of the condition. If one patient developed AIDS (and hence it became clear to others that infection was in the centre) the relationship of the doctor and the patients who had not been told they were infected/ at risk would be lost. The only way that this would not happen would be if the doctor crossed his fingers and hoped that AIDS would not emerge. This was inevitably not going to be the case, though might have been thought to be a possibility based on Dr Craske's baseless 0.2 to 1% statistic (see above). Dr Ludlam had been fully warned of what would happen if patients developed AIDS and some or all of the patients who were positive were not told clearly of their position. Trust in him would be completely and irreparably

[2230] HCDO0000273_066_0005
[2231] HCDO0000273_066_0005

undermined. However, given his long history of not telling patients about important medical information or how information about them was being used, to have done so at this stage would have been difficult. That was, however, a situation of his own making. This is why Dr Craske concludes that telling the patient was the only option "tenable on moral and ethical grounds".[2232]

9.12 Dr Craske also mentioned that preliminary information suggested that HTLV III could be inactivated by heating at 60 degrees.[2233] This appears to be the foundation of the diversionary tactic employed by Dr Ludlam in the way in which he conveyed the news to the Edinburgh patients. The relatively good news that the products in future may be able to be virally treated was presented to those at the Edinburgh meeting in December 1984 (see below). That news was of course largely irrelevant to those who were already positive for antibodies to HTLV III and was an important part in misleading those who attended the meeting into misunderstanding their status.

9.13 Certain assumptions appear to be made about the course may follow of the patient is not told. For example, it appears to be assumed that if the patient were not told it would mean that monitoring the patient's family (in particular spouses) for possible signs of infection would not be possible.[2234] That, of course, seems logical. However, as the research analysis in Edinburgh shows, this was not the consequence in Edinburgh. Both of the patients whose evidence the Inquiry has (the living members of the cohort) had family members who were assessed, though the primary patient did not know that he was infected. This is assessed elsewhere in this submission. However, it appears that Dr Ludlam managed to devise a strategy whereby patients could not be told but family members could still be monitored, a possibility not even contemplated by Dr Craske. In addition, family members in addition to spouses were tested by Dr Ludlam, showing that they too were known to be at risk of infection.

9.14 The testing regime advocated by Dr Craske included both monitoring for T cells abnormalities and "the response to intradermal injection of skin test antigens as

---

[2232] HCDO0000273_066_0005
[2233] HCDO0000273_066_0004
[2234] HCDO0000273_066_0003, para (d)

an assessment of cell mediated immunity".[2235] There is evidence of the Edinburgh positive patients shaving their T cells measures from the published research as well as of skin testing being carried out on them.[2236]

Emergence of evidence about the infections

9.15 In that context, testing was undertaken in Edinburgh at the instigation of Dr Ludlam. Testing was able to be undertaken by Dr Richard Tedder of the Middlesex Hospital from whom the Inquiry has heard evidence. His claim was that Dr Ludlam remained convinced at this point in time that his patients were unlikely to have been infected as he continued to be of the view that the causative agent of AIDS was unlikely to have entered the donor pool from which most of the products with which his patients had been treated had been made.[2237] This was despite the fact that since the 1983 Lancet publication, their immune function defects had gone unexplained.

9.16 The research context in which patients' blood samples came to be selected and sent by Dr Ludlam to Dr Tedder is discussed elsewhere in this submission. It appears from the papers that the Edinburgh patients' sera was included amongst the haemophiliac sera which was tested for anti-LAV and anti-HTLV-III as part of the research project involving both Dr Craske and Dr Tedder (and others) which was eventually published in the Lancet on 1 September 1984.[2238] The results of the positive tests on the Edinburgh patients were known by that time. The context in which patients were selected for their samples to be sent to Dr Tedder for testing

---

[2235] HCDO0000273_066_0003

[2236] PRSE0004285 – 24 May 1984 letter from Dr de Bono (cardiologist) saying that it would be in order to proceed with skin tests on haemophiliacs. This appears to be an example of someone from the same area with little or no knowledge giving local ethical approval in a cursory fashion. There was no real scrutiny of what the work involved. See also LOTH0000038_006 (1985?) – Ludlam form for Ethics of Medical Research Sub-Committee for Medicine and Clinical Oncology

[2237] WITN3436003 @ para 103 (Professor Tedder)

[2238] PRSE0000197

is also discussed elsewhere in this submission. It is asserted that they were selected based on their known T cell deficiencies which had been measured in the spring of 1983 by Dr Ludlam's research team and then continuously, culminating in tests in the autumn of 1984 which, in the context of one patient having suffered an acute glandular-fever like to a factor VIII transfusion clearly created a concern. That the patients who were selected all tested positive clearly indicated that Dr Ludlam knew which ones were most at risk. Therefore, he must have known how to work out who was least likely to be safe. It is unclear if any of those were sent for testing teste negative.

9.17 Patients did not provide explicit or informed consent for studies to be carried out on blood or tissue samples provided by them, either as part of the ongoing immune function study or the testing undertaken by Dr Tedder or as part of the post-infection studies discussed below. This is despite an assertion when seeking ethical consent for the post-infection studies that informed consent would be obtained (as is discussed elsewhere). Patients were not asked to give and did not give consent to results of the studies taking place being published. In addition, in his evidence to the Penrose Inquiry Professor Ludlam accepted, rather reluctantly, that the publication of years of birth of the eighteen seropositive patients in the 1988 Lancet article (discussed below)[2239] was a mistake.[2240] This enabled patients potentially to be identified. Dr Ludlam's patients included a wide group (involving haemophilia A, haemophilia B and vWD patients) whose immune function was being monitored. From within that group there was a group of HIV infected patients (the infected Edinburgh cohort) and a wider group. Which continued to be studied which included the infected cohort and other haemophilia A patients who were not positive for HTLV-III but who had received the factor VIII concentrate batch thought to have infected all but one of the cohort (the "implicated batch"). Members of these groups were never told as individuals that they were part of a significant group or groups worthy of study.

[2239] PRSE0004673

[2240] Penrose Inquiry transcript for 28/06/11 (day 39) (Professor Ludlam); 63 (4) – (16); [PRSE0006039_0063]

The December 1984 meeting

9.18 By December 1984, Dr Ludlam and various others knew about the fact that patients had tested positive for HIV antibodies since at least October. The known risks of easy transmission of AIDS (which had been established early on in the epidemic) sexually or via bleeding (a particular risk for the infected severe haemophiliacs) had inexplicably been allowed to expose others to the risk of infection for at least two months. That that time-period had been allowed to elapse endangered others unnecessarily. There is no evidence that there was any plan to divulge this essential information to patients other than as a result of the contact from a journalist at the Yorkshire Post. Even then, it appears that the medical establishment (and Dr Ludlam in particular) required to be forced to act, rather than being honest with his patients in order to protect them and their loved ones. This was the result of the domino effect of mis-information, described elsewhere in this submission. The fact that it took a threat of the press releasing the story and the reluctance to share the information based on the domino effect combined as the reasons why the efforts made to disseminate the tragic news was handled quite as ineptly as it was.

9.19 In the period after he found out about the positive tests, Professor Ludlam to Professor L. Aledort, asking for his views on the possible HTLVIII infectivity of haemophiliacs and their blood samples due to recent concerns about patients.[2241] His attitude to this dilemma seems to have been based on a perceived need not to alarm patients about also need to protect staff, as opposed to the patients' right to know. He referred to memory of HBV outbreak in Edinburgh. Nothing appears to have been learned since the late 1960s. In November 1984 stated that the epidemiology was the same for HIV as with HBV and so should be treated the same way. There was a risk for the public health point of view and so people needed to

[2241] LOTH0000097_017 – 16 November 1984 (guidance of public health measures and the HBV outbreak in Edinburgh)

know. Despite this he stated that a reasonable explanation would have to be given to **some of the patients** despite the risks being the same as HBV. It seems it was not his intention to tell all of the patients immediately, despite these known risks.[2242] One former member of his staff described Professor Ludlam as not necessarily a good communicator.[2243] His lamentable attitude to the patient's right to know suggested that this was an understatement.

9.20 In the event, it was only when it became apparent that a story was going to appear in the press[2244] that steps were taken to inform haemophiliacs that Scottish donor population was infected with the virus. The SHHD had been told by SNBTS that the infections had all come from a single infected batch. It was clearly the impending threat of publication which had prompted the contact with SHHD – the results had been known since October. Professor Ludlam accepted in his Penrose evidence that the reason for the meeting was to let the patients know about the donor pool being infected before reading that in the press.[2245] As ever, ministerial involvement sems to have results from press attention and the advice was that the patients should be informed and not find out via the press.[2246]

9.21 Against this background, a public meeting at the Royal Infirmary of Edinburgh on the evening 19 December 1984 was chosen for this purpose. The planning of the meeting in these circumstances was inevitably haphazard but this position stemmed from the fact that (a) there had no proper appreciation of the risk of infection occurring before the positive tests, with result that that was no contingency planning and (b) no clear plan was formulated in October 1984 when the news of the infections became apparent. This was all the result of the head in the sand, wilful blindness approach to the clear risk which had not been appreciated sooner and had resulted in the infections occurring in the first place.

[2242] 16 November 1984 - Ludlam on the cohort - PRSE0000774

[2243] PRSE0001055_0005 – Alison Richardson

[2244] See PRSE0000810 (12 December SHHD internal memo showing that they were aware of the possibility of publication at that time)

[2245] Penrose Inquiry transcript for 28/06/11 (day 39); 10 – 15; [PRSE0006039_00010 to _00015]

[2246] PRSE0001293 (12 December 1984)

The damage caused by the infections was immediately being compounded by the response to the news of them.

9.22 Details of what precisely occurred at the meeting come from various sources. An invitation was sent out to patients on 12 December 1984.[2247] The invitation oddly appears to have been addressed to patients across Scotland and not just from the Edinburgh centre. It makes no reference to the meeting being anything other than a discussion led by Drs Ludlam and Forbes about general concerns which had been publicised about AIDS. There is no suggestion that the meeting is about any infections having occurred at all. Handwritten notes are available which contain an entry "prepared to inform if have antibody". There is no note as to which patients had been tested nor is there a note to the effect that if a person wanted to know whether he had been tested and was positive, he would have to ask to find that out and the result at a separate meeting.[2248]

9.23 It is unclear whether patients from other parts of Scotland were invited or attended. Not all patients who were known to be infected or at risk of being infected attended the meeting. The vague nature of the invitation did not make it clear that this was anything other than a general seminar. The meeting was conducted orally and without visual aids. No written information was provided or distributed at the meeting. Those attending would have had a limited ability to grasp and absorb the information they were being given. The handwritten notes recovered make it clear that studies had been taking place for some time, involving testing of immune function and skin tests (the latter of which the patients would have known about). Patients had no knowledge of this and must have been unsure if any of this concerned them. The possibility of one or several batches having been involved is mentioned (contrary to the message given to SHHD by the SNBTS). There is mentioned of half of those tested having developed antibody. The significance of this is not noted as having been relayed. Family members of haemophiliacs were urged not to give blood (as referred to in a letter from Dr

---

[2247] PRSE0003264 (12 December 1984)
[2248] PRSE0002419 (19 December 1984)

Ludlam to Dr McClelland dated 31 December 1984).[2249] It seems likely that this is why Dr McClelland would have been asked to attend the meeting. In evidence, he expressed the view that if he were a patient he would have been very, very disturbed not to know about this grave information as soon as possible.[2250] There was no suggestion on his part that the information was or should have been understood to be anything other than grave.

9.24 Those who attended the meeting have given evidence to the effect that the nature and purpose of it was unclear and most importantly that patients were given completely the wrong impression about what had happened and that they might be positive for the virus which caused AIDS. It was assumed that those who had been infected had been told individually beforehand and so those who had not been told (none of the them who attended the meeting as no such individual communication taken place) assumed they were not infected. [2251]

9.25 Evidence from one from those who attended the meeting with his brother (also a haemophiliac) was to the effect that were given impression by Dr Ludlam that they were the lucky ones and that they would be okay under direct questioning from them as to whether they could have been infected.[2252] One brother was infected with HIV and HCV, the other with HCV. This was a direct lie. The attitude displayed at the meeting and in its aftermath was one of blind hope that, despite the positive tests, everything would turn out all right. The treatment regime had been reckless and the consequences were now all down to chance. This same attitude was seen later when a previously untreated patient was infected in Edinburgh in May 1986. He was told not to worry and was monitored after he left Edinburgh by Professor Ludlam. Like those left in ignorance as the potential severity of their positive status in December 1984, he was left with the impression everything was all right. Instead, their very lives were hanging in the balance and their consultant was watching to see what might happen.

[2249] PRSE0001009 (31 December 1984)
[2250] IBI transcript for 28/01/22; 54 to 55 (Dr McClelland)
[2251] WITN2190001 @ para 16 (first written statement of Robert Mackie)
[2252] WITN2203001, para 4 (first statement of WITN2203)

9.26 The article in the Yorkshire Post appeared the day after the meeting.[2253] Patients would not have appreciated and did not appreciate they had to come forward individually to find out whether they personally had been tested or to find out whether they as individuals had been infected.[2254] At some time after the meeting and almost certainly after the New Year an advice sheet was sent to Edinburgh patients.[2255] Any patient reading the advice sheet would not have appreciated that there was a possibility he had already been tested or that if he wanted to find out whether he had been tested and the result of the test he would have to come forward and ask for that information. The tone is reassuring – paragraph 2 suggested that AIDS has only affected 3 haemophiliacs in the UK. Page 2 indicates that precautionary changes in lifestyle need not be introduced into the patient's wider contacts in society beyond his family. Paragraph 8 emphasises the importance of the new heat-treated products. This would have seemed hardly relevant if the patient reding it were already infected. Paragraph 9 concludes by stating that the meetings (in December) had been arranged for reassurance and urges a continuation with treatment as normal. The advice sheet is very general in nature. Its primary purpose appears to be reassurance. It is unclear why this would have been the message chosen in the circumstances. Contact details are provided for follow up (without any specific direction as to why that might be desirable) were provided for both the Edinburgh and Glasgow centres.

9.27 One infected patient was able to locate a copy of the letter which had been sent. He was still a child at the time and so the letter was sent to his parents. That same patient went to live for many more years, ignorant of his infection (as is discussed in some detail below).

9.28 In the same way as there appeared to be no urgent action taken within the haemophilia centres to inform patients of the positive results and minimise the risk of further spread of this highly transmissible disease, similarly the transfusion service seemed to take until December 1984 to seek to take any preventative measures. Although this was emerging as a national issue (withy infections all over

---

[2253] PRSE0004577 (20 December 1984)
[2254] Penrose Inquiry transcript for 8 June 2011 (day 29); 8 (2) – (10) (Alison Richardson); [PRSE0006029_0008]
[2255] PRSE0002785

Scotland), it was once again Dr McClelland who took the lead. He proposed to Dr Ludlam in your letter of 12 December 1984 that Dr Ludlam would write to his patients advising them that their wives and partners must not give blood.[2256] They had already known for a fact for 2 months of haemophiliac HIV infections had occurred in Edinburgh. It is unclear what advice was provided to other centres or whether this indeed happened anywhere in Scotland. It might be said that due to the sexual transmissibility of HBV and the transmission risks of NANBH that it had been unsafe for partners of haemophiliacs to be donating before this anyway. In the same way as those who had had previous blood transfusions were not excluded, this group had been allowed to donate to this point in the drive for ever more and more plasma.[2257]

Beyond the December 1984 meeting

9.29 The confused picture of information conveyed to patients of the Edinburgh haemophilia centre relating to the risks of AIDS in 1984/ 1985 is further added to by the evidence of an elderly patient given to the Inquiry by his daughter. She told the Inquiry that her father had tested negative for HIV in 1984 (from his notes) but that a letter was sent to her father's GP by Dr Ludlam in January 1985 talking about the risks of AIDS, the antibody positivity of certain unidentified patients and information about minor precautions.[2258] The letter was sent to the GP and not the patient. It is clearly a circular sent to many such GPs. It contains no way of

---

[2256] LOTH0000005_065

[2257] Para 80 of Brian McClelland statement at WITN6666001 – his and another Scottish RTC which were discarding red cells due to the prevalence accorded to meeting the demand for plasma

[2258] WITN3477001 @ paras 19 and 20 (first statement of Carolyn McGimpsey); WITN3477010 haemophilia unit in Edinburgh of his father, brother and sister. The results of this testing were included in the haemophilia patient's records.[2258] This shows that the interests of the centre in trying to understand the consequences of infection stretched beyond the patients in the unit themselves. It also shows that there was a known transmission risk to family members which was allowed to exist. None of these individuals could have been aware of the risks as the patient and hence his relatives were not even aware of the fact that the patient himself was infected, until he was told in 1991.

knowing of the patient is infected or not. It suggests no further action to find out. It is unclear why it was being sent to the uninfected patient's GP at all.

9.30 The letter sent out by Dr Ludlam was, of course, also issued in respect of patients whom he knew to be positive on the Tedder testing. Professor Ludlam's insistence that the position with regard to these patients was clear is in direct contrast to the evidence of patients, as is noted elsewhere. Further, the letter which was sent out after the meeting does not provide any clarity either. The letter does not suggest that the patient should make an appointment to find out about their HIV status. It eclipsed an advice sheet about AIDS and started that an appointment could be made with Dr Ludlam via his secretary to discuss the contents of the advice sheet. It provides no information about testing having taken place or the need for patients to come and find out about the results. One patient who received this GRO-D GRO-D[2259] In response to a subsequent complaint made to the GMC by this patient, Dr Ludlam characterised this latter as being an explicit invitation to make an appointment to find out their HTLV-III status.[2260] He suggested that the onus was on the patients and that they had not taken up his offer of a meeting. This was simply an inaccurate statement as the letter makes no reference to testing or the possibility of a meeting taking place in connection with the results of any such testing. This patient, like others, was inappropriately reassured by the way that this was handled by Dr Ludlam that he was not infected. the letter of course also was at pains to point out that factor concentrates which would be used from that point onwards would be heat treated to kill the AIDS virus. Evidence heard by the Inquiry from Dr Peter Foster was that this was not an accurate statement of the position at that time. The heat treatment regime which had been introduced was thought to have the desired effect based on investigations which had been done on similarly heated products by others.[2261] The PFC product had not yet been tested in vivo and so this

---

[2259] GRO-D

[2260] WITN3365029_001_0044, _0045 and _0138

[2261] INI transcript for 15/03/22; 137 to 138 (Peter Foster)

assurance could not be given. For infected patients (like this one) it was of little real relevance that the products would be safe going forward – the non-heated products had already done their damage. The safety of the product going forward would only be relevant to this who were uninfected. It was perfectly reasonable for this also to be taken to be a reason for a recipient of this letter to think that he must therefore be uninfected. It is submitted that this was a clear diversionary tactic. The idea was to dazzle patients with what appeared to be good news – the products would now be heat treated and would be safe – in order to divert their attention away from the bad news that some of them (like this patient) had been infected. This was a dangerous and irresponsible way to handle matters. It was known that close contacts of these patients were thereby put at risk. They were being tested also by the unit, as is discussed elsewhere in this submission. It has also been submitted to the Inquiry by Professor Ludlam that it was not known at that time what a positive antibody test meant in terms of the likelihood that it would result in the positive patient going on to contract AIDS. Again, this appears inconsistent with this letter, which talks about the risks of AIDS which suggests that the links between a positive test and AIDS were clearly in the thinking of Dr Ludlam at the time, though not properly communicated to the patients. In any event, the risk of a patient contracting an AIDS defining illness with a positive test should have been able to be predicted at that time. By this time, it was known that the deranged immune function being shown by these patients was the same as patients who had contracted AIDS in other communities in the US. It was known that they had been exposed to the AIDS-causing virus. Their diminished immune function (caused in part by the virus and in part by the reaction to the concentrates' protein content as shown by the pre-infection study) rendered the patients liable not to be able to resist opportunistic infection. That was by definition AIDS, as the other report of the disease had shown going back to 1982. There was enough known for it to be deemed likely that these patients would go on to develop AIDS, as the references to AIDS in this letter and advice sheet demonstrate. The problem was that information about AIDS was communicated without the patients knowing that they were at risk of getting it. The advice sheet also does not mention testing or that patient might be positive. Its final page had

a section entitled "reassurance" which would hardly be appropriate of the news of the positive tests was being communicated. The information was to the effect that simple precautions around exposure should be taken with families only but no change was needed with regard to other contacts. Again, this did not seem to convey that there was a public health risk, which there was. As this patient pointed out, he became sexually active as became an adult, something which meant others beyond his immediate family were being out at risk. It should be noted that in Glasgow, though it would appear from the advice note which contains Glasgow contact details, patients also received the same inappropriately reassuring advice sheet, the letter sent to patients did include information about testing and a specific invitation to an appointment.[2262]

9.31 Further, there is evidence available to the Inquiry which speak of patients having been tested in Edinburgh for HIV without their knowledge or consent, even after the initial non-consensual Tedder testing in 1984. GRO-D GRO-D GRO-D[2263] The evidence available to the Inquiry was that the very act of testing for HIV created stigma and prejudice, not to mention the invasion of personal autonomy which such testing involved. A further important element of this late testing is that he could have been infected (as many other Edinburgh patients were) but that infection not have been discovered until that time.

9.32 There is also evidence available to the Inquiry of Edinburgh patients who were at risk for HIV not being tested until long after their possibly infective HIV treatment, thus creating an unnecessary risk of onward transmission of HIV/ AIDS. One patient GRO-D GRO-D

[2262] PRSE0000859 – letter from Professor Forbes dated 8th January 1985

[2263] GRO-D

GRO-D The residual need to test for HIV at that time would tend to suggest that the patient's HIV status was unknown and he had been treated with a concentrate in 1983. There was a risk that he may have been HIV positive over that whole time, suggesting that his HIV status had not been checked in Edinburgh, where he was infected.

Glasgow

9.33 It appears clear from evidence available to the Inquiry that the fact of positive tests had been known to the clinicians in Glasgow and indeed publicised more widely within the Scottish NHS some months before the patients were told. A seminar on the fact of infection of 18 Glasgow haemophiliacs with HTLV III by Dr Karin Froebel took place on 14 October 1984.[2265] There appears to be more interest in research related to the factor VIII baches from the PFC which had been contaminated with HTLV III then in telling patients about this fact.[2266] This created an unnecessary risk of infection. It appears to be the case that the Scottish NHS was keen to get its position on these infections clear before seeking to remove that risk.

9.34 Glasgow patients were sent a letter dated 8 January 1985.[2267] Unlike Edinburgh (or anywhere else in Scotland as far as is known) the patient was given an appointment, an indication that they would be tested and an opportunity to ask questions about the tests. While the letter is not candid as to whether a recipient of it had already been tested and the risks which had a positive test had created, the letter was somewhat more helpful and informative for patients. The problem for both Glasgow and Edinburgh is that patients by this stage had not been or had not been adequately informed of the risks and secretly stored samples had tested without consent. Positive patients had to be told their results without being

---

[2264] GRO-D

[2265] PRSE0001141 – it appears that research was underway which was due to be published about the west of Scotland HTLV III infections in due course

[2266] MACK0001839_0002

[2267] PRSE0000859 (8 January 1985)

advised that they had been at risk or tested without permission. In those circumstances, the news would inevitably come like a bolt from the blue. It is unclear to what extent in Glasgow, patients were told the results of tests which had already been carried out without their permission. Even of patients were told, by that point the trust of the patient had been lost and the harm of the infection irreparably compounded. No risk had been set out. Samples had been stored, research undertaken and published and the patient had tested without permission.

9.35 It seems that some patients may not have taken up the offer of an appointment, perhaps labouring under similar misapprehensions after the December 1984 as the Edinburgh patients. A further letter was sent out in April 1985.[2268] This seems like a letter being sent to haemophiliacs talking about "concern about the risk of AIDS" and sending out a Haemophilia Society information booklet. It invites patients to attend a regular clinic or make a special appointment and says that they have "already advised many of our patients about AIDS". The letter refers to tests having been done on stored samples and about 10% being antibody positive, confirming that tests were done without consent. Then letters mentions cryo being used for mild patients as an option. By this point does that posed a risk of HIV transmission which concentrate did not have (not mentioned).

Outcome

9.36 It was known known that the Scottish blood supply had been contaminated by this time. Despite this, the public were being told that "they do not have anything to worry about, whether they are getting blood transfusion or other treatment with blood products".[2269] This message was misleading and known to be so.[2270] This

---

[2268] HCDO0000273_049 (1 April 1985)

[2269] See articles in "Evening News" @ PRSE0003234 and PRSE0003667

[2270] See Briefing note 5/12/1984 - PRSE0003032 "The general tenor of the articles is to give Scotland a somewhat cleaner bill of health than we know to be justified. We understand that Dr Cash is not entirely happy with the reporting of his remarks, but they do have the effect of preparing the ground for any subsequent reporting of

ethically unforgiveable inertia on the part of the haemophilia directors was clearly having an effect on those closest to their infected patients but also on public health generally.

9.37 The December 1984 meeting was not confidential. The message which is imparted was unclear. The wrong impression was created when certainty needed. Patients reasonably left with the impression that must have been the lucky ones as they thought that if they had been infected that they would have been told confidentially. This was the impression gained of the meeting by Alison Richardson, a clinical psychologist, from her dealings patients who had attended the meeting in subsequent years.[2271] Interestingly, Nurse Reynolds also relayed a story of a further meeting in 1987 which had been convened by Dr Ludlam about HIV testing. She described that meeting as being one which Dr Ludlam had hoped would be attended by the parents of a patient who had not yet been informed of his positive status. She also opined that the meeting was pointless as a general meeting no personal information could be conveyed.[2272] This coincides with Ms Richardson's impression of what the purpose of the December 1984 meeting had been, namely to try to coax those whom Dr Ludlam new to be positive (but could not tell) into asking for a test.

9.38 This was despite the fact that the UKHCDO had recommended that antibody positive patients should be informed and that advice should be given about risk of transmission to spouses and the use of barrier contraception.[2273] No recommendation had been made about the discussion about how patients should become infected or that patients should be told that this should be treated as anything other than a diagnosis of being infected with the agents causative of AIDS. No specific recommendation was made about advice regarding other risks, like from bleeding in the infected haemophiliacs. Thought eh advice was inadequate in these aspects the need for patients to be informed to manage the

---

the actual position that needs to be made. No statement can be made at the moment until the haemophilia directors resolve the very difficult ethical problem of what action to take with regard to their patients about the matter "

[2271] PRSE0001055 @ para 8 (statement of Alison Richardson)

[2272] PRSE0001844 @ para 25

[2273] PRSE0002282_0004

immediate risks was clear. In this regard, Dr Ludlam and his colleagues singularly failed. Risks to family members, who were unnecessarily endangered.

National developments

9.39 The SNBTS and SHHD response to the outbreak of HIV infections in Edinburgh was also misguided and dangerous. It appears that no guidance or assistance was given to the haemophilia clinicians regarding what to do by the Scottish office at all. SNBTS appears to have played little role other than Dr McClelland having attended the 19 December 1984 meeting. SHHD knew of the situation but a press briefing to the Minister dated 20 December 1984 stated that *"It would not be appropriate at this stage to issue any statement on the discovery of antibodies in the Scottish haemophiliacs.* [2274]*"* Given that this was a major public health crisis, it seems hard to understand why. The apparently reassuring message given by the Press Release issued by the SHHD on 20 December 1984 was simply misleading.[2275] This outbreak made clear that AIDS had arrived in the donor population in Scotland. It could not be known how widespread the problems was. Given the lengthy prodromal phase of the disease and the lack of any specific test, there was no real protection. This was a major public health crisis. The public had a right to know about it what it meant. The spin which was attached to the message of the infections directed towards the patients was also directed towards the public. The release led with the message that a heat-treated factor VIII was now available. This was of no real relevance to the non-haemophiliac public or indeed to those who had been infected. It was an act of misdirection which attempted to get the message onto a positive piece of news and direct attention away from the tragedy which was unfolding and had been caused by domestic blood and a domestic blood product. The message that the infections in Edinburgh had been caused by a single batch was also at the forefront of the response. It was not accurate, even at that time

[2274] PRSE0002251 (20 December 1984)
[2275] PRSE0000225 (20 December 1984)

(as is discussed in more detail elsewhere in this submission). Again, it was an attempt to give the impression that this was an isolated incident – it was not and it could not be known if it was. Paragraph 3 focusses on the relative risk of AIDS when compared to commercial products. This was of little relevance to the unfolding crisis and was an unnecessary publicity effort. In any event, it was known by this stage that infections had also occurred, predominantly in Glasgow from commercial material as well. The message was inaccurate.

9.40 At a more national level, the evidence available to the Inquiry suggested that it was not even known and ministerial level that infections had occurred which were attributable to domestic blood products.[2276] The problems continued to be a matter relating to the dangers of imported products, in their minds. The fact and implications catastrophic discovery were not communicated or acted upon.

Yorkhill

9.41 The chaotic system at Yorkhill which had resulted in patients being treated away from the hospital on prophylactic regimes The Inquiry heard evidence of parents being told of their children's HIV infections in corridors[2277], in what otherwise seemed like routine appointments and/ or without their spouse present. No counselling or formal support was offered for what must have been the most devastating news to hear. The way in which patients and their parents were informed about the many HIV infections at Yorkhill was unacceptable. Unlike the occurrence of the infections themselves, the diagnosis of HIV infection took place in the regime which was under the control of Professor Hann, who became the centre director there at the start of 1983. He made innovations to the treatment regime there which moved reliance on imported concentrates to use of far greater amounts of domestic factor VIII. For the boys infected with HIV that came too late.

[2276] See references to the evidence of Lord Clarke below in this regard; IBI transcript for 23/07/21; 103 (Lord Glenarthur)

[2277] WITN2239001 @ para 15 (first written statement of WITN2239)

The news of their diagnosis must have been devastating for the boys and their parents. The way in which the news of the infections was imparted clearly compounded the harm.

9.42 One case from Yorkhill involves a particularly egregious delay in a patient being informed which did not appear to apply to others. This patient and his parents had moved to Inverness when he was 10 in around 1984. He was not informed of his HIV infection until he was 14 in 1988.[2278] The infections of the other boys who had been treated with the same products as this boy had been known about since 1985 at the latest. No effort appears to have been made to trace this boy who had moved out of the area. This showed a lack of care and potentially endangered his family and other close contacts. The process by which the news was broken was equally poorly managed. An AIDS leaflet was sent to the boy's parents in 1987.[2279] Much like the leaflet which was sent to the Edinburgh patients by Professor Ludlam in January 1985, this must have been relatively meaningless without context or knowledge of the risk. In 1988, his parents were called to a meeting where they were told – he was not present. It appears self-evident that the information imparted at this time cannot have been sufficient as a further "detailed meeting" required to take place thereafter which did not take place until 1990.[2280] Further information about the circumstances in which this boy came to be found to be positive and be told of his diagnosis after many years is available to the Inquiry from a surprising source. A letter from 1989 written by Dr Ludlam to Mr Watters of the Haemophilia Society appears to relate to the case.[2281] This unsolicited letter was written by Dr Ludlam as he had been told that Mr Watters had been approached about the case and the delay in diagnosis by Dr Rizza. The reason for Dr Ludlam's involvement remains unclear but is appears that he had been charged with appeasing Mr Watters and hence the irate family. The story which he had managed to elicit from Dr Taylor in Inverness has been that the boy had been tested for anti-HIV (with the consent of his parents) in 1985 and found

---

[2278] WITN2149001, para 6 (first statement of WITN2149)
[2279] WITN2149001, para 6 (first statement of WITN2149); WITN2149005
[2280] WITN2149001, para 6 (first statement of WITN2149); WITN2149006
[2281] LOTH0000006_029 (15 June 1989)

to be positive but that. There appears to be no good reason why Dr Taylor could not have explained this to them. That Dr Ludlam became involved in 1989 is indicative of the prevailing mood by that time within the UKHCDO that there needed to be a consistent management of the disaster which the State had caused and the extra harms which it had created by its failure to manage it properly and in the best interests of patients. Dr Ludlam was hardly likely to be critical of this harmful series of events as he also had a patient who had been infected with HIV as a boy who did not know of his HIV status at that time and would not find out until 1991. In any event, no clear explanation for this delay and the inevitable health risks and psychological damage which it created is offered. It is suggested that there was a sense that the parents did not want to know. This was despite the fact that (unlike many others) they had been offered the opportunity to consent to a test and had agreed. The boy's feelings in the matter seem to have gone completely ignored.

Significant delays in diagnosis of HIV being imparted to patients after early 1985

9.43 Clear evidence is available to the inquiry of failings on the part of Dr Ludlam to inform at least two Edinburgh patients of their HIV positive status for a significant period after the December 1984 meeting. Alison Richardson (a psychologist who became involved in the counselling of HIV positive patients in Edinburgh generally and at the haemophilia centre from 1987) gave evidence to the Penrose Inquiry about the state of knowledge of patients and the anger of those who were told.[2282] She went on to state that:

"I remember best the dilemma about a person with haemophilia who was under sixteen years old. My impression was that this person was among an initial group

[2282] PRSE0001055 @ paragraph 12 (statement of Alison Richardson)

who had been tested for HIV without his consent or his parents' consent as part of a test of the HIV test itself. I remember debating over and over again do we tell the child, his parents or do nothing. I think Dr Ludlam's view was to keep trying to persuade them to have the test openly. I think that eventually, a few years later when the individual was 19 years old, he was tested for HIV. I subsequently saw this person, for treatment many years later"[2283]

9.44 The fact that there needed to be secrecy about the initial testing meant that this person was not told for many years. Despite the clear dilemma which this presented for Ms Richardson, it appears that not telling the patients or his parents was Dr Ludlam's decision. In her written statement to the Penrose inquiry, Ms Richardson expressed the view that the purpose of the December 1984 meeting had been to try to get patients to come froward to be tested after having identified a risk but without telling patients that testing had been done on any particular individual. Dr Ludlam of course knew that they were already positive (or at least some of them were). The clandestine nature of the testing had put him "between a rock and a hard place". The problem was (according to Ms Richardson, the fact that some patients die not come forward for testing. They were therefore not tested in the open and could not be told. She identified 5 patients who fell into this category.[2284] The tenor of her evidence is supported by the evidence of Billie Reynolds, a nurse who worked within the centre from July 1986, who has stated that a number of Edinburgh patients were not told of their HIV status long after their clinician knew them to have tested positive.[2285] She relayed a story of one patient being admitted with symptoms at some point after 1990 who was not aware of his HIV status at that time and was told in the middle of the night.[2286] Another (who was a child at the time of his infection) was told at the age of 17 by Dr Ludlam and the unit social worker, contrary to his parents' wishes and the

---

[2283] PRSE0001055 @ paragraph 8 (statement of Alison Richardson)
[2284] PRSE0001055 @ paras 7 - 9 (statement of Alison Richardson)
[2285] PRSE0001844 @ para 13
[2286] PRSE0001844 @ para 14

views of the nursing staff as he was terrified about AIDS.[2287]

9.45 There are only two members of the HIV infected Edinburgh cohort who are still alive, as far as we were aware. Both of these have given evidence to the Inquiry were not told for some years after the positive tests in 1984. Robert Mackie was a severely infected haemophiliac who (along with other members of his family) had been treated at the Edinburgh centre for many years. He was not told of his diagnosis until January 1987. The delay in his diagnosis caused inevitable distress but also caused him to question why he had been given the treatment he had and caused a deep sense of mistrust for the medical profession, in particular Dr Ludlam. He had been continually reassured that the products he received were safe.[2288]

9.46 Another member of the Edinburgh cohort whose evidence has been given to the Inquiry is anonymised witness WITN2232. He was infected as a child. His case was also looked at in the Penrose Inquiry where he was known by the anonymised pseudonym "Mark". He was not informed of his HIV positive statis until around 1991, many years after his infection had been revealed to Dr Ludlam by Dr Tedder. In her evidence, Nurse Reynolds made clear that she knew of his HIV positive status in 1986 and that (contrary to his claim) Dr Ludlam had not tried to make him aware of his HIV status at that time. Despite a request from the staff in the unit that he and/ or his parents be told in 1987, Dr Ludlam refused to do so, her impression being that he could not bring himself to do so. [2289] She was unaware of this patients ever having expressed the wish that he not be told of his status (which Professor Ludlam claimed had been the position) and did not accept that that assertion (which Dr Ludlam had made) was true.[2290] She had been moved to make her statement to the Penrose Inquiry after hearing Professor Ludlam's evidence, with which he disagreed in this and other regards. On her account, the position taken by Professor Ludlam appeared to differ as between this patient and the other patient who had been infected as a child. In this case, Professor Ludlam had

---

[2287] PRSE0001844 @ para 20 and 22
[2288] WITN2190001 @ paras 6 and 7 (first written statement of Robert Mackie)
[2289] PRSE0001844 @ para 19
[2290] PRSE0001844 @ para 24

claimed that he did not tell the patient as he did not want to know. In the other case, she gave evidence that Dr Ludlam had told the 17 year old patient, despite it being contrary to his parents' wishes.

9.47 The limitations on the number of living patients who were infected with HIV at the Edinburgh haemophilia centre does not mean that the Inquiry does not have ample evidence that the delays in patient being told were widespread. WITN2202 gave evidence to the Inquiry as Mrs AD to the effect that her late husband, a haemophiliac infected with HIV who later died of AIDS was not told until he requested a test of himself and his family in December 1986.[2291] This story was corroborated by his brother. He added that it led to his late brother stopping treatment until he died of AIDS.[2292]

9.48 Other evidence is available to the Inquiry about infected members of the cohort and the circumstances in which they were informed of their infections. Evidence related to two of the infected patients was given to the inquiry by thew widow of one who was also the sister-in-law of another (ie the two infected patients were brothers). One was told of his infected status in 1987, the brother-in-law. The other (her late husband) had asked at that time whether he too was infected as they had used the same treatments. He was told that he was not infected. Later that year he was told that he was in fact infected. He had questioned the diagnosis about which he was sceptical anyway as he had started to become ill. He died the next year.[2293] The cumulative effect of this evidence is that there was a widespread failure on the part of Dr Ludlam to inform these HIV-positive patients of their diagnosis for years later he knew that they were infected. This created unnecessary risk for the loved ones and other contacts of these patients. Taken together, it renders the excuses given by Professor Ludlam for why individuals like the man infected as a boy less reliable. That evidence should not be accepted. He did not tell others for no good reason. That makes it more likely that he in fact had no good reason not to tell that individual. The same witness also pointed out the fact that there was a completely unacceptable system for ensuring that the

[2291] WITN2202001, para 17 (first statement of WITN2202, also Mrs AD)
[2292] WITN2203001, para 6 (first statement of WITN2203)
[2293] WITN2665001, paras 5 and 6 (first statement of Linda Grigor)

spouses of patients like her be tested. The option was casually offered to her via her husband. She was aware of some widows who were advised not to be tested at all, creating a public health risk.[2294] In her case, the risk of her being infected had been created by the delay between the hospital finding out (presumably in late 1984 as part of the Tedder testing regime) and 1987. She was not provided with medical assistance in connection with the risk that she might be infected. She was not the patient of the haemophilia unit, after all. This was a wholly unacceptable system demonstrated the lack of care which the unit had for the infections and the consequent public health risk it had caused.

9.49 Further similar evidence was provided by another affected representative witness whose brothers were both infected with HIV in Edinburgh as a result of their haemophilia care under Dr Ludlam. It is not clear whether they are in fact members of the cohort or otherwise infected with HIV in Edinburgh. One brother was able to see a note on Dr Ludlam's desk that the other (who had lived abroad but had lived back in Edinburgh from the summer of 1984) was HIV positive. The infected brother did not know, again creating an infection risk which the witness brother recognised had caused a risk to his children, ex-partners and current sexual partners.[2295] The witness was unaware of the precise date but this practice is consistent with the evidence of others analysed above.

9.50 When individuals were told about their positive test advice about risks inadequate, they received no counselling. By late January 1985, it appears that in Edinburgh Dr Ludlam's attention had reverted to the more mundane scientific matter of the size of the vials in which factor VIII was sent to the hospital.[2296]

9.51 The implications of these delays are clear. They were significant breaches of ethical rules. They created an unnecessary public health risk. They made is increasingly difficult for important information to be imparted to patients about what the diagnosis meant, what the prognosis was and how precautions might be taken to try to maintain the health of the infected individuals, how to minimise the risk of

---

[2294] WITN2665001, para 7 (first statement of Linda Grigor)
[2295] WITN2304001 @ para 7 (first statement of Michael Lyons)
[2296] PRSE0002712 (29 January 1985)

cross infection of others and the importance of maintaining treatment for the patient's bleeding disorder.

Information provided to those who were told about their anti-HIV positive status

9.52 It is important to realise that a positive test with the virus which by this stage was known to cause AIDS was a death sentence, or at least was reasonably thought to be in the mid-1980s. Furthermore, the clear and well-known stigma associated with the disease (given its association with lifestyles which were generally rejected socially at that time) meant that the No amount of support or counselling could ever have made up for or dealt with the magnitude of the diagnosis. Having caused the infections, the support provided by the State in Scotland was generally inadequate. This caused a significant compounding of the harm.

9.53 It is important to understand one element of the failing in this regard. There is no evidence that any counselling or support gave any weight to the need for patients to be told and to have clearly explained to them how this could have happened. One must bear on mind that most patients were advised that he products they had received were safe. They had been told that these products were made domestically from the blood of voluntary donors. They had not known that they had even been tested. They must have been shocked and disappointed by the fact of their infections but also the fact that a risk had materialised which they did not know they were running and for which they had not known they were being tested. They received no clear explanation for any of these things. This was the start of what the infected and affected community have come to know as the "cover-up". The risk had been kept secret – patients had generally been told in Scotland that there was none. The testing had been kept secret. Indeed, the research in Edinburgh and Glasgow had been kept secret, although most patients remained in the dark about that. Patients had been unwittingly compliant in that research. It was necessary that this state of ignorance continue in order for the research to continue. Dr Ludlam in Edinburgh was already submitting applications

for ethical consent for ongoing research into the condition of these patients. These clear omissions from the say that patients were, in general, handles in the aftermath of their positive tests must have had the effect of undermining the relationship between doctor and patient. These doctors continued to offer a key lifeline for these patients in the management of their bleeding disorders.

9.54 The Inquiry heard evidence that patients were not and also about the risks of onward transmission or the management of the infection, requiring to rely on public sources of information.[2297] This also applied at the time when AIDS was diagnosed in one case where no clear information was given, given to the feeling on the part of the patient's widow that things were being hushed up.[2298] Patients who had been infected by the NHS were made to feel like an inconvenience, not a priority.

9.55 Another element of the discussion with the patients who were infected which appears not to have taken place related to hepatitis. If these individuals had become infected with HIV, it was highly likely that they would also be infected with NANBH and also have been exposed to HBV as a result of their treatment. This was acknowledged by Alison Richardson.[2299] Almost all were severe haemophiliacs, with only two moderates. Those who had been studied were known to have had immune suppression from the Glasgow and Edinburgh studies from 1983 and 1984. The suppression of their ability to fight the effects of their hepatitis was an important part of their management. Though no treatment was available for any of these conditions, management of drinking/ diet etc could have made a contribution to trying to limit the effects of the conditions with which they had been infected. Yet, the evidence suggests that there was no discussion with the patients about this elements of their situation. They remained largely in the dark about their hepatitis and the impact of co-infection.

[2297] WITN2665001, para 12 (first statement of Linda Grigor)
[2298] WITN2665001, paras 10 (first statement of Linda Grigor)
[2299] PRSE0001055 @ para 11 (statement of Alison Richardson)

HCV

Bleeding disorder patients

9.56 It would be wrong to assume that HCV infection amongst bleeding disorder patients was all discovered automatically by the fact that they were all subjected to regular testing regimes. The fact that the prevalence of the disease was so high in the donor population (resulting in a likelihood of infectivity on first infusion with a concentrate of any origin by at the early 1980s), combined with the geographical spread of the areas covered by each haemophilia centre and the management of patients (in particularly at the more mild end) remotely from the system of regular attendance at a centre created a risk that patient shad been infected by bleeding disorder treatment but did not know about it. The possibility that such groups existed was brought to the attention of the Scottish government in its investigation into limited elements of the blood contamination disaster in Scotland in 1999/ 2000. The failure to so anything about that possibility at that time is discussed on more detail below. certainly nothing had been done before that time. Patients were undoubtedly infected in this community who were never identified, never offered treatment or any other help. They may have died or suffered significant illness or disability in ignorance. They were not only infected by the State but left by the State to suffer the consequences of their infections alone.

9.57 Delays in patients/ parents being told led to a lack of treatment opportunities and an opportunity to moderate lifestyle. This undermined trust and compounded harms and was unethical. For many the possibility that they could have infected family members was the worst torture of all. These failings represented a continuation of serious public health issues crested by the attitude taken by the medical profession to the risks and the creation of vectors of infection with the potential that they might unwittingly infected other and expanding the crisis unnecessarily (in particular for haemophiliacs who bled a lot). The harms of infection were unnecessarily compounded.

9.58 The Inquiry has plenty of evidence available it of patients or their parents only being informed about HCV infection long after testing was available (by 1991 at

the latest, or earlier by diagnosis based on ALT levels). GRO-D

GRO-D

GRO-D Another elderly haemophilia treated in Edinburgh tested positive for HCV in 1991 (as per his records) and was not told until 1995.[2302] Another was asked in 1993 how he was getting on with his HCV infection in 1993, which was the first he had heard about it. He was told to go and look up information about the disease at that time, which was shortly after he had got married.[2303]

9.59 Evidence was also available of the concerted efforts of the medical professionals to downplay the severity of the diagnosis/ prognosis. The information available about the potential severity of the disease by 1991 when anti-HCV testing was available is narrated elsewhere in this submission. This information ought to have been made available to patients about prognosis but also infectivity risk. As to prognosis, GRO-D

GRO-D

9.60 Risks of HCV transmission were inconsistently provided to patients. This is particularly important in light of the evidence routinely heard by the Inquiry that one of the key impacts on so many infected patients was, somewhat selflessly, less to do with themselves and more to do with the risk that their infection may have resulted in the infection of their loved ones. These cases were rendered more serious where there was a delay in diagnosis (creating a risk of unwitting infection) or inadequate information about transmission risks to enable proper management

---

2300 GRO-D

2301

2302 WITN3477001 @ para 9 (first statement of Carolyn McGimpsey)

2303 WITN2233001, para 7 (first statement of Steven Newby)

2304 GRO-D

2305

of them, leaving the infected individual with the feeling that they had unwittingly and/ or unnecessarily out their loved ones in danger. Evidence of the anxiety caused by loved ones having to be tested themselves was particularly impactful. Such anxiety would, of course, have been all the more natural in cases of bleeding disorder patients whose bleeding risk created a transmission risk which would not necessarily exist in other households.

9.61 There is evidence available to the Inquiry that certain patients infected with HIV in Edinburgh not knowing that they were also infected with HCV, which of course they all were due to the high prevalence rates. One widow gave evidence to the effect that her husband had what was probably NANBH on his death certificate when he died I August 1988 (as thought the virus had been isolated it could not have been directly tested for at that time). She had not known of the diagnosis and neither had he.[2306]

9.62 This caused difficulties for widows accessing Skipton and other HCV related payments at later dates as it was hard to prove what stage of the HCV had been reached. This is an element of the Skipton scheme which seems rather illogical. The State was able to save money payable to co-infected patients based on the fact that the infected were killed by one infection before the other had chance to get that bad. There is also a medical illogicality about it based on co-infection with HIV, the immune-suppressant effects of which would inevitably have made the effects of HCV more pressing than they otherwise would have been. The stage 1/ 2 analysis is based on a single virus paradigm which is not relevant in a co-infection of that nature.

Glasgow

9.63 The fact that Glasgow patients appear to have been offered an appointment in connection with the HIV crisis in January 1985 is discussed elsewhere in this submission. In Glasgow, of course, there was the complication that patients would were severely infected at least would have been treated in a different hospital as

[2306] WITN2665001, para 4 (first statement of Linda Grigor)

children when they may have been exposed to infection. One severe haemophilia A patient who fell into this category gave evidence to the effect that he was called in to the GRI to have a test for HIV. Based on other evidence, this sounds like it was in around January 1985. He was 22 at the time. He told the Inquiry that he was offered a test for HIV.[2307] Other evidence available to the Inquiry shows that patients' retained samples had already been tested by this point. Further tests appear to have been offered to cover up the fact that non-consensual testing had taken place. This, of course, would be a reason why patients (including Glasgow patients who were invited to the meeting) could not be told at the December 1984 meeting in Edinburgh whether they were positive or not. Such a course would have revealed that individuals had been tested without their knowledge or consent. The approach of sounding the alarm in a general sense and inviting patients for a test (which had already been carried out) was a way of getting round this obvious ethical issue. This particular patient recounts that the good news of his negative HIV test was used as a background to his NANBH diagnosis being revealed to him.[2308] The use of this context to break this bad news was certainly not in his best interests. The possible effects of the NANBH (known by that time to be a potentially seriously harmful and even fatal disease) were downplayed. This contrasted with the information he received from the liver specialist about the potential severity of the disease. He was told to bear the terrible news alone. He was offered no psychological support. This testimony is reminiscent of much else heard on the subject by the Inquiry. Interestingly, he also to the Inquiry that (unusually) it was explained to him what products were thought to have infected him. The context was thus a clear admission that this was an NHS infection caused at the hospital (GRI) where the news was being broken.[2309] In circumstances where the NHS had caused harm, it appears that its normal instinct to break bad news with support and care was abandoned. It seems that the perception of the obligation extended only to breaking the news, telling the patient to get on with it

[2307] WITN2118001 @ para 6 (first statement of WITN2118)
[2308] WITN2118001 @ para 6 (first statement of WITN2118)
[2309] WITN2118001 @ para 6 (first statement of WITN2118)

and nothing more. This was simply not good enough and certainly compounded the harm of the infection having been caused in the first place.

9.64 Though GRI patients were generally told of their positive HIV status in a more orderly fashion than elsewhere is mentioned above. However, witness Mrs Y[2310] gave oral evidence to the Inquiry of her late husband, a mild patient not having been tested for HIV until 1988, despite having been treated with concentrates in the first half of the 1980s (mostly at Yorkhill). he was infected with HCV and not HIV, though the failure to offer him a test had meant that his family could have been exposed to infection between 1985 and 1988. She described the unsatisfactory circumstances in which her late husband found out about his HCV infection, having been tested without his knowledge and the paucity of information with which he had been provided. She also described that when her late husband asked Professor Lowe how he had come to be infected, he was told that it could not be worked out. This was inaccurate as he had received few treatments and the exercise was carried out and recorded in is medical records by the staff.[2311]

9.65 The delay in telling people about their diagnosis meant that it was allowed to deteriorate without being managed as efficiently as it might have been. one Glasgow patient informed the Inquiry that he had to rely on his own research even after he received a presumptive NANBH diagnosis in 1985 about ways to manage his infection, including alcohol abstinence, diet etc.[2312] He received no information in this regard at the haemophilia unit and waited for a liver unit appointment for some time. Though this patient received an early presumptive diagnosis and was able to use his own initiative to access some useful information (in the pre-internet era), others did not find out for another decade or more and did not get that information which must have caused deterioration and further harm, including psychological harm.

[2310] WITN2288001

[2311] WITN2288005

[2312] WITN2118001 @ paras 9 and 10 (first statement of WITN2118)

Dundee

9.66 Failings surrounding patients being told about their HCV diagnosis was one of the major issues in the Dundee centre. One deceased patient's daughter had carefully reviewed his records which revealed that he had tested positive for HCV certainly by 1992 but was not told until 1996. This is despite the fact that there was discussion about the positive test between the hospital and the patient's GP and a negative HIV test was intimated to him in 1992 (the HIV test also having been conducted without his knowledge or consent).[2313] The Inquiry heard evidence that even being tested for HIV could have negative impacts on an individual in terms of the effect on the availability of insurance or stigma at the hands of other medical professionals who read the notes. This patient was also positive for parvovirus at that time, a fact which was also withheld from him for at least 4 years.[2314] Some patients had a lesser delay in waiting for their diagnosis. One found out in 1993, rather opportunistically as he attended in relation to a bleed in his finger and it was mentioned to him that he was infected by his GP.[2315] His GP was therefore aware as a result of earlier testing but he had not been told. The patient was scared about the possibility of cross infection and that the disease could be serious. He was provided with inadequate information to allow him to process the unexpected news.[2316] This regime appears to have been the result of the rather unsophisticated regime at the Dundee centre, where treatment was not cutting edge and the systems for patient involvement and information were limited. The widow of another patient explained that she only found out about his infection in 1995 when he approached a nurse at the hospital for the information, having been told by his brother that he had just been diagnosed. The diagnosis was not confirmed until 1996 when the likely consequences were played down. He was specifically told that the genotype he had was not a bad one in terms of prognosis, which turned out to be completely inaccurate. He required a liver transplant

[2313] WITN2087001 @ paras 6 and 7 (first written statement of WITN2087)
[2314] WITN2087001 @ paras 10 and 18 (first written statement of WITN2087)
[2315] WITN2083001 @ para 6 (first written statement of William Barry)
[2316] WITN2083001 @ para 8 (first written statement of William Barry)

around 10 years later and subsequently died.[2317] The unsophisticated operation in Dundee meant that no counselling was offered.[2318] Another mild vWD patient was not tested for HCV until 1995.[2319] Though he was unaware of any testing prior to that, something must have triggered the request to come to be tested, which of course could have been done from 1991 at the latest. Another patient (severe haemophilia A) was not told until called in by Dr GRO-D in 1995.[2320] Others were not told until even later, including one mild patient in 1998. He received little information about the infection, its management or implications.[2321] As he was an infrequent attender at the centre he appears to have been forgotten by Dr Cacchia.

Yorkhill

9.67 Evidence is available to the Inquiry that patients/ their parents were not given clear information about managing HCV infection. One patient said that his parents had been told he was "antibody positive" in what he perceived as an effort to downplay the seriousness of the diagnosis and had little advice about management.[2322] A similar story was presented by a witness who found out about his infection whole being treated at Yorkhill in 1994, though he had in fact been infected with HCV at the GRI in 1983. He described him and his parents being told about the infection out of the blue in 1994 and being told that he had been infected 10 years previously, with very little information being passed on.[2323] The HIV patient referred to above was not told about his HCV infection until around 1993 or 1994 when he was 20 or 21. A letter from the consultant to whom he was referred for this infection (produced to the Inquiry) worryingly suggests that he

[2317] WITN2091001 @ paras 8 and 9 (first written statement of WITN2091)
[2318] WITN2091001 @ para 10 (first written statement of WITN2091)
[2319] WITN2175001 @ para 8 (first written statement of Ian Joy)
[2320] WITN2086001 @ para 7 (first written statement of Barclay Bisset)
[2321] WITN2290001 @ paras 6 and 7 (first written statement of WITN2290)
[2322] WITN2200001, paras 8 and 9 (first statement of WITN2200)
[2323] WITN4183001, paras 6 to 11 (first statement of Joseph Monaghan)

had been given limited and inadequate information and also that that consultant doubted the date of his infection ad predating 1989 as testing had not become available until 1991, a confusion of the date of infection and the date of diagnosis.[2324] Another mild haemophilia A patient who was infected at Yorkhill was told at the GRI in 1993 that he was positive for HCV. Oddly, he was called to the centre to be told along with his haemophiliac brother and his mother, as if the thinking was that families could be told in batches. His records also reveal that he was tested at Ruchill Hospital (infectious diseases) in 1992.[2325]

Inverness

9.68 One of the facts of the more rural treatment offered at the Inverness centre was that patients operated more remotely from the centre than elsewhere. This meant that regular testing as less likely to have occurred. One such Inverness patient found out from his GP in 1995 that he had been tested (and was positive for HCV) visiting the Aberdeen centre in 1991.[2326] Another severe haemophilia patient in Inverness who had been treated with factor VIII concentrate in the 1970s and 1980s did not find out about his HCV diagnosis until 1996.[2327]

Those who might have been infected by factor concentrates beyond the bleeding disorder community

9.69 There is a residual category of patients who were identified in the evidence heard by the Inquiry, who are likely to have been infected by their exposure to blood products but whose treatment was not for a bleeding disorder, including those

[2324] WITN2149001 @ paras 10 and 11 (first statement of WITN2149); WITN2149007
[2325] WITN2185001 @ para 11 (first statement of WITN2185)
[2326] WITN2306001 @ para 10 (first statement of Hugh MacInnes)
[2327] WITN2275001 @ para 5 (first statement of David Thomson)

who were treated with factor IX concentrate for its coagulant properties in settings other than haemophilia. Dr Aileen Keel gave evidence to the Inquiry that it was brought to her attention factor IX concentrate (a pooled product) was given to "tens of thousands" of patients in Scotland falling into this category.[2328] Despite being urged to undertake a Lookback exercise to identify, diagnose and offer support to these patients, again the State simply turned a blind eye to the inevitable devastation which its actions had caused.

9.70 Falling into the category of patients who received factor concentrate from outwith the bleeding disorder community, one witness received factor VIII for operations he underwent on his nose in 1983 and 1988, the former being the more likely source of his infection due to the advent of heat treatment in the intervening period. This patient has been unable to access any financial support and was told that he did not meet the criteria for payments to be made under the Skipton Fund, despite being infected with HCV.[2329]

vCJD

9.71 On many occasions, the Inquiry has heard evidence to suggest that the approach to the vCJD crisis was very different from the approach to earlier viral threats. In relation to the threat of vCJD infection from blood and blood products the evidence suggests that the government response was not very different at all. This evidence is indicative of the government having an attitude towards informing patients which was at the opposite end of the spectrum from what might expect in the interests of patient autonomy and empowerment. In her statement to the Inquiry, Dr Aileen Keel set out that the Scottish Government's approach was not to tell patients that they may have been exposed to risk.[2330] This represented an outdated, inappropriate attitude to patient engagement. At an annual meeting of

[2328] IBI transcript for 25/07/22; 96 to 97 (Dr Aileen Keel)
[2329] WITN2283001 @ paras 4 and 29 (first written statement of Andrew Whyte)
[2330] Aileen Keel witness statement (WITN5736003) @ para A50(b)

haemophilia directors, transfusion directors and government medical advisors, Dr Keel had not been not keen on haemophilia directors wish to inform all haemophilia patients of the vCJD risk due to that not being the approach preferred by other doctors who are treating immune compromised patients who were at risk and advocates consistency of approach.[2331] In that she was in disagreement with Professors Ludlam and Lowe.

Other pathogens

9.72 The need to tell patients about the risk of emerging pathogens, the known unknowns, was recognised by the immunologists on the expert group. Given the type of patients they would generally be dealing with, they are likely to have a good sense of what the patient needs to know about. This risk never appears to have been discussed with bleeding disorder patients, despite the risks from these pathogens being identified above.

10. The role of government and other agencies in the treatment provided to those with bleeding disorders in Scotland

a) Structural background

10.1 As is addressed elsewhere in this submission in some detail, prior to formal devolution in 1999 (consequent upon the provisions of the Scotland Act 1998) matter rating to health were administratively devolved to the Scottish Office and more particularly the Scottish Home and Health Department (SHHD). Due to the fact that the SHHD was a relatively small sub-department, there was a

[2331] LOTH0000082_009 – 14 June 2004

considerable indirect effect of the DoH/ DHSS on Scottish decision making was considerable. The DoH with its greater resources and wider remit had access to the greatest amount of information and knowledge about health matters. However, this indirect effect on decision-making about Scottish matters was clearly not an effect which government ministers and advisors realised that they had. There was therefore no consideration of Scotland's particular circumstances by those who had access to the greatest amount and quality of information.[2332] There was limited interaction between the DoH advisors and their Scottish counterparts. Even if advisors within SHHD knew about considerations for Scotland, the evidence available to the Inquiry shows that they were not provided with access to the best evidence upon which to make bespoke decisions about Scotland. The consequence of this throughout the period with which the Inquiry was concerned was a culture of the SHHD using the guise of requiring to follow the same policies as they were all part of the same government as the DoH as, in fact, meaning that the power to make bespoke decisions was not exercised.

10.2 There were another structural components of the system which meant that decisions were made for Scotland without consideration of its particular circumstances, most particularly the fact that the responsibility of the Secretary of State for Scotland for licensing matters was exercised on his behalf by the Medicines' Division of the DoH.[2333] Again, this meant that decisions about licensing (including those related to the licensing of blood products) were taken on UK wide basis. As the evidence relating to the position in Scotland makes clear, Scotland's requirement (due to investment in the PFC from the 1960s) was very different from that of the rest the UK. As licensing was a reserved matter, this created the anomaly that products were licensed without consideration of the need for them to be available within the Scottish NHS.

[2332] IBI transcript for 19/07/21; 67 to 68 (Diana Walford)
[2333] IBI transcript for 19/07/21; 16 (Diana Walford)

b) The governmental handling of the risks of blood contamination between 1975 and 1985

UK-level in the period prior to the emergence of the AIDS threat

10.3 The context in which HIV emerged as a threat to recipients of blood and blood products is considered in some detail above set by the lack of priority given to blood/ blood products in the period before the emergence of the AIDS threat. This sis shown by the fact that the commitment by David Owen to self-sufficiency (in England and Wales) was not followed through. That same commitment had been made in Scotland in the 1960s (discussed below) at which time planning for and investment in the PFC allowed significant move towards Scottish self-sufficiency. However, the inability of blood and blood products to force itself to the top of the government agenda in the late 1970s, despite the commitment made by lord Owen had ramifications for Scotland also. The lack of priority given to these matters at UK level, despite the Owen warnings demonstrated a lack of attention being paid to the safety of blood and blood products. As the SHHD was reliant on such attention being paid to these important issues within SHHD for clear and timely information and advice to be shared with them, this lack of attention within the DoH had a knock-on effect for Scotland too. The lack of clear thinking about long term planning not only affected the rest of the UK but the lack of readiness for the emergence of new viral threats in UK-wide. This created what was described as the "golden interval", a period during which increased use of commercial concentrates and unchecked clinical freedom were allowed to occur. This also had effects for the safety of patients in Scotland, as is discussed elsewhere in this submission. Thus, the inefficiencies and inadequacies of the DoH in paying attention to the need to protect the recipients of blood and blood products from viral threats had a UK-wide effect.

10.4 Structurally, the internal split between blood and blood products which were dealt with within the Med SEB section whereas infectious diseases were dealt with

within Med IMCD section showed a lack of appreciation of the intrinsic relationship between blood and infectious disease. The effect of this (addressed in the context of AIDS below) was that information about blood and blood products was handled by different people from the information available to do with new emerging viral threats. Had the full extent of information about threats been available and the advice taken from experts in both areas combined, the government as a whole would have been able to take a more rounded and thus balanced, accurate view of the situation and thus the best thing to do about it. Thus, advice could be taken from those with an interest in one side of the debate (such as from Professor Bloom whose principal interest was in the haematological management of bleeding or from Drs Tovey/ Gunson, the expert advisors of the government in transfusion matters whose secreta meetings with the minister were likely to have been focussed more on the maintenance of the blood supply and hence the interests of donors) which may seme expert and convincing via one department (Med SEB) without there necessarily being any consideration of the other side from virologists, experts in infectious diseases or epidemiologists (advising the Med IMCD). As is discussed in detail above, this caused the system to result in limited, unbalanced advice being relied upon without full consideration of both sides of the debate in the AIDS crisis (see detailed analysis above).

10.5 Further, it was clear from the evidence heard from those involved in the operation of the system of advice set up to avoid, not accept responsibility. In the evidence heard by the Inquiry about decision-making in government health departments, everyone blamed each other. Though ministers often accepted that ultimate responsibility lay with them, they would often say that they relied upon medical advice so completely and often unquestioningly that, in effect, they were claiming that they could not be blamed. Their medical advisors sought to point the finger at their expert advisors. In turn, the expert advisors said that they could not be deemed responsible as they were independent of government. The Inquiry should identify this as a clear failure of system. There must be a collective responsibility for the failure of that system. All of those involved made a contribution and so they should all be deemed to be to blame. This pattern was also seen in the evidence relating to the Scottish Office, which was a less well informed, more

poorly resourced microcosm of the larger, national departments. The whole system appeared to be set up to evade and not take responsibility. Responsibility should be in the nature of government. It should be that the buck stops here, a place where the ultimate responsibility for the operation of the NHS must be deemed to lie on the basis that the government is democratically accountable.

10.6 Connected to this is the clear issue of clinical freedom. The evidence shows that the government consistently formed the basis of the government's attitude towards decision-making. In effect, clinical freedom meant an abrogation of governmental responsibility and also actually meant anarchy. Freedom to do anything cannot possibly be right. Government had a democratic requirement and a statutory duty in health matters to provide checks and balances on that freedom which throughout the relevant period was used as an excuse for anything out to government. This was particularly the case for a medical profession whose attitude to decision making involved little patient involvement (as discussed below). Thus, the profession was a fallible one which did not itself account to patients or involve them in decisions. It was a profession which needed to be checking by government. It was not. Instead, the government adopted a predominantly deferential attitude to the absolute freedom of the medical profession, not based on judgement but based on the fact that it gave the government an excuse to avoid accountability.

10.7 Further to the above, there was a problem at the core of the system of medical advice. As is noted elsewhere, advice about the significance of emerging disease had from the 1970s at least been based on incidence, not risk of the occurrence of infection. The information about incidence was limited due to the poor systems for disease notification. Thus, this system was not set up to react swiftly, in particular to insidious diseases spread silently by infection and hence to fail as reaction inevitably too late. As is noted above, advice was often taken from the wrong people, such as haematologists were bound to focus on the benefits for the management of bleeding and not other elements in which they were not expert. The system allowed the impression to be taken by ministers that briefing they received was based on advice was being taken from multiple sources. This was not always true as the same small group of advisors were relied upon. In any event, in

the late 1970s and early 1980s, the evidence showed that information from experts was not freely shared with the likes of government advisors like Dr Walford.

10.8 It was also a general theme of the evidence heard from government witnesses (including ministers) and indeed clinicians that there was not enough money to finance possible plans. The system was not a long-term project (as it required to be) but based on annual, *ad hoc* budgeting. This was realised by commentators at the start of this period.[2334] The fact that by the first half of the 1980s, the Secretary of State for Health (Lord Fowler) seemed to sum up the position as being that there was not enough money to pay for a better system of blood product usage in the UK was a flawed argument which made the hallmarks of a stock answer which had not been considered in this specific context. In his statement he said that the DoH is a constant battleground between trying to provide excellent healthcare and cost.[2335] The fact was that huge sums had been and continued to be paid out for the treatment of haemophiliacs. This was an area in which lack of money was not the issue. Budgets which accounted for huge sums being spent on imported products had no doubt resulted from the civil service system of merely budgeting for next year on the basis of what had expense the year before. Much had been spent in this area before and so huge sums continued to be expended in the first half of the 1980s. The issue was the management the sums which had been allocated to haemophilia care. As had been correctly predicted by the commentators in 1974, lack of capital investment at that time created a false economy as it created a need to rely on expensive foreign imports given the unquestioning acceptance of the need for concentrate heavy treatment regimes. In any event, the lack of financial ability to improve the system at that crucial time showed that those who had predicted issues in 1974 based on the lack of national

---

[2334] DHSC0100024_126 (1974) – note the reference to economic fallacy that a failure to make capital investment in the NHS at that time would result in more, not less money being spent in the long run due to the expense which would be associated with importing foreign blood products as opposed to making them in the UK (in the right hand column)

[2335] para 0.14 of Lord Fowler statement at WITN0771001

management of the blood transfusion system and the lack of capital investment in the fractionation centres were correct.

Scottish Office level in the period prior to the emergence of the AIDS threat

10.9 The evidence available to the Inquiry suggests that there were regular meetings between the SHHD and SNBTS during this period but the structures within government appeared to result in there being insufficient knowledge or little interest within SHHD in blood or blood components to allow a reactive approach to the emergence of a viral threat which would be required to take decisive action to prevent it. This continued into the period when AIDS began to emerge as a threat. Over his period the constitutional arrangements meant that vast swathes of matter relating to Scotland were handled by the Scottish Office as part of "administrative devolution". Responsibility for all of these matters was thinly spread amongst a small handful of ministers. The result of this was that there was little time for ministerial engagement in matters like the safety of blood and blood products, which were handled by civil servants with little real involvement, resting on the assumption of the safety of the blood supply in light of the voluntary donor system. The little time for Scottish business in Parliament meant that the chances of getting issues such as the particular concerns of patients about the risk of viral disease onto the political agenda were slim to none. There was simply no system of transparency of or accountability for decision making in this area. The Inquiry has no evidence that the obligation to operate the NHS in the interests of patient and patient safety resulted in any meaningful engagement with the patient community in connection with the safety of blood. The predominant themes which emerge from the evidence include (a) the dominance of medical advisors in decision making in this area and the lack of challenge to their advice and (b) the complete dependence on the resources of the DoH in setting the agenda in the response to viral threat, given the lack of resources within the thinly stretched Scottish Office. Lord Fowler said that he expected there would have been contact

between the officials in the respective territorial health departments.[2336] There was not. Dr Walford only rarely had such contact.[2337] There is evidence of key expert group meetings taking place which did not have SHHD, only DoH involvement.[2338] In such circumstances, it would not have been possible for the Scottish medical or other civil servants to take an independent view and advise ministers of they did not attend. Many such meetings which did have SHHD presence had multiple DoH advisors present and one SHHD advisor. This had the appearance of Scotland having a watching brief as opposed to a main participating role. It is useful to contrast this with the system operated when the Scottish Parliament was created (discussed in detail below). This at least provided the chance for matters to be placed before the Parliament by patients via the petitions process and for some element of government scrutiny via the Health and Community Care Committee. No such scrutiny on the issues relating to infected blood appears to have happened at Westminster before or after the Scotland Act. The subservience of the SHHD to the DoH was summed up by Lord Fowler who said that the control of the SHHD over health was just a theory and that, in practice, the territorial departments just followed what the DoH did.[2339]

The emergence of the AIDS crisis

10.10 Much of the advice provided to government and the actions taken by government in response is analysed in section above about haemophilia treatment, The following additional matters have become apparent on the evidence. A key element of the evidence heard by the Inquiry in this regard was that it was well

---

[2336] para 2.18 of Lord Fowler statement at WITN0771001

[2337] IBI transcript for 19/07/21; 65 (Diana Walord)

[2338] CBLA0001005 – CBLA scientific and technical committee meeting (October 1979), page 4. Matter of national policy being discussed on the production of blood products. Question raised about advisability of Scottish representation on this committee as there was not a close link between those running BPL and PFC; Committee on the safety of Medicines meetings, eg ARCH0001709_001 (22 September 1983); CSM sub-committee on biological products, eg ARCH0001710 – 13 July 1983 – Mr Watt but no SHHD involvement

[2339] IBI transcript for 21/09/21; 22 to 23 (Lord Fowler)

established thinking within the department by spring 1983 at the latest that AIDS was transmissible by blood and blood products, probably due to a virus as a result of the available evidence from the US, which is discussed in detail above. The accepted analysis of the evidence had discounted alternative theories for immune irregularities in homosexuals or haemophiliacs. In addition, it was known and accepted by that time that AIDS was likely to be fatal This shows that attempts to suggest that there was any considerable scientific traction in the alternative theories as to the AIDS risk based on additional immune irregularities in haemophiliacs (like the antigen overload theory held to by Professor Ludlam) are illusory. Whilst there was of course evidence that there was an additional immune dysfunction caused by concentrates alone, this was not sufficient to displace the importance of at least a Working assumption that AIDS was transmissible by blood and that patients in receipt of blood or blood products were thus at risk.

10.11 The systems within the DoH are important in analysing the fitness of the department to react to such risks. The evidence available to the Inquiry shows that despite the pre-existing knowledge (discussed above) that dangers from blood or blood products could and inevitably would present themselves subtly and rapidly, in particular via pooled products, the system was not sufficiently dynamic or reactive. In her statement to the Inquiry, Dr Walford spoke of the DHSS becoming involved where there was an "identified hazard with risks to public health".[2340] This resulted in the government only taking active involvement when the risk had materialised and hence it was too late. For example, it took until January 1985 for EAGA to be convened. Expert bodies only seemed to be consulted when the non-experts in the department sought their advice. That was inevitably always too late. The systems were not set up to be sufficiently reactive in the interests of public health to the predictable threats from blood. The system appeared to lack direction – the government expected information about the risks to come from the clinicians in the field, the doctors expected to receive guidance on the risks and how to deal with them from the government. In 1983, Dr Walford confirmed the government's reliance on Centre for Disease Surveillance and Control (CDSC)

[2340] para 47.8 of statement of Dr Diana Walford (WITN4461001)

for information about infections. The Minute confirms that the government did not know about the Bristol AIDS case until after he had died. The reporting systems were confused and defective, in particular in relation to the domestic threat.[2341]

10.12 The pre-existing systems meant that there was little chance of a sufficiently reactive response being mounted. In response to the question as to who took ultimate responsibility for mater pertaining to the safety of blood she replied that the "levers [of the system] were not fit for purpose".[2342] This was an acceptance that the system was inefficient and certainly did not work well for putting public safety first. Despite the clear dangers of blood and blood products, the close connection between blood and infective disease was not reflected in the administrative structure of the department. Blood was dealt with by the Med SEB section (where Dr Walford worked) and infectious disease in the Med IMCD section.[2343] Thus, emerging information about infective diseases was not handled along with decision making about blood and blood products. For example, Dr Walford accepted in her evidence that she did not know that CDSC were testing for IDS in 1982, het Dr Sibellas in Med IMCD did and that it would have been good to have known that.[2344] Ministers not routinely involved. The fact that blood and blood products were the province of Lord Glenarthur, the most junior minister in the department and a member of the House of Lords meant that (a) despite the clear threats to public health from blood, it was not seen a matter worthy of high priority in the department and (b) the likelihood of the matter rising up the political agenda was low, given the fact that the person predominantly responsible was not a member of the elected chamber. The reason for this was given by Lord Clarke, namely that (apart from HIV and hepatitis) the blood transfusion service was deemed to be an "oasis of non-controversial calm".[2345] Despite the dangers well known to be associated with blood and blood products (and the awareness that advisors like Dr Walford had from around 1979 about the dangers of NANBH),

---

[2341] PRSE0003196, page 4 (reference centre directors meeting of 19 September 1983)
[2342] IBI transcript for 21/07/21; 193 to 194 (Diana Walford)
[2343] para 2.31 of statement of Dr Diana Walford (WITN4461001)
[2344] IBI transcript for 19/07/22; (39 to 40) (Diana Walford)
[2345] IBI transcript for 27/07/22; 23 (Lord Clarke)

these were not realised in the department. Blood products were also described by Lord Clarke as an area of calm. As a result, AIDS took the department by surprise.[2346] It was simply not ready not equipped to deal with it, despite the background of NANBH and HBV, a sexually and blood borne virus which could also prove fatal. Once again, these elements were redolent of a system which accorded, likely due to the deference to the medical profession generally but also the inappropriate faith in the safety of the system which the voluntary donor principle had created. To the extent that they were, the evidence shows that the system did not lend itself nothing done urgently, as was necessary and predictably so.

10.13 The analysis conducted within the department of what do to was inappropriately based on an analysis of incidence of AIDS and not risk of HIV infection, despite early knowledge about the latency period of the disease. For example, on 17 October 1983, at a meeting of the Advisory Committee of the National Blood Transfusion Service, Dr Walford, DHSS, said that there had been 24 cases of AIDS reported in the UK, two of whom were haemophilia patients and one of whom had died, and that comparison with 'reported incidence in the UK [possibly US] haemophilia population' suggested that the UK could anticipate between two to four deaths from the disease among people with haemophilia from the disease.[2347] This was despite the fact that in May 1983, the World Federation of Haemophilia reported that the CDC strongly suspected that there were more people affected by the virus than show signs of it.[2348] Of course, Dr Walford said in her evidence that "I think it was implicit in anybody who had to do with blood transfusion that you knew that, potentially, blood transfusion could transmit an agent that we'd never hearing of before, never seen before, didn't know about".[2349] The matter was eventually elevated to the Prime Minister only in 1998 when the issue of the "consequences" of the disaster required to be dealt with, when she was deemed

---

[2346] IBI transcript for 27/07/22; 20 to 21 (Lord Clarke)
[2347] Minutes of the Eighth Meeting of the Advisory Committee on the National Blood Transfusion Service Held on 17 October 1983– PRSE0000834 at page 4
[2348] DHSC0001236 – 18 May 1983
[2349] IBI transcript for 19/07/22; 121 (Diana Walford)

to have an "interest".[2350] Even into 1985, the need for there to be BOTH anti-HIV testing and heat treatment which was questioned by Minister of State Kenneth Clarke MP, minister of state for health (as was) (a) misunderstood the seriousness of the problem and (b) the need to protect both the haemophilia and blood transfusion recipient communities.

10.14 It is very clear that the emerging threat of AIDS was not given sufficient priority. There appears to have been no appreciation whatsoever of (a) the severity of the disease and the likelihood of its spread (no epidemiological advice, apparently) leading to a lack of urgency or (b) focus on the possibility of the domestic pool becoming breached/ the likely impact due to pooling of even a minor breach of the system for the bleeding disorder population. No consideration at all prior to 1985 of the likelihood based on international travel that the disease could already be in the UK, already be in the donor pool or that there was a possibility that the disease could be spread by blood transfusions. For example, Lord Clarke was not aware of outbreaks of HIV infection caused by domestic blood products in Edinburgh, diagnosed in the UK by Dr Tedder in October 1984.[2351] When testing became available his reaction was to question whether it was also required along with heat treatment.[2352] He was of the view that the outlay of £2 million on HIV testing was not justified based on the fact that "there were so few AIDS cases". The threat to the transfusion population appears not to have been appreciated, even at that point.[2353] It appears clear that he was going against his expert civil service and medical advice in connection with testing as a memo clearly illustrates that an attempt at persuasion had been made which had fallen on deaf ears.[2354] His attitude towards spending the money was summed up when be asked at the time how many fatalities had been caused by blood transfusion, as if there was only an obligation to act when people were already dead.[2355] In his evidence when faced with material from the time he admitted that he was not aware that the

---

[2350] HMTR0000001_006 (1988)
[2351] para 7.67 of Lord Clarke statement @ WITN0758001
[2352] ibid
[2353] para 7.46 of Lord Clarke statement @ WITN0758001
[2354] DHSC0000425
[2355] DHSC0002482_012

incubation period of the disease was so long.[2356] This, of course, was well known and was crucial to determining the level of risk. Further, in response to the Galbraith letter he stated that Dr Galbraith had been spot on and that, if only they had known about that, they would have saved thousands of lives.[2357] The information was, of course, available and indeed available to Dr Field and if it had been appreciated, many lives amongst those who were not infected by the spring of 1983 could and should have been saved.

10.15 By the time he came to give evidence to the Inquiry, Lord Clarke seemed still to be labouring under important misapprehensions about the threat at the time. He was generally dismissive as to the extent of the problem, even in 2021. He seemed to dismiss the possibility that government may have had a role to play in providing information which might get the patients about the risk, assuming that clinicians were monitoring the problem and were advising the patients about the risks. He said that there was no good in going out and telling patients they were going to die, as if their deaths were inevitable. In 1983, most of the Scottish infections were yet to happen and so were not inevitable. He was of the view that taking less factor VIII could not have done any good. This was a key error. Given the relatively low prevalence of HIV in the donor population, taking less would have minimised risk. Certainly, in domestic products, using less would probably have avoided infection.[2358] The whole issue of AIDS was seen in the department as an American problem but that many of the products which were being used here were from America was not apparently realised. This had the knock-on effect of the threat to the domestic blood supply being sidelined in importance. As is discussed elsewhere, this is a significant issue for Scotland where far more patients were treated with domestic concentrates and whose infections could thus have been prevented by a more informed and proactive governmental approach.

10.16 There appears to have been no apparent awareness within the DoH or the government more generally of the LAV discovery in France in 1983 or its significance. At the very least, this shows a lack of awareness of the urgency of the

---

[2356] IBI transcript for 27/07/21; 149 (Lord Clarke)
[2357] IBI transcript for 27/07/21; 150 to 151 (Lord Clarke)
[2358] IBI transcript for 27/07/21; 186 to 187 (Lord Clarke)

situation and the need to explore all possible avenues for development of a defence strategy.

10.17 There was apparently little or at least insufficient cumulative appreciation of the risk of AIDS (enough in itself to take drastic action) and the other existing threats, including NANB hepatitis which was known by 1983 to be a potentially fatal disease.

10.18 It is examined in detail above that the department allowed itself to be misled by the haematologists, in essence Professor Bloom, as regards the bleeding disorder patients that they could not do without the products or they would die or suffer significant ill health.[2359] This was an overstatement of the position, as is explored elsewhere. It shows no nuance as regards the different risks for different severities of patients. It showed no thinking orientated towards temporary solutions, also discussed elsewhere. The position of the Biological Sub-Committee of the Committee on the Safety of Medicines is discussed above.[2360] The public health advice from Dr Spence Galbraith was completely ignored and not even disseminated more widely than the department. Professor Tedder also gave evidence to the Penrose Inquiry to the effect that he had met Dr Walford at an NIH meeting in Washington, that he went to the DHSS after that meeting to discuss plans to deal with this new disease (AIDS) which sounded like HBV. He was told to go away and stop rocking the boat.[2361] This blind approach smacks of shopping around for expert advice which suits the minimum intervention, minimum cost priority of the government as opposed to an approach focused on prioritising the safety of the patients. As is noted above, the failure to take account of or properly analyse the of the Council of Europe recommendation relating to minimising the AIDS risk which was also not promulgated more widely to clinicians. Despite this being directed at governments, the government took no role in implementing the

---

[2359] Despite this the key minister (Lord Glenarthur) had little recollection of Professor Bloom or the UKHCDO - IBI transcript for 22/ 07/21; 49 to 49 (Lord Glenarthur)
[2360] PRSE0002597
[2361] PRSE0006049

part of the recommendation which recommended that patients should be informed of the risks.[2362]

10.19 Given that they were being led by clinicians like Professor Bloom, the government took no active role in passing information or advice to the medical profession about the risks or their management. In her evidence, Dr Walford recognised the possibility of a CMO "Dear doctor" letter being issued to doctors.[2363] For some reason the emergence of AIDS with its 40% mortality[2364] was deemed not to be a not a situation in which it was necessary for the CMO to "draw attention to wider public health concerns involving the medical community at large", as Dr Walford defined when one might be used.[2365] One ought to have been. Insofar as information being passed to patients was concerned, it appears that the CMO had been led to believe by Dr Gunson that patients were being kept informed of the risks by haemophilia centre directors.[2366] The evidence shows that this was not accurate.

10.20 The convenient reliance on the medical profession's insistence on the "conclusive proof" before action was taken took no account at all of (i) the inherent dangers of blood and in particular blood products and (ii) the need for a system which could never rely on only acting when the risk was conclusively established. Public pronouncements in this regard misled the public, including those who received blood and blood products. This also showed a lack of a focus of the cumulative risks of blood and blood products. This was despite the fact that (as addressed above) Dr Walford's views on the severity of NANBH had been clear for some years before the AIDS crisis.[2367] In September 1980 she had shared a memo in the departments stating that 90% of PT hepatitis caused by NANB, that it could be rapidly fatal, in particular in patients with pre-existing liver disease. It was accepted that it could lead to progressive liver damage. In addition, information

---

[2362] The need for such advice to be provided is seen by DHSC0002231_037 (Baroness Masham letter with answer) and DHSC0002229_085 (parliamentary question from Mr Gardner). Lord Glenarthur stated the department would not issue instructions to practitioners, as already sufficient guidance and information available
[2363] paras 73.5 and 73.6 of statement of Dr Walford (WITN4461001)
[2364] as per Dr Craske in HCDO0000517_002 in March 1983
[2365] para 73.6 of statement of Dr Walford (WITN4461001)
[2366] IBI transcript for 19/07/22; 52 to 53 (Diana Walford)
[2367] IBI transcript for 19/07/22; from 110 (Diana Walford); WITN0282008

was pronounced publicly by UK government health minister without consideration of the position beyond England, this gave a misleading impression to the public. When asked why the UK imported blood products from the USA, Lord Glenarthur said: 'We have to import Factor VIII, which is an agent used in the cure for haemophiliacs. We shall need to continue to do that until we are self-sufficient ourselves'.[2368]

10.21 The economic ramifications of the decision-making played a part. The fact was that the system of licensing and control which existed in the UK actually provided no protection as it was subservient to the foreign and domestic producers of the products. It was not possible in England and Wales for the tap to be turned off as there was no plan B. Equally in Scotland the standards of the domestic production were not subject to any real sanction as there was a total reliance on the production from the PFC. Virtually anything could have been done and they could not simply have switched the machines off. Cancellation of contracts was not only an economic impossibility but also a medical one.

10.22 The lack of accountability of the government was seen in the evidence of Lord Clarke who seemed very keen to avoid responsibility and lay responsibility at the door of his colleague, Lord Glenarthur and limit his own involvement.[2369] He claimed to have been given little briefing on AIDS despite the fact that he was the minister primarily responsible for dealing with the threat from blood and blood products.[2370] There was no evidence of any of the minister receiving briefing about the risks from the UK donor population. They certainly received no briefing regarding any assessment having been done of the likely spread of AIDS into the donor population despite Lord Glenarthur admitting that IVDU was known to be "rife" at the time.[2371] Lord Glenarthur admitted to requiring to rely on what he had read in the papers about AIDS.[2372] Dr Walford provided a briefing to Lord

---

[2368] PRSE0001886 (Hansard, 14 July 1983, columns 893–894, 14 July 1983, House of Lords)
[2369] IBI transcript for 27/07/21; 68 (Lord Clarke)
[2370] Witness statement of Lord Glenarthur (WITN5282001) @ para 1.7
[2371] Witness statement of Lord Glenarthur (WITN5282001) @ para 1.9
[2372] IBI transcript for 22/ 07/21; 33 (Lord Glenarthur)

Glenarthur when he took up his post in July 1983.[2373] This advice did not draw his attention to the Dr Spence Galbraith letter of 9 May 1983 and his reasoned warnings about the need to withdraw post 1978 US concentrates.[2374] The minute makes no mention of the public health implications of the disease or measures which need to be taken to ensure that those at risk are aware of the risks. In his statement, Lord Glenarthur pointed out that Dr Walford was a haematologists by training and not a virologist or expert in infectious diseases. There is no evidence that in lights of that he sought out advice did you take from experts virology or in the field of infectious diseases.[2375] It was Lord Glenarthur's understanding based on the clinical advice which he received that there were "no realistic alternatives advanced to the policy adopted [with regard to AIDS and blood/ blood products]".[2376] No consideration was given to the possibility of temporary solutions to minimise the risks, examined elsewhere in the submission. Even the "possibility of exploring any alternative strategies" was not even put to him.[2377] As is discussed above, the "no conclusive proof" line which ministers were advised to take was misleading. It did not include the qualification which Dr Walford detailed at para 86.7 of her statement from the Q&A briefing to the effect that though not conclusively proved, it was likely that AIDS was caused by a virus. The advice in the briefing note to Lord Glenarthur of 20 July 1983 ("the assumption is that such transmission may be possible"[2378]) was not consistent with the comment of Dr Gunson to the CMO in that there was a "strong possibility of an infectious agent which had been implicated in transfusion of blood and blood products".[2379] He was advised without any basis that measures which might deter high risk donors would induce a "panic-induced collapse in the supply of blood".[2380]

[2373] DHSC0002309_124 (advice from Dr Walford on taking up post as DHSS minister – June/ July 1983 as per para 12.3 of Lord Glenarthur's statement)
[2374] PRSE0003286
[2375] Witness statement of Lord Glenarthur (WITN5282001) @ para 6.10
[2376] Witness statement of Lord Glenarthur (WITN5282001) @ para 0.5
[2377] Witness statement of Lord Glenarthur (WITN5282001) @ para 35.2
[2378] DHSC0001109
[2379] **NHBT0001067**
[2380] DHSC0000419 - Hansard, 18 March 1985 – page 2, column 2

10.23 Lord Clarke also claimed to have had little briefing on the risk of AIDS from blood and blood product due to the number of other matters with which he had to desal in his role as minister of state for health from 1982, though he also claimed that it was not his area of responsibility.[2381] In reality, Lord Clarke appeared to have a significant role in reality and his approach seemed to be that DoH decisions required ultimately to be only about money, and not about patient safety. Lord Glenarthur recalled that Lord Clarke had had a role as he recalled that "Some submissions, particularly in areas of complexity or controversy, were also copied to Minister of State for Health".[2382] Lord Clarke take part in meetings related to key issues (such as the meeting which took place on 6 July 1983 involving the Minister of State for Health and the Under Secretary of State relating predominantly to the formulation of the wording for the donor exclusion leaflet).[2383] He claimed that he did not have "policy responsibility for decisions relating to BPL" but did become involved in issues to do with cost and project management – ie he did have responsibility.[2384] He stated that the DHHS had responsibility for "some aspects of public health".[2385] This evidence suggested a lack of clarity about the role of the department in maintaining public health (its primary statutory responsibility) and a lack of clarity internally as to who was in charge of the risks from blood and blood products in the ministerial team. One got the impression from his evidence that ministerial responsibility was decided largely on the basis of who happened to be available on any given day. This was a system which was not designed for the effective protection from the impending fatal viral threat. These were the manifestations of the structural issues relating to responsibility accepted to have existed in the department by Diana Walford. The structural issues in the DoH were the same as those in the Scottish system. Professor Cash described that throughout the 1980s "who had the duty of care to ensure that blood and plasma was safe in the UK was unclear".[2386]

[2381] para 3.1 of Lord Clarke statement @ WITN0758001
[2382] Lord Glenarthur statement (WITN5282001) @ para 6.3)
[2383] PRSE0004727
[2384] para 4.6 of Lord Clarke statement @ WITN0758001
[2385] para 2.1 of Lord Clarke statement WITN0758001
[2386] page 1 of PRSE0003395

10.24 Lord Clarke's desire to evade structural responsibility despite the evidence of his clear involvement in decision making and public pronouncements about the position also ended to his attitude towards the doctors. He was the ultimate champion of clinical freedom. He said that that "the DHSS was not responsible for treatment decisions relating to individual patients"[2387] and that the "clinical freedom" of clinicians was "closely guarded".[2388] When one looked at his evidence in toto, it was hard to decern what role the DHSS or he had in the promotion of health at all. In his parliamentary response on 14 November 1983, he pointed out that treatment was in the hands of local clinicians expert in the treatment of patients with bleeding disorders.[2389] He was prepared to give this reassurance despite the fact that even by August 1984, in a section about product prescription in the care of haemophiliacs written by Dr Charles Rizza, doctors within the NHS were told that the risk of AIDS from transfusion therapy was not clear, despite acknowledging that haemophiliacs had contracted the disease. The advice to the prescribing doctor was to carry on with the treatment regimes to which the patients had become accustomed.[2390] Those very same clinicians were being guided even by August 1984 to carry on as if nothing there was no risk at all.

10.25 Lord Fowler also pleaded ignorance of most matter relating to the emergence of the AIDS crisis, preferring to focus on his undoubted commitment to the AIDS cause in the years after the infections with which the Inquiry is concerned. This was despite the fact that an article which was prescient about his attitude to the subject of blood and blood products (which would likely have been brought to his attention) was written in May 1983.[2391] There were thus opportunities for him to have a greater involvement in the emerging crisis. As haemophiliacs were deemed to be high risk for HBV infection in the DHSS, they should have been considered to have been at high risk from AIDS given knowledge about the similarity between transmission routes from the outset in 1982.[2392] Even when he did become

---

[2387] para 2.2 of Lord Clarke statement @ WITN0758001
[2388] para. 2.24 of Lord Clarke statement @ WITN0758001
[2389] para 4.19 of Lord Clarke statement WITN0758001 and PRSE0000886
[2390] PRSE0003189 @ PRSE0003189_0010
[2391] MACK0002666_033 or DHSC0002227_037 – article entitled "Fowler's blood money" (May 1983)
[2392] DHSC0001726 (JCVI recommendations in 1982 about the high risk groups for HBV).

involved from around 1985, no effective efforts were made by the government to minimise the risk of those who had tested positive for the antibodies for HIV to avoid the stigma associated with AIDS, in particular in schools for those already infected.[2393] The focus on prevention appeared to leave little room for them. The sums which Lord Fowler announced for the fight against the spread of AIDS were too late for them.[2394]

10.26 Policies or strategies were adopted with insufficient challenge either from within government or outside it. Ultimately, a minister who classified himself as being relatively uninvolved and uninformed made or significantly influenced decisions on economic grounds without any challenge. When advice was to do nothing, he followed it without question. When advice was given to act (such as in relation to anti-HIV testing) he saw it as his role to challenge those below him who were qualified then he was not. This was an inherently dysfunctional system. Connected to this was an apparently total lack of public health accountability. Public health was classified as partly the role of the minister of state for health by Lord Clarke. However, no consideration appears to have been given at all of the risks of this new, fatal disease easily transmissible sexually (in heterosexual as well as homosexual community) being spread more widely in society by those who received blood and blood products becoming infected.

10.27 We have inferred elsewhere from the attitude of the medics that by the time the AIDS crisis became apparent, the actual attitude was the "canaries" who had received large amounts of commercial concentrates by 1983 would already have this disease if it was indeed transmissible by blood and so there is little they could do. The view was thus formed that they may as well carry on treating them for the bleeding disorders which these patients had. The system meant it was too late for them. This appears to have been the government's thinking as well or at least highly influential in it. No consideration was given to those who could be spared the infection. No separate consideration of the position in Scotland whereby the start of 1983 most of the infections were yet to happen. Policy decisions were

---

[2393] DHSC0000490, transcript of a TV interview involving Lord Fowler and David Dimbleby and Peter Jones in which Dr Jones is very critical of the response re the stigma in schools)
[2394] MACK0002657_038 (late 1985 press cuttings)

reached in the context of that English position without separate consideration of the difference for those in recipients of UK concentrates whose infections could have been prevented based on (a) a failure to appreciate the difference in the risks for the two groups and (b) a failure to consider that the domestic risk was different from the imported risk.

10.28 Even when decision-makers identified some measures that might help to reduce risk but delay in implementing them, for example the time taken to get ministers to ratify the donor leaflet and then the need to change it frequently. In any event, civil servants appear to have doubted the ministers' ability to understand the purpose of the donor leaflet. One said:

"I am afraid I cannot accept that the leaflet should not be seen "as a leaflet which you read and then change your mind about giving blood." To my mind this is precisely what it is intended for although the message has had to be slightly obscured for obvious reasons. Clearly we must bow to Ministers' wishes on the matter of handling the distribution ... but ... I am not sure that Ministers have fully understood the pros and cons."[2395]

10.29 The evidence suggests that the reality of the threat was under-appreciated and misunderstood by ministers. Lord Clarke stated that refer the importance of people not being deterred from receiving blood transfusions was a key a factor in his thinking around the donor leaflet. Given the false reassurance he and others were taking from the incidence as opposed to the risk, they had not equipped themselves sufficiently with information about the likely number of people infected by UK blood or blood products based on epidemiological analysis to be able to assess whether those people should be so deterred.[2396] The old mantra of donor priority over end user safety was a central part of the thinking, hence the

[2395] PRSE0003725 (DHSS Memorandum of 25 July 1983) (this appears to have been written by Dr Oliver (see memorandum of 4 July 1983 - PRSE0000158, reference to his room being room 108).
[2396] Para 7.111 of Lord Clarke statement at WITN0758001

avoidance of asking patients about their sexual histories, despite sexual history being a key indicator as to risk. In fact, by this point in Scotland, as Dr Perry told the Inquiry, improvements in yield of factor VIII from new technologies used in the production of factor VIII concentrate used at the PFC meant that the need to collect so much blood had diminished (see fractionation commentary elsewhere in the submission). The driver for plasma had been the need for factor VIII, not the red cells of which there was a surplus. A drop in donors at this point could have been tolerated by the system. In any event, the interests of safety demanded it. Further, the government appeared to take no role at all in the management of the public health risks after infections were known to have occurred in early 1985, at the latest.[2397] Lord Clarke did *"not want the leaflet to go out with call up cards. The leaflet is an information leaflet and cannot be seen as a leaflet which you read and then change your mind about giving blood".*[2398]. He said that if you had been remotely promiscuous you would be put off the idea of giving blood voluntarily if you received the leaflet with your call up card.[2399] These not the very people he ought to have wanted to deter from giving blood at that time. Lord Fowler appears also to have been of a similar view as *"The SoS was of the view that the wording was "too strong".*[2400] This approach to the leaflet were completely inappropriate in light of the potentially fatal threat. It is noteworthy that these two most senior ministers claimed to have had little knowledge and involvement in matters. In fact, they were making key decisions without any real effort to acquaint themselves with the facts to be able to do so efficiently. The memo which refers to the wording being too strong was written by a Scottish civil servant, Dr Bell. The fact that he was writing about the attitude of the DoH ministers to the leaflet once again demonstrates the extent to which, at this stage in the chronology at least, matters were being controlled by the DoH and not the SHHD, despite the powers of the SHHD to take a different, mor proactive position if they had wished to do so. Of

---

[2397] See reference to the Edinburgh outbreak at para 68.1 of Lord Glenarthur's statement @ WITN5282001 and the information in the Professor Bloom letter of early 1985 that a high proportion of UK haemophiliacs had been infected, para 70.1 of Lord Glenarthur's statement @ WITN5282001
[2398] DHSC0001511
[2399] IBI transcript for 27/07/21; 97 (Lord Clarke)
[2400] PRSE0000049 (Dr Bell memorandum)

course, they had access to the draft leaflet of Dr McClelland which was used for a time in the SESBTS (analysed above). Lord Clarke summed up his lack of awareness of the need for clear safety measures to be taken to exclude high risk donors when he described asking people about their sexual practices in order to prevent those deemed to be at high risk of AIDS from donating blood be "being homophobic for the sake of it".[2401] There was simply no awareness of the extent of the risk from the domestic blood supply. Astoundingly, Lord Clarke said that "The problem here was the US blood supply. Did we ever have any evidence that people got AIDS from the UK blood supply?".[2402] The attitude to the introduction of provisions to reduce the collection of infected blood at this time governed by the apparent impression that all donors were "responsible people" and that there was therefore little or no risk.[2403] Of course this included, for example, donors to whom the disease may have been transmitted unwittingly by sex who were not questioned directly about their sexual practices. The SHHD was led by this narrow and uniformed attitude to the risk.

10.30 The lack of urgency can be contrasted with the reaction to the much smaller risk of vCJD transmission years later, which involved stopping the use of plasma derived from this country. This was a more reactive and proportionate to the risk, given the dangers of blood. The system out not to have needed the HIV crisis to learn that as (as above) the dangers were all apparent from outbreaks of HBV from industrialised production methods anyway from decades before.

c) <u>The period between 1985 and 1991</u>

10.31 The role of the Scottish Office/ SHHD over this period in relation to the recognition of a separate risk in Scotland of infection for the recipients of blood and those with bleeding disorders is discussed in detail elsewhere in the submission. The

---

[2401] IBI transcript for 27/07/21; 76 (Lord Clarke)
[2402] IBI transcript for 27/07/21; 145 (Lord Clarke)
[2403] DHSC0000419 - Hansard, 18 March 1985 – page 2, column 2

government had a significant role to play over this period addressed in relation to various important matters, including the introduction of an HCV safe factor IX and factor VIII concentrate in Scotland, anti-HIV testing, surrogate testing for NANBH and anti-HCV testing.

I. TREATMENT WITH TRANSFUSIONS

General

1.1 This section of the submission, which refers to Terms of Reference 1 and 6, is presented on behalf of over 100 people who contracted their infection via transfusion (some of whom have tragically died and are represented by relatives). Of those, approximately 20% received their transfusion in or after 1987, the date by which we say surrogate testing should have been introduced to reduce the risk of transfusion-transmitted HCV. Transfusions of labile blood products were used across the spectrum of medical specialisms, and range from 2 units of blood to massive transfusions. Some received transfusions over an extended period of time as a result of ongoing treatments for underlying illnesses such as leukaemia, whereas other received limited units in a single transfusion.

1.2 Amongst Thompsons' clients there are also a small number of individuals who either passed a transfusion-transmitted infection to a loved one, or who have contracted such an infection from their relative.

1.3 As we set out elsewhere in this submission, we say that the system of blood collection in Scotland was unsafe, and was driven, primarily, for the purposes of collecting plasma to keep up with the ever increasing demand for the unnecessarily aggressive treatment regimes of those with bleeding disorders. That, we submit, resulted in blood being taken from donors who ought to have been excluded from donating red cells. Those red cells were used for transfusion, transmitting HIV and HCV.

1.4 The Inquiry has heard evidence regarding multiple different approaches to clinical transfusion practice. The evidence regarding practice at the time this Inquiry is

concerned with across the broad spectrum of medical fields has been relatively limited. It is submitted that *some* themes can be gleaned from the written and oral evidence, but that given the absence of evidence (despite the undoubted best efforts of the Inquiry and its core participants' to obtain such evidence) of extensive national protocols and detailed guidance for practitioners who might be required to prescribe transfusions to patients, the absence of such evidence is, in itself, a matter of note.

1.5 It is our primary submission that, over the years, there has been insufficient regard blood to the risks associated with its administration to the patient. As is discussed elsewhere in this submission, those involved in collecting blood appeared to have too much focus on the needs and concerns of the donor, rather than necessarily considering the risks to the end-user of the donation.

1.6 Those involved in the administration of transfusions appeared to be unaware of the risks associated with regards to the transmission of blood-borne infection, and little, if any guidance, was given to clinicians regarding best practice when determining whether to transfuse blood.

1.7 Within this section of the submission, we refer to a number of individual cases to evidence or demonstrate further the submission presented. There are, in many instances, a number of other examples of similar evidence that we seek to rely upon; for brevity we do not refer to each statement or piece of evidence in which the submission is demonstrated.

2. The statistical evidence about the numbers and places of infection via blood transfusions in Scotland

2.1 As set out in the statistical analysis section above, The Penrose Inquiry found that there were at least 18 transfusion recipients who were infected with HIV as a result of that transfusion. In the course of this Inquiry, evidence has been heard that 18

is the minimum number of HIV infections resulting from transfusion; Dr Gillon suggested that *"there would have been one or two probably missed*[2404]*".* Dr McClelland noted that this meant that there were at least 18 separate donations which were HIV positive[2405], demonstrating that there were at least 18 separate 'breaches' of the system in place to seek to ensure that donations were not taken from HIV positive donors. There are at least 10 HIV infections contracted via transfusion in Edinburgh.

2.2 The position with regards to HCV infection is far less clear. In the Penrose Inquiry, various attempts were made to assess the numbers; ultimately the conclusion was reached that approximately 2,500 individuals were infected with HCV via blood transfusion. In this Inquiry, a hybrid model has been adopted by the statistics expert group which resulted in a mid-point calculation of approximately 2,740 individuals being infected via this route.

2.3 This Inquiry is aware that the Penrose Inquiry made a single recommendation to seek to identify patients who might have contracted infections via transfusion by offering tests to anyone in Scotland who had a blood transfusion before 1991 and had not previously been tested. Amongst those on whose behalf this submission is presented there is no-one who was identified as having HCV as a result of this recommendation, although there are a number of people who have been diagnosed with HCV since the recommendation was made in 2015. There is an ongoing need to identify those who have been infected via blood transfusion; by definition, those who have been infected that way in Scotland have had the infection for many decades. Treatments have improved considerably, and it is clear that the elimination strategy of the Scottish Government cannot succeed if those who might have been infected via blood transfusion are missed.

2.4 Amongst the core participants represented in this submission are affected representatives of a transfusion recipient who contracted both HIV and HCV[2406]. That individual was given 4 units of blood in 1984 in response to internal bleeding arising from an ectopic pregnancy. She was diagnosed in 1986 with HIV, and in

---

[2404] IBI transcript for 19/02/22: 134(23) to 135(4) (Dr Jack Gillon)
[2405] IBI transcript for 28/01/22: 163(11) to 163(22) (Dr Brian McClelland)
[2406] WITN2103001

1994 with HCV. Given the common routes of infection between HCV and HIV, and the reasonable inference that at least a significant proportion of the those who tested positive for HIV were never tested (or, if they were tested, were not told of their results) for HCV, we submit that there is a real possibility that there would, in fact, have been more such 'co-infections' in the transfusion community in Scotland than are known about in this Inquiry.

2.5 Amongst the core participants on whose behalf this submission is drafted include individuals treated with transfusions who have been infected with Hepatitis B and Cytomegalovirus or their representatives. Given the small numbers of individuals involved, we submit it is impossible to draw any thematic conclusions regarding the circumstances of such infections. This does not diminish the effect that these infections have had on the individuals concerned. GRO-D GRO-D GRO-D and a gentleman who contracted CMV following a transfusion, causing him to lose his sight[2408].

3. Timing of infections

3.1 Approximately 20% of the core participants on whose behalf this submissions is presented received their transfusion in 1987 or later. For reasons set out elsewhere in this submission, we argue that surrogate testing should have been introduced in 1987. Those participants could and should have been given blood that was safer than in fact it was by virtue of such tests being implemented.

3.2 Those who received transfusions at an earlier date could also have had the risks they were exposed to reduced with better donor selection and, in some cases, the administration of less (or no) blood.

[2407] GRO-D

[2408] WITN5274001

4. The evidence heard by this Inquiry regarding transfusion practice and guidance in Scotland

4.1 There appear to have been multiple attempts to provide *some* guidance for clinicians involved in the administration of transfusions to patients, as far back as 1949. There are some common themes and developments seen across the relevant time period in this guidance, as will be broadly identified below. There is little evidence before this Inquiry regarding the effect of such guidance, and whether such publications were widely known about amongst the medical profession or whether the recommendations were adopted.

4.2 From the earliest guidance, there was recognition of the need to ensure that records of transfusion were kept, *"preferably in the patient's case notes AND on the special card or form…attached to the bottle"*[2409]. It was noted that doing so *"may be the only means of tracing and checking a donor's blood of there is any question of incompatible transfusion or homologous serum jaundice"*. Furthermore, it was noted that any such cases of serum jaundice were to be reported immediately to the Regional Transfusion Officer. It was also recommended that each hospital should keep a record of various details of all transfusions of blood and plasma, including, *inter alia,* the name of the recipient, the serial numbers of the bottles of blood or product transfused, the clinical reason for the transfusion, and any reactions experienced by the recipient. In 1949, it was noted that *"the necessity of accurate recording is not yet fully appreciated"*. For reasons set out below, it is our submission that this remained a considerable issue throughout the period over which this Inquiry is focused.

4.3 P. L. Mollison's textbook, "Blood Transfusion in Clinical Medicine", was first published in September 1951. It was noted that in patients who had lost 1000-1500ml of blood, the *"body can temporarily adjust itself to the lowered blood*

[2409] DHSC0200152_013

volume and blood pressure can be maintained"[2410]. He also states, without clear explanation that, *"Whenever the patient has severe injuries, transfusion should be given immediately, whether or not the patient's condition appears to be bad. When in doubt, transfuse"*[2411]. No consideration appears to be given to the possibility of discussing the issue with the patient, or their representatives, nor to the concept of consent more specifically. With regards to anaemia (as opposed to acute haemorrhage) he advocated a more conservative approach, recommending that *"transfusion should be used as a method of treating anaemia only when the anaemia cannot be cured by the administration of iron, liver or other haematinics"*, noting that the risks of transfusion are "*large compared with those of conservative treatment"*[2412]. He notes that in patients who have suffered haemorrhage which is likely to recur, transfusions should be administered where the haemoglobin is 7-8g/100ml. Surgical patients, he recommended, should not undergo their procedure with a haemoglobin level of less than 10g/100ml; where a patient is admitted for a non-urgent operation but found to be anaemic, *"the alternatives are... to postpone the operation, if necessary for several weeks, whilst the anaemia is treated by iron or other appropriate measures, or to prepare the patient for immediate operation by giving a blood transfusion. Evidently, this dilemma could often be avoided by carrying out a routine haemoglobin examination at the time when the operation is first decided upon. Once more it must be emphasised that transfusion carries a definite hazard and must not be employed simply for convenience*[2413]*"*. In perinatal cases, he notes that a woman with a haemoglobin concentration at full term of 10.5g/100ml cannot be considered anaemic, and that many women could have their anaemia treated by administration of iron in the period prior to giving birth. In those women where their anaemia does not respond to haematinic agents, Mollison recommended that transfusions were administered to ensure that the haemoglobin level was not less than about 9g at the onset of labour.

[2410] RLIT0001567_0039
[2411] RLIT0001567_0044
[2412] RLIT0001567_0048
[2413] RLIT0001567_0050 (our emphasis)

4.4 Mollison recognised the risk of transmission of disease, namely homologous serum jaundice, in 1951. He noted that *"the transmission of the virus of hepatitis by the transfusion of pooled plasma at one time threatened to prevent altogether the use of plasma. When it is recalled that in one of the first series to be studied (Morgan and Williamson, 1943), nine out of fifty patients receiving a plasma transfusion later develop an illness lasting three to twelve weeks, the seriousness of the problem can be realised*[2414]*.* He appears to take comfort from the move away from large pool plasma. Although brief mention is made of the incidence of jaundice after whole blood transfusion, he does not provide any specific guidance or matters for consideration in this section of the text in respect of blood (as opposed to plasma) transfusion.

4.5 By 1954, the Notes of Transfusion were updated to include reference to the assessment that the incidence of homologous serum jaundice was thought to be approximately 0.8% for whole blood transfusions, and 1.5% for small pool dried plasma transfusions[2415]. The need to report all cases of homologous serum hepatitis to the RTD was set out in bold type. The need to transfuse in severe injuries was noted, although with specific reference to that injury being accompanied by blood loss[2416].

4.6 By the second edition of Mollison's textbook, published in August 1956, a section regarding the selection of blood donors was added to the text[2417]. It is noted that the transfusion service *"accepts as a donor any person in good health between the ages of 19 to 65 inclusive, providing there is no recent history of illness or any past history of jaundice… It is best not to bleed any donor who feels unwell; in the case of doubt it is wise to record the donor's temperature and to postpone bleeding if the temperature is significantly raised. According to McBride and Hervey (1953), approximately 2 per cent of prospective donors give a history of previous jaundice. It has been recommended that such persons should not be used as donors because it is not known how long a person may remain a carrier of hepatitis virus. It is*

[2414] RLIT0001567_0179
[2415] DHSC0200153_018
[2416] **DHSC0200153_007**
[2417] RCPE0002067_0013

probable that many virus diseases can be transmitted by transfusion although very little information on the subject has been collected."

4.7 With regards to the circumstances in which transfusions may be administered, Mollison notes that *"clinical impressions suggest that the haemoglobin concentration should not be allowed to fall below 9g/100ml. Evidently this is a minimum. The ideal should be to replace approximately as much whole blood as the patient has lost*[2418]*"*. The advice to transfuse in the case of any doubt where a patient is assessed as severely injured is removed, but the focus on the severity of the injury, rather than the patient's presenting condition remains[2419]. The advice regarding transfusion in anaemic patients and pre-operative patients remains the same. However, for perinatal women, the recommendations were changed slightly. It is noted that, in post-natal women who lost more than the average amount of blood when giving birth, and who had been moderately anaemic at the time of labour were, in some hospitals, being given a transfusion of a single unit of blood. Mollison stated that *"this practice is open to considerable criticism. A transfusion of a single bottle of blood raises the haemoglobin concentration by a relatively small amount (approximately 10 per cent in a woman) and carries small but definite risks",* although his primary concern regarding risks appears to be in respect of Rhesus incompatibility. He goes on to state, *"If a patient is judged to require only a single bottle of blood, the chances are that she does not require transfusion at all*[2420]*"*.

4.8 As regards the risks of blood-borne illness transmission via transfusion, Mollison notes that the incidence of carriers of hepatitis is probably in the region of 0.5%[2421]. He considered the relevance of liver function tests and appeared to agree with the suggestion of Fitch et al that a rejection of a donor on the basis of abnormal liver function test would *"cause acute embarrassment to donor panels*[2422]*"* but does not seem to consider the effect, in this section of his book, on

---

[2418] RCPE0002067_0052
[2419] RCPE0002067_0057
[2420] RCPE0002067_0063
[2421] RCPE0002067_0220
[2422] RCPE0002067_0221

the recipients, notwithstanding the fact that his book appears to be primarily for clinicians responsible for transfusing blood into patients. We say this is reflective of a central theme throughout the clinical transfusion system; that considerable concern was given to donors and the effect on them of finding out that they might be carrying a serious disease, with far less (if any) concern to the ultimate recipients of the potentially infected blood.

4.9 In 1958, a revised "Notes on Transfusion" was issued. The introduction noted that "*transfusion therapy should be undertaken only after careful assessment of the patient's clinical condition to determine the nature and quantity of fluid to be transfused... a transfusion should never be given without a definite indication; not only is this in the patient's interest but supplies of blood are not unlimited and with the ever-growing demand for blood it is imperative that it is not used unnecessarily*". The guidelines largely replicate the advice given in the 1954 version although it is stated that *"preferably, no major surgical procedure should be carried out unless the haemoglobin is at least 10.4g per cent... If haemoglobin level cannot be restored by appropriate medical treatment, pre-operative transfusions may have to be given*[2423]*".* The need for record-keeping is reiterated and follows the previous version of the leaflet. The data regarding the incidence of homologous serum hepatitis is absent from this edition, save that it is noted that the risk is considered to be "little if any greater" when transfusing small pool plasma as against whole blood[2424].

4.10 In 1960, George Discombe's "Blood Transfusion; A Guide to the Practice of Transfusion Within Hospitals" was published (second edition). It was described as a "*pamphlet... written primarily for the temporarily registered doctor doing his first resident appointment. It stresses the difficulties and possible dangers he has to avoid*[2425]*.*" It is noted that in the period between 1955 and 1959, *"blood transfusion has become safer than ever before; but to maintain this high standard everybody concerned must understand what he is doing"*. Dr Discombe states that *"no person known to have had hepatitis is ever accepted as a donor, but many*

[2423] WCAS0000008_0006
[2424] WCAS0000008_0012
[2425] RCSE0000002

persons acquire the virus without developing any symptoms of the infection, and these individuals who have had 'sub-clinical' attacks can convey the infection if their blood is injected into a susceptible recipient. When whole blood is transfused, the incidence of hepatitis in the recipients is about 0.16 per cent. This is not very hight but it is many times higher than the incidence of any other disease caused by transfusion; and not infrequently the hepatitis is very severe and may cause death, prolonged invalidism or hepatic cirrhosis. This is a very important danger and must never be forgotten when assessing the need for transfusion[2426]". As regards when to consider transfusion, Dr Discombe advised that, *"One may take the most elaborate precautions to provide safe transfusions, but yet fail to benefit the patient. Blood transfusion has certain definite indications, and should be used when indicated, never as a general tonic[2427]"*. He notes that in cases of significant haemorrhage, *"the principal abnormality is that the whole blood volume is reduced so much that the circulation is barely maintained, even with the help of intense peripheral vasoconstriction"*. He does not provide a haemoglobin level at which transfusion would be required in such circumstances. He states that *"there is one very common use of transfusion which to my mind is inexcusable – the use of transfusion to raise the haemoglobin of a patient just before operation when, in fact, the anaemia is due to chronic blood loss and could have been corrected by premedication with iron. This is very common in gynaecological work, especially in the management of patients with menorrhagia caused by fibroids; in my opinion, every woman placed on a surgical waiting list should be treated with small doses of iron[2428]"*. He goes on to note that *"it will be possible to avoid transfusion in many cases. Many patients bleed, but few must have whole blood, and most can be kept alive and will recover quickly even if they receive only plasma or dextran. Transfusion should be avoided if possible, for it does add slightly o the risks that the patient is exposed to"*.

4.11 In the third edition of his book, published in 1961, Mollison notes that *"As a general rule, any adult who is in good health and has not recently had any serious*

[2426] RCSE0000002_0018
[2427] RCSE0000002_0021
[2428] RCSE0000002_0022

illness is suitable as a donor. Every transfusion service has detailed regulations which slightly modify this general statement". Of the risk of viral diseases, he states, "e*asily the most important is serum hepatitis. Because it is not known how long a person may remain a carrier of the virus, it has been recommended that anyone with a history of jaundice should be rejected as a donor*[2429]". With regards to the use of transfusions, he repeats his views in respect of haemorrhaging patients and those experiencing anaemia that can be improved by use of relevant haematinics. For pre-operative patients, he notes that there is evidence that when packed cell volume has fallen below 30% with a corresponding haemoglobin level of about 10g/100ml, there may be some cardiac function effect, such that he recommended haemoglobin levels are raised to above 10g ahead of any surgery, and 12.5g and 13.5g/100ml for women and men respectively for major surgery. The possibility of "conservative measures" is "stressed[2430]". The advice given in the second edition regarding pregnant and post-partum women is broadly repeated. Dr Mollison, in a chapter entitled "Other unfavourable effects of transfusion" notes that serum hepatitis "*may be so mild as to cause only transient liver dysfunction without clinical jaundice or so severe as to cause fatal hepatic necrosis*[2431]".

4.12 By 1963, "Notes on Transfusion" was updated to specifically state that "*the use of transfusion to correct moderate or slight degrees of anaemia that could be overcome as effectively, if more slowly, by other means, seems unjustifiable unless some cogent reason for speed of recovery exists. In some instances failure to institute simpler and safety but equally effective treatment earlier leads to the quite unnecessary use of blood transfusion*[2432]". It is noted that *"blood is collected by the regional transfusion centres from donors in normal health and, as far as can be ascertained, free from diseases transmissible by transfusion*[2433]". Similar

---

[2429] RCPE0002068_0012
[2430] RCPE0002068_0068
[2431] RCPE0002068_0290
[2432] JPAC0000162_021_0004
[2433] JPAC0000162_021_0022

references to hepatitis as were seen in previous editions are repeated in the 1963 edition.

4.13 The fourth edition of Mollison's textbook, published in 1967, broadly repeats the indications for transfusion from the 1961 edition. The differences between serum and infectious hepatitis (with express reference to hepatitis B and A viruses) are set out for the first time, noting that *"the term post-transfusion hepatitis covers infections due to both viruses. It appears that most cases of post-transfusion hepatitis are due to virus B and this may be due to more widespread immunity to virus A in the population....The preponderance of the 'long incubation period' form among cases of post-transfusion hepatitis is shown in a series of approximately 500 cases reported to the Ministry of Health between 1944 and 1963. In 84 per cent of the cases the incubation period was 60-180 days and was shorter than 50 days in only 7 per cent[2434]"*. It is noted that *"the incidence of icteric hepatitis is much higher in patients who receive blood from large numbers of donors. For example in patients undergoing open heart surgery involving the use of a pump-oxygenator and the transfusion of 20-25 units of blood, Sharp and Eggleton (1963) observed jaundice at about three months in 5 our of 100[2435]"*.

4.14 In 1972 Dr Cash noted that *"Although the medical profession has long recognised the concept that there are no therapeutic roses without thorns, there is no doubt that the dangers of blood transfusion in all its forms, have yet to be fully defined. However, in the ardour of therapeutic endeavour, we are frequently guilty of forgetting those hazards which have already been well documented. Moreover, compared to 20 years ago new types of patients, such as those on chronic renal dialysis and marrow ablation for leukaemia are being exposed repeatedly to the hazards of blood transfusion."* He noted that *"recent data published by the Registrar General (1971) would suggest that the number of deaths attributable to blood transfusion are comparable to those complicating general anaesthesia. Almost 50 per cent of the post-transfusion deaths were due to hepatitis[2436]"*. He stated that, *"It is sometimes forgotten that a much more conservative approach in*

[2434] RLIT0001570_0323
[2435] RLIT0001570_0324
[2436] PRSE0002637_0005

the use of blood transfusion by our clinical colleagues could make a significant impact on the incidence of post-transfusion hepatitis. In a critical appraisal of transfusion practice in the surgical units of a large hospital over an 8-month period, Morton (1969) reported that the administration of a significant proportion of blood was either unnecessary or questionable.... The reduction of the use of blood by no transfusion at all or using safe alternatives could have as great an impact on the incidence of post-transfusion hepatitis as current techniques for Australia antigen testing[2437]*".*

4.15 In the fifth edition of *Blood Transfusion in Clinical Medicine*, published in 1972, reference is made by Dr Mollison to the fact that *"the discovery that a proportion of carriers of [serum hepatitis] have an antigen – 'Australia' (Au) or 'Hepatitis-associated-antigen' (HAA) – in their plasma has at last provided a test by which at least a proportion of infectious donors can be identified. Donors should be tested for Au antigen at the time of each donation. In view of the fact that individuals may remain carriers of the SH virus for a very long period it has been recommended that anyone with a previous history of viral hepatitis should be rejected as a donor*[2438]*"*. The recommendations regarding the haemoglobin levels of patients necessitating a transfusion remain as in previous editions (9g/100ml), although where volume loss amounted to 20-30% (1-1.5 litres in a normal adult male) it was noted that such volume loss could be replaced with erythrocyte-free fluids. It was noted that major surgical intervention can be successfully achieved in some circumstances with the use of plasma-substitutes alone; *"open-heart surgery without a transfusion of any blood at all was performed in five Jehovah's Witnesses; immediately after operation PCV* [Packed Cell Volume] *lay between 16.5% and 32%; convalescence was prolonged but all patients recovered*[2439]*"*. There is a more extensive review of the issues surrounding viral hepatitis in light of the identification of the Australia antigen, although no specific guidance is given in that chapter as to how to manage the risk.

[2437] PRSE0002637_0006
[2438] RLIT0001573_0016
[2439] RLIT0001573_0083

4.16 The 1973 'Notes on Transfusion' include express reference to the risk of serum hepatitis on the first page when referencing the indications for blood transfusion[2440]. The identification of the Australia antigen results in a specific reference to the fact that *"the rejection of blood donations giving positive tests for the presence of Australia antigen or its antibody diminishes the risk of transmitting hepatitis, the methods of screening at present applicable do not detect antigen or antibody in every instance."* It is noted, in bold-type, that any cases of serum hepatitis were to reported immediately to the RTD along with serial numbers to allow investigation[2441].

4.17 Two years later, in 1975, the sixth edition of 'Notes on Transfusion' were published. The only significant change between the fifth and sixth editions was that reference to 'serum hepatitis' was and 'Australia antigen' was broadly replaced by reference to hepatitis B.

4.18 The commissioning of the PFC prompted Dr Cash to produce further guidelines, specific – it seems – to Scotland, in 1975[2442]. There was a clear effort to move towards red cell concentrates being issued in the first instance in response to all requests for blood. One of the claimed advantages for using red cell concentrates as opposed to whole blood was *"reduced incidence of post-transfusion hepatitis"*.

4.19 In the sixth edition of Mollison's *Blood Transfusion in Clinical Medicine,* published in 1979, it is, for the first time, noted that *"the most important diseases transmissible by transfusion are hepatitis in its several forms…[2443]"*. The same guidance regarding anaemia caused by recurrent haemorrhage which is likely to happen again is repeated from previous editions (that is, such patients should be transfused when their haemoglobin levels fall as low as 7-8g/100ml), as is the guidance that *"many pre-operative transfusions could be avoided if it were routine practice to determine the patient's Hb concentration at the time when operation is first considered as there would then more often be time to treat the anaemia with iron etc"*. The previous advice regarding ensuring PCV of 30% prior to major

---

[2440] HCDO0000861_0004
[2441] HCDO0000861_0023
[2442] SBTS0003061_001
[2443] RLIT0001569_0014

surgery was replaced with a recommendation that 20% was adequate in otherwise healthy patients, but it was noted that *"although most clinicians seem likely to continue to demand that their patients shall have a PCV of at least 30% before undergoing major surgery, it does seem that in healthy young adults there is little need to insist on a higher figure*[2444]*"*.

4.20 With regards to post-transfusion hepatitis, Mollison writes, *"viral hepatitis, acquired from the donor, remains the commonest lethal complication of blood transfusion. The discovery in 1968 that the viraemic phase of serum hepatitis (hepatitis B or HB) could be recognized encouraged the hope that all infectious donors could be detected and post-transfusion hepatitis thus eliminated. Although the transmission of hepatitis B virus (HBV) is now almost completely preventable, it has become clear that other viruses, not yet defined, play a substantial role and that much remains to be done before post-transfusion hepatitis (PTH) is completely prevented. Hepatitis transmitted by transfusion may or may not be associated with jaundice; the diagnosis of non-icteric PTH is usually based on a rise in liver enzymes during the known incubation period...*[2445]*"*. It was further noted that *"the introduction of HBsAg testing has greatly reduced the incidence of cases due to hepatitis B but has had a disappointing effect on the overall incidence of post-transfusion hepatitis*[2446]*"*

4.21 Although Dr Mollison highlighted the risks associated with post-transfusion hepatitis in 1979, this does not seem to have been a view shared with transfusion directors at the time. Dr Brian McClelland gave evidence to the Penrose Inquiry that in the period 1980-1989, *"many of the decisions taken, or not taken, can only be understood in the context of a widely held view that, despite an increasing body of evidence to the contrary [NANB Hepatitis] was rarely transmitted by blood, and was usually not particularly serious"*[2447]. In his oral evidence to this Inquiry, Dr McClelland spoke of his pursuit of a project to carry out prospective study, which, he told this Inquiry, *"would have given us the information that this really was*

[2444] RLIT0001659_0034
[2445] RLIT0001569_0340
[2446] RLIT0001569_0342
[2447] PRSE0003729_0001

something we had to take seriously. But I should say it wasn't just the transfusion directors and people who were playing down the disease. The virological experts, most of them were as well"[2448]. Dr McClelland spoke of his efforts to get funding for his proposal and the fact that the *"senior virologists on the briefly constituted MRC committee really, really poured extremely cold water on the proposal, quoting an earlier study which he said showed that non-A non-B hepatitis wasn't a problem in the UK – transfusion related non-A, non-B wasn't a problem".* Yet, at around the same time, Dr Mollison had published a book stating that post-transfusion hepatitis was a "lethal complication" of transfusion. Whilst it is accepted that Dr Mollison did not differentiate between HBV and HCV, in circumstances where testing had been introduced for HBV (albeit with evidence that HBV was being transmitted in haemophilia patients at that time notwithstanding the tests[2449]), and where he noted expressly that the testing had resulted in a 'disappointing' effect on the incidence of PTH, it is submitted that this is further evidence that there was a failure on the part of the SNBTS to take account of all relevant information.

4.22 A study carried out by the Central Management Services in England and Wales regarding blood and blood product usage in 1982 was reviewed by the SNBTS, who produced a proposal for modifications regarding their own policies in 1983. It was noted that a study specific to Scotland *"could not be justified, on the grounds of cost and the time likely to elapse before broadly similar findings were available for Scotland"*[2450].

4.23 The modified recommendations included ensuring that each RTC *"accepts a formal responsibility for encouraging good practice in those Hospital Blood Banks for which they are responsible for supplying blood and blood products"*. The proposal was at least annual meetings of representative staff from the RTC and clinicians from various specialities *"to discuss transfusion practices in the associated hospitals"*. It was also recommended that, *"the PFC considers the practicability and feasibility of numbering individual bottles (vials) with a unique*

[2448] IBI Transcript for 28 January 2022; 79(9) to 80(11) (Dr Brian McClelland, day 2)
[2449] MACK0001033
[2450] PRSE0000525_002

number to facilitate a system for recording blood transfusion and improved stock control" and *"that to facilitate the tracing of units of blood, a chronological file of details showing patient's name, unique number of the units crossmatched and a signature for the removal of a unit from the Blood Bank should be kept"*[2451]. Furthermore, it was recommended that *"the need for a record in the patients' notes of the batch number of SPPS transfused should be emphasised and guidance issued to those concerned at ward level* [2452]*"*.

4.24 It therefore appears that, notwithstanding the extensive guidance in place at the time of the CMS report and the SNBTS' review of it, there was an acceptance that the guidance was not being adequately followed.

4.25 The seventh edition of Mollison's textbook was published in January 1983. It retained the same text regarding the *"most important diseases transmissible by transfusion are hepatitis in its several forms...*[2453]*"*. It is noted that *"although most clinicians prefer to use transfusions of whole blood in treating patients with extensive blood loss there is much disagreement about the most appropriate fluid to transfuse in treating moderate haemorrhage. On simple physiological grounds it seems obvious that no other fluid could be better that whole blood although it must be remembered that blood which has been stored in the cold is devoid of functioning platelets, and may have 2,3 DPG-depleted red cells which are temporarily less good than fresh cells in giving up oxygen to the tissues. However, it is not on the grounds of simple physiology that the use of various substitutes for whole blood is widely advocated. Blood is not available in unlimited quantities and should not be used when an adequate substitute is available; blood transfusion involves many hazards and should certainly be avoided in treating small haemorrhages which can be dealt with adequately by the transfusion of a plasma substitute or of an infusion of Ringer's lactate solution*[2454]*"*. The guidance regarding when to transfuse remained broadly the same as in previous editions, save that in respect of post-operative transfusion it is noted that *"The practice of giving*

[2451] PRSE0000525_003
[2452] PRSE0000525_004
[2453] RLIT0001571_0016
[2454] RLIT0001571_0037

'topping up' transfusions post-operatively with the idea of brining the patient's Hb concentration up to an acceptable level is widespread, but there are variable opinions as to what constitutes an acceptable level. In healthy young adults it is difficult to justify transfusions at levels above 8g/dl since, when the anaemia is due solely to previous blood loss, the administration of iron in adequate amounts will result in the cure of the anaemia within a matter of weeks. On the other hand, in patients who have impaired cardiac or pulmonary function there may be a good case for giving transfusions at lower levels of Hb e.g. 10g/dl. It has been shown that following operations associated with marked post-operative haemorrhage a higher percentage of women than men are transfused and it has been suggested that this is because there is a tendency to use the same level of haematocrit or Hb in women as in men in deciding whether transfusion is required. There would be substantial saving in blood if the normal difference in haematocrit between men and women were taken into account in deciding the need for transfusion.[2455]". With regards to post-transfusion hepatitis, Mollison writes, *"Although the transmission of hepatitis B virus is now largely preventable, it has emerged that other viruses, not yet characterised, can also cause post-transfusion hepatitis ad that it will not be possible to eliminate PTH until tests for these other viruses have been developed.[2456]"*. In respect of NANBH, he writes that, *"this rather clumsy term is used to describe hepatitis in which both HAV and HBV have been excluded. The term hepatitis C is not used because there is evidence that there is more than one kind of non-A, non-B virus and because no specific tests have yet been developed. The mode of transmission of non-A, non-B hepatitis may sometimes be similar to that of hepatitis B. Non-A, non-B hepatitis is prevalent following transfusion or other percutaneous exposure; it is commoner in populations of low socio-economic status and is probably spread by close person-to-person contact: it is associated with a chronic carrier state… as a rule, non-A, non-B hepatitis is symptomatically mild. Patients seldom need to be admitted to hospital. Nevertheless, up to 60% of cases have abnormal alanine aminotransferase (ALT)… levels for more than 1 year;*

[2455] RLIT0001571_0072 to 0073
[2456] RLIT0001571_0399

if a liver biopsy is taken, most of these cases show histological evidence of a significant chronic liver disease and approximately 10% show features of cirrhosis[2457]*"*

4.26 In March 1983, a survey of blood transfusion practice in the south east region of Scotland was carried out. The introduction noted that, *"In the absence of a Regional Transfusion Policy or of Hospital Transfusion Committees, an initial exercise was undertaken by a group of clinicians and transfusionists as preparation for the introduction of Transfusion Committees, ordering policies, and the regular provision to clinical users of audit information"*. It was noted that the survey had the objective of determining (a) "*to what extent clinicians are using well-defined transfusion policies", and (b) "whether stated transfusion policies are based on knowledge of the native complications, indications and costs of the available products"*. It was also intended to *"increase the awareness of clinicians of the questions underlying the current transfusion practices and prepare the ground for further exercises involving studies of ordering and transfusion practice and the regular provision of audit information"* and to "*detect problems affecting clinical users inherent in the current arrangements for the provision of transfusion support"*[2458]. The study was limited to perioperative blood requirements of consultants and senior registrars in surgery and anaesthesia. There was concern noted regarding the number of respondents to the survey who said they were unaware of the risks associated with the administration of various woven colloids. The survey noted that *"the degree of risk of viral hepatis association with blood transfusion was generally unknown. Viral hepatitis is, in fact, now regarded as the single most important complication of blood replacement therapy (Urbaniak and Cash, 1977). All donations are tested for the HbsAg associated with type B viral hepatitis but recent studies have demonstrated several other responsible agents. This non-A, non-B hepatitis, hepatitis C has become important*[2459]*"*. It was noted that *"the high proportion of 'don't know' or incorrect responses indicated an urgent need for more educational information"* and recommended actions

---

[2457] RLIT0001571_0401
[2458] WITN6666024_0001
[2459] WITN6666024_0007

included the establishment of a transfusion committee and the provision of audit information. It was further noted that *"the implications of newly emerging problems in transfusion transmitted disease (AIDS) etc and the urgent need for increasingly tight scrutiny of the risk versus benefit factors in transfusion and the promotion of auto-transfusion became important"*[2460].

4.27 In December 1983, Dr McClelland drafted a report and proposals for the SNBTS following a visit to New York and his participation in the WHO Conference in November 1983. Although the focus of the report was broadly in respect of seeking to reduce the risk of donors who might transmit AIDS being accepted as donors ahead of the identification of the virus causing AIDS, he set out a series of proposals for consideration regarding the use of blood. In the clinical transfusion context, he proposed that *"one or more clinical centres should undertake a detailed study of the extent to which autotransfusion could replace conventional random donor transfusion in routine practice, including an assessment of the additional recurring costs which such a programme would create"*[2461].

4.28 The Inquiry has heard evidence from Dr Jack Gillon regarding the feasibility of autologous transfusion. He set up a service in 1987 in the donor centre of SEBTS with the view of minimising the risks to patients associated with the risk of transmission of infection as *"the driving force"* behind the programme[2462].

4.29 It appears that there were no updates to Notes on Transfusion between 1975 and 1984. In the 1984 edition, the guidance that major surgery should not be carried out where the haemoglobin is less than 10g/dl is repeated. In addition to repeat guidance regarding record keeping in the patient's notes and the laboratory notes, it is stated for the first time that the laboratory notes *"should be preserved for not less than seven years*[2463]*"*. With regards to complications and dangers of transfusion, post-transfusion hepatitis is noted: *"several causative viruses are known or suspected as being transmissible through transfusion of blood and some blood products. Hepatitis B is one of these and its existence in blood donations or*

[2460] WITN6666024_0009
[2461] WITN6666011_0025
[2462] IBI transcript for 19/01/22: 77(9) to 77(18) (Dr Jack Gillon)
[2463] PRSE0004766_0017

products may be indicated by the presence of its surface antigen. Until suitable tests are available to identify other viruses concerned, there will continue to be a risk associated with the use of whole and plasma reduced blood, concentrated red cells, platelets, human antihaemophilic globulin, cryoprecipitate, factor IX concentrate, fibrinogen and thrombin. Hence donation identification numbers of all blood and blood products used should invariable be recorded in the case notes". In respect of non-A, non-B viruses, it is noted that *"the clinical course may be acute, or chronic leading to cirrhosis"*.

4.30 There is no reference to AIDS in the 1984 booklet. It appears that the booklet was not issued by all NBTS Directors and was not in circulation in the West of Scotland[2464] and the Scottish RTDs were unsatisfied with it[2465]. The guidance available to clinicians in the absence of the handbook is unclear and seems likely to have been inconsistent across the country given the independence of each Scottish RTD.

4.31 Dr Tony Napier in 1987 published a textbook, "Blood Transfusion Therapy: a Problem-Oriented Approach". He recommended that in cases of massive blood loss, *"the general strategy should be to combine blood and other fluids to maintain the haemoglobin above 10g/dl and the haematocrit over 0.30[2466]"*, noting that *"for otherwise fit patients it seems that an acceptable compromise between established facts, the demands of plasma component programmes and clinical anxieties is to have a routine policy of only supplying whole blood or plasma protein where an estimated blood loss of* at least 40% *has occurred"*. He noted, with regards to the harmful effects of transfusion that *"until the advent of AIDS as a transfusion problem, the safety of blood transfusion was all too often taken for granted[2467]"*. He noted that, *"since a degree of risk is inescapable with any transfusion procedure, it is best to obtain informed consent from the patient whenever possible[2468]"*.

[2464] PRSE0003628_0007
[2465] SBTS0000093_134
[2466] RLIT0001565_0167
[2467] RLIT0001565_0318
[2468] RLIT0001565_0319

4.32 Notes on Transfusion were replaced with the Handbook of Transfusion Medicine in 1988 or 1989[2469]. It sets out in some detail the processes for requesting and receiving blood from the blood banks but does not deal with the issue of consenting the patient. The information regarding the need to record the specified details in the patient's notes previously seen in Notes on Transfusion is not replicated within the earlier version of the Handbook and the 1989 version states, *"Details of all blood components infused (including the donation numbers) must be entered into the patient's case record together with the compatibility report provided by the transfusion laboratory[2470]"*. In terms of risks of viral transmission via transfusion, it is noted that *"no serological screening test is yet available to detect the responsible viruses, although this may be introduced in the foreseeable future…the true incidence of post transfusion hepatitis is very difficult to establish because many cases are not reported and most cases are asymptomatic and detectable only by prospective studies which monitor liver enzyme levels."* It is also noted that, although all blood donations are screened for HIV-I, *"a very small proportion of infective donors may fail to be detected because the antibody has not yet developed at the time of testing[2471]"*.

4.33 In perioperative patients, the Handbook notes that *"surgical and anaesthetic practice has tended to be guided by the belief that a haemoglobin level below 10g/dl (haematocrit below 30%) indicated the need for perioperative red cell transfusion. There is little or no firm evidence supporting this belief and experience in recent years suggests that patients with severe anaemia may tolerate anaesthesia and operation without major morbidity or mortality resulting from anaemia itself. Evidence from clinical and physiological studies does not support the necessity for the '10g/30% rule. Experimental evidence indicates that in healthy*

[2469] The lack of clarity results from the two versions available on Relativity at NHBT0099310_002 and PRSE0003047. It appears that the former is a draft, which was formally published in 1989 having regard to the publication date and the introduction, as well as Dr McClelland's evidence regarding publication dates (WITN6666001 paragraph 22).
[2470] PRSE0003047_0021
[2471] PRSE0003047_0029

humans cardiac output does not increase dramatically until the haemoglobulin falls below 7g[2472]*".*

4.34 In 1989, Dr (as she then was) Marcela Contreras wrote an article, "New Trends in Blood Transfusion". She noted that *"education of clinicians on the proper use of blood is now becoming an accepted aspect of medical training. Responsible clinicians are re-examining the benefit-to-risk relationship of blood transfusion. However, there is a great deal of ground to be covered since many clinicians consider blood and blood components on the same level as any drug that they prescribe. In some countries, the establishment of Hospital Transfusion Committees has helped a great deal towards a more rational use of blood and it is expected that such committees will be established in more and more hospitals worldwide… The knowledge that HIV infection can be transmitted by blood transfusion has made clinicians and the general public realise that blood transfusion can be dangerous"*[2473]. In her oral evidence to this Inquiry, Professor Contreras said that it was her experience that the guidance in Notes on Transfusion cautioning against over us of transfusion in the period from 1980 onwards was not adhered to "*until later*", and that prompted her to consider the issue of education of treating clinicians as part of her centre's responsibility[2474].

4.35 Also in 1989, the Working Group on Transfusion Practice and HIV Infection in Scotland reported on its findings and recommendations following its establishment in May 1987[2475]. It had originally been set up to consider transfusion and HIV infections, but broadened its scope to general transfusion practice in 1988. It was noted that "*the demand for blood and blood products has been increasing relentlessly in recent years. Increased awareness of potential harmful effects of transfusion, however, has already led to some changes in transfusion practice by hospital clinicians. Overall there has been little co-ordination of efforts to develop rational prescribing policies. The principal aim of doctors involved in the prescription of blood and blood products should be to reduce to a minimum the*

[2472] PRSE0003047_0033
[2473] NHBT0057960_0001
[2474] IBI transcript for 02/12/21: 153(4) to 153(19) (Dame Professor Marcella Contreras)
[2475] NHBT0010270_003

exposure of patients to heterologous blood[2476]. It was noted that "*the content of undergraduate medical curricula has not kept pace with the rapid advances in transfusion medicine practice. There is certainly a need for more teaching time than one lecture in transfusion medicine presently provided in the medical undergraduate curriculum in most universities*". The proposal was linked to the need for research into the risks of transfusion and the influence of education on the use of blood and blood products. It was noted that research needed to include "*such basic questions as the appropriate haemoglobin level in various types of hospitalised patients…the aim should be to develop professional consensus on the indications for prescribing blood and blood products based on scientific data and in particular, well conducted clinical trials rather than surgical and anaesthetic folklore*[2477]". The Working Group recommended the establishment of hospital transfusion committees in all major hospitals "*whose aim should be to audit the use and abuse of blood and blood products , to monitor standard procedures and to review new developments*". This recommendation suggests that the recommendations in March 1983 to set up hospital transfusion committees as set out above were not implemented, whether adequately or at all. Dr McClelland's evidence to this Inquiry was that a transfusion committee was set up following the 1983 survey but "*it didn't prosper…the environment wasn't quite right for it…it was some years before I would say we had a functional transfusion committee*[2478]".

4.36 Dr McClelland provided an interim report of a European collaborative audit of blood transfusion practice in elective surgery at a symposium on 12 December 1991[2479]. The audit (the "Sanguis project") began in 1989, it having been determined that there was no comprehensive body of evidence comparing transfusion practices across Europe in respect of 6 surgical procedures. Even in the initial stages of the process, it was apparent that there were wide differences in the clinical approaches across the hospitals studied. In an article connected to the release of the interim report, it was noted that "*it is well known that in a high*

[2476] NHBT0020270_003_0007
[2477] NHBT0020270_003_0007
[2478] IBI transcript for 28/01/22: 134(2) to 134(18)(Dr Brian McClelland)
[2479] SBTS0003883_128

proportion of cases, blood is seen simply as a useful red fluid to be ordered without profound thought, often by junior doctors and inexperienced staff. It is not seldom given in arbitrary quantities to achieve undefined clinical or physiological end points, like, for example, to improve the colour of the patient[2480]*"*. The final report, published in 1995, found *"spectacular differences in the quantities of blood that people used"* across Europe, both between countries and within them[2481].

4.37 In 1995, a report from the Working Party set up by the Clinical Resource and Audit Group was published. It was recommended that, *"in view of evidence that there are failures to provide patients with basic information (e.g. warning of the probable need for transfusion) there should be local procedures for briefing patients who are likely to be transfused*[2482]*"*.

4.38 The inconsistency in the amount of blood being ordered and/or transfused between different hospitals or surgeons was long-known to be an issue in Scotland. Dr George Galea gave evidence that during his time in Aberdeen (1984-1993) audits were carried out that demonstrated varying approaches by surgeons even within the hospital his centre served. His team established the Maximum Surgical Blood Ordering Schedules in response, leading to a reduction in the use of blood[2483]. He noted that, *"the safest blood is the blood that's not given"*.

4.39 Notwithstanding the guidance reviewed above, the Inquiry has heard evidence from clinicians regarding the limited (or indeed, non-existence) of guidance relating to the use of blood in various specialisms in the 1970s and early 1980s in Scotland and elsewhere as far as they were concerned. Dr Gillon, for example, said that he had no recollection of any formal guidelines during his time as a gastroenterologist at the Western General, notwithstanding the fact that he himself had a lecturing post between 1979 and September 1984[2484]. He described the knowledge of transfusion generally in hospital settings as "not good" during this time period.

[2480] SBTS0003883_095_0001
[2481] IBI transcript for 28/01/22: 128(14) to129(1) (Dr Brian McClelland)
[2482] SCGV0000099_065_0002
[2483] IBI transcript for 03/12/21: 22(17) to 24(4) (Dr George Galea)
[2484] IBI transcript for 19/01/2022; 7 (2) – 8(4) (Dr Gillon)

4.40 In parts of Scotland, the regional transfusion centres were more closely involved in the process of responding to requests for transfusions than was the case elsewhere in the UK. Some of the RTCs provided the blood bank service directly to the hospitals, and would carry out the relevant pathology tests required in the administration of transfusion (e.g. blood matching)[2485]. We submit that this gave a greater opportunity for at least some of the Regional Transfusion Directors in Scotland to monitor and assess blood usage, compliance with guidance, and clinical practice. This could and should have led to closer co-operation between those taking blood from donors and those administering blood to patients, with increased education of the associated risks, and better record keeping (given that the blood passed through fewer departments).

5. The circumstances in which the transfusions were given

5.1 The types of medical situation in which individuals were given blood transfusions amongst the core participants on whose behalf this submission is made vary widely. Even within cohorts of patients who received their transfusion for ostensibly similar reasons, their experiences vary widely. It is our submission that this may well be reflective of a lack of detailed, medical specialism-specific policy (or lack of recognition of the existence of such policies where they might have existed) regarding the administration of transfusions.

Trauma

5.2 There are a number of individuals within the cohort of core participants represented by Thompsons Scotland who received blood as a result of a traumatic injury, including those who received transfusions following assaults, road traffic accidents, and accidents at work. Many such individuals received significant numbers of units of blood.

[2485] IBI Transcript for 27/01/2022; 13(12) to 14(1) (Dr Brian McClelland)

Obstetric and Gynaecological

5.3 Amongst the core participants represented by Thompsons Scotland are a number of women who received transfusions in connection with obstetric or gynaecological intervention.

5.4 One witness spoke of requiring a transfusion at the age of 17 in 1981 when she suffered a miscarriage. She awoke to found she was having a transfusion, and was not told the reason for it or any risks associated with it[2486].

5.5 An anonymous witness has provided a statement in which she sets out that she was given 2 whole units of blood in 1978 following the birth of her son. Her haemoglobin count was 10grms[2487] and she did not appear to have bled heavily[2488]. It will be apparent from the guidance set out above that such treatment would seem to have been contrary to at least some of the guidance in place at that time.

5.6 A witness who gave oral evidence to this Inquiry spoke about the traumatic circumstances of her son's birth in 1988[2489], leading to an emergency caesarean section. In the days immediately following the transfusion, the witness explained that she was admitted to the infectious disease ward in Monklands Hospital. She received no explanation as to the reason for her admission to this hospital, and was discharged about a week after her son's birth. Approximately 1 month later, she was admitted to a different hospital and given more blood in response to a post-partum infection leading to a haemorrhage. About 9 months later, the witness was admitted to Monklands Hospital for a barium meal in light of her ongoing ill health. Those investigations revealed an irregularity in her oesophagus which prompted a biopsy. She experienced complications arising from that biopsy which necessitated a significant blood transfusion. Although the witness has sought details of the transfusions she received with a view to tracing the source of her infection, such details have not been forthcoming. Accordingly, it is not

---

[2486] WITN2076001
[2487] WITN2085001 at paragraph 4
[2488] WITN2085002
[2489] For the avoidance of doubt, the references to 1998 in the transcript for 03/07/19 are mistaken; the witness and counsel to the Inquiry both referred to 1988.

possible to state definitively whether the obstetric intervention was the source of the HCV infection, or the post-biopsy complications, although the evidence she gave regarding her ill-health immediately after the transfusion associated with her the complications arising from her son's birth is perhaps suggestive of the fact that the infection occurred at that time. The transfusions all occurred in the time period after which we say surrogate testing should have been introduced.

5.7 Other witnesses note transfusions following ectopic pregnancies, hysterectomies, and caesarean sections.

Medical

5.8 Some patients were infected during the course of treatment for conditions such as renal failure necessitating dialysis, in the course of treatment for cancer, acute medical conditions, and as a result of complications of other diseases such as Crohn's disease.

5.9 A core participant represented by Thompsons was infected with HCV as a baby in 1959 when given a transfusion following her premature birth. Her own daughter was infected during the course of her birth; neither knew of their respective infections until 2019[2490].

5.10 The Inquiry has heard anonymous evidence from the widow of a man who contracted HIV/AIDS as a result of blood transfusions required in connection with his treatment for leukaemia in 1983 under the care of Dr Ludlam. He died in 1984, having not been told he had contracted AIDS[2491].

Other

5.11 In her evidence to this Inquiry, Dr Aileen Keel testified that DEFIX was administered to patients to reverse the effects of warfarin or other anti-coagulants where the patient was a risk of bleeding. She stated that there were "tens of thousands" of

[2490] WITN4186001
[2491] WITN0136001 (anonymous)

patients who had received such treatments, and no realistic way of tracing the recipients of such products in light of the way the records were kept, with no centralised database in which administration of this product was monitored. Dr Ludlam recommended that recipients of non-virally inactivated DEFIX should be included in the Lookback process for HCV, noting that the Coagulation Factor Working Party was unanimous in its views that Lookback should include such recipients, notwithstanding the fact that Dr Keel had notified them that this approach had been decided against. Nevertheless, the CFWP renewed their calls for recipients to be included in the Lookback process[2492]. It seems that such calls were ignored; Dr Keel advised Dr Ludlam that there were a number of issues with extending the Lookback programme to those who might have been infected via the administration of DEFIX, referring, in part, to the fact that other fractionated blood products had the potential to transmit HCV and had, by implication, been administered to patients outwith the bleeding disorder community. Dr Keel's response[2493] does not state what thought had in fact been given to extending the programme to include such recipients. Rather, it seems that the approach was to *minimise* the number of individuals that might fall within the terms of the review. We submit this was entirely the wrong approach. In circumstances where there was awareness of a potentially broad number of recipients of infected blood products and a lookback process underway, calls to ensure as many people as possible were traced should not have been dismissed.

5.12 Heat treated DEFIX was not introduced in Scotland for "routine use" until the autumn of 1985[2494]. It is not clear when heat treated DEFIX would have been used for anticoagulant reversal therapy. Like other pooled products, it was likely to be 100% infective for those patients who received treatment prior to the heat treatment. In circumstances where there has been no lookback or attempt to trace patients who received this product, it is our submission that there is a potentially enormous cohort of patients who have been infected with HCV as a result of treatment with blood products in Scotland who have not been identified. Dr Keel,

---

[2492] DHSC0003538_022
[2493] DHSC0002557_005
[2494] IBI Transcript for 01/04/22: 14(23) to 15(3) (Dr Robert Perry)

in her oral evidence, appeared to take some comfort from her belief that a clinician treating patients with non-heat treated DEFIX would be 'monitoring' their patient and might test them for HCV when anti-HCV testing was introduced in 1991. In fact, on 26 September 1995, she wrote to Dr Ludlam and noted that, given that most patients would have been treated on a short-term basis, they were likely to have been lost to follow-up care[2495].

5.13 On balance, we submit that it is unlikely that many of the patients who were treated with DEFIX in the period prior to October 1985 for anti-coagulant reversal would remain under the care of the clinician for at least 6 years between the introduction of heat treatment and the introduction of testing, much less consider the risks of hepatitis having been transmitted in this way. Rather, we consider it more likely that the general experience of those who received transfusions over the relevant periods would be replicated with regards to lack of follow up. It is not clear that those administering DEFIX in such circumstances would in any event be aware of the particular risks associated with the use of the product.

5.14 In light of the evidence heard in this Inquiry, we submit that it would be reasonable to assume that there may be a cohort of patients who survived the incident in which DEFIX was administered and who (a) are unaware of their potential blood-borne infection, or (b) having been diagnosed with such an infection have been assumed to have contracted it through means other than the administration of a blood product. It would also follow that patients who received a vCJD implicated batch of DEFIX would likely not have been warned of their potential exposure to the disease; it was estimated at an SNBTS Notification of vCJD Risk Group meeting on 30 August 2004 that there were approximately 20 recipients of DEFIX who might have been affected by the implicated batches of PFC DEFIX[2496].

6. Consent to, and knowledge of, receiving transfusions

[2495] DHSC0002557_023
[2496] **NCRU0000146_116**

6.1 Amongst the core participants on whose behalf this submission is made, the overwhelming majority have no recollection having been advised as to any risks of the transmission of blood-borne viruses prior to the transfusion being administered. In some cases, the individual apparently required a transfusion in circumstances where they were not capable of giving consent or having any discussion as a result of their medical presentation. There is little evidence to suggest that their next of kin were advised of the issues surrounding transfusion in circumstances where their relative was incapable of having such discussions. We say that it is notable that within the various sources of guidance reviewed above, we have been unable to find any reference to the need to obtain informed consent before Dr Napier's book in 1987. As recently as 1994, the British Committee for Standards in Haematology were considering proposals regarding the need for consent to be obtained to blood transfusion. It concluded that, *"the risks associated with blood transfusion were not of such a magnitude that there should be a legal requirement for informed consent to transfusion".* It was noted that the ethical duty did extend to informing patients of the fact of transfusion, and, in effect, deferred further consideration of consent matters to each medical specialism Royal College or the Department of Health[2497]. We suggest that the fact that the medical profession who were consulted for this review felt that the level of risk was the metric by which consent of the patient ought or ought not to be required is indicative of the failure to recognise the autonomy of the individual and the 'paternalistic' attitudes that the Inquiry has heard evidence of. In any event, the belief or assertion that the risks were of insufficient magnitude is, we say, plainly wrong; by 1994 the risks associated with transfusion were known, in many cases, to have been fatal.

6.2 Furthermore, it seems that individuals were inconsistently advised as to the fact that they had received a transfusion after they had sufficiently recovered to be able to take that important information in. In 1999, it was found that 17% of adults transfused between May 1995 and May 1996 were unaware that they had

[2497] DHSC0004486_097

received a transfusion[2498]. We submit that in the years over which this Inquiry is principally concerned, the percentage of people being made aware of the fact of their transfusion is highly unlikely to be greater than the position in 1995/6, and may in fact be rather less.

6.3 During the period in which HIV and HCV were being transmitted via transfusion, there was very limited guidance given to practitioners about consenting patients for transfusion. In 1994, the Task Force of the British Committee for Standards in Haematology concluded, having consulted practitioners, that there was no need to consent patients in light of the fact that, according to those practitioners, the risks did not warrant consent being taken.[2499]

6.4 All too often, as Dr Contreras identified in her 1989 article, it appears that blood transfusion was considered simply one of the drugs that could be prescribed, without recognition of the potential longer term implications of any complications arising from the use of blood that might not be the case for other medications, which perhaps had undergone greater studies regarding long term safety and efficacy, and were produced subject to strict manufacturing standards, rather than being sourced from human beings.

6.5 The Inquiry has heard evidence from an oral witness who was expressly against the idea of a transfusion because she was concerned about the risks associated with the procedure and felt she required further information. She told this Inquiry that she was told by her doctor that the blood was "totally safe" and, despite being content with the alternative of longer term bed rest, the doctors continued to press her to accept the transfusion. In due course, the witness' husband was taken aside and told that the transfusion was necessary because there was a risk of a further haemorrhage that would risk her life. In response, the family decided to consent to the blood, believing there to be a medical emergency, and consented on that basis. Nevertheless, the blood was not transfused immediately, and instead the transfusion was only started the next morning. The witnesses both gave evidence that the consent was given only if the transfusion was necessary to

---

[2498] WITN3101017
[2499] DHSC0004486_097

deal with a medical emergency, and felt that issue was only described as a medical emergency when the doctors were told that this was the only circumstance in which they would consent. In the event, with the blood being transfused the following morning, they felt that the transfusion was not in fact given in the emergency circumstances which they had specifically consented to[2500].

6.6 The consequences of not being aware of either having had a transfusion or the risks associated therewith are multiple and are explored in more detail below. Some individuals experienced prolonged health issues which were either dismissed summarily by doctors, attributed to causes other than the underlying blood-borne infection, or even ignored by the individual themselves. Some, upon being diagnosed eventually with a blood borne infection, were accused of contracting it through means other than the receipt of blood and blood products. Some were disbelieved by their own doctors as to the reality of their transfusion. Some found out about their infections only after passing it on to members of their families. Such consequences might have been avoided had patients receiving transfusions been given appropriate knowledge and advice from the outset.

6.7 There appears to have been inconsistent practice not only regarding advising an individual as to the receipt of a blood transfusion, but also in recording the fact of that transfusion in the clinical notes. Again, this gave rise – and continues to give rise – to tangible difficulties for such individuals. In addition to the problems faced by those who were not aware of the fact of their transfusion until long after they had received it, as the Inquiry is aware, there are individuals who, in the absence of a record of a transfusion in their medical records, have been unable to access the support schemes for victims of the contaminated blood disaster.

6.8 Even in elective surgeries, it appears little thought was given by practitioners across Scotland to discussing the merits or otherwise of blood transfusion in any particular circumstance.

[2500] IBI transcript for 03/07/19: 101 to 110 (Gillian and Stanley Fyffe)

6.9 There are some individuals whose next of kin did not know they had even received a blood transfusion, despite the fact that their relative was unable to consent to, or discuss the need for, a transfusion[2501].

7. The identification of patients infected by blood transfusions in Scotland

7.1 The Inquiry has heard evidence of lookbacks undertaken in respect of both HIV and HCV in Scotland.

HIV

7.2 Dr Gillon gave evidence to the Inquiry about having conducted an HIV Lookback to try to identify patients who had been infected with HIV as a result of a transfusion of red cells or other blood components in Scotland (see above). Such an exercise was left to regional authorities to make their own arrangements. There was no agreed national policy signed off by the national medical and scientific director and issued formally through the QA systems with appropriate document control. It was the responsibility of each regional transfusion director to ensure implementation. There was no national donor administration system in the early years. As Dr Gillon made clear the system was dependent on adequate record keeping, which would inevitably cause issues with accuracy. Given that the State had infected individuals with a fatal disease which was easily transmissible by sexual or other intimate contact, the systems in place for the identification of individuals infected in this way were an inadequate public health response. Once again, this is clear evidence of the State compounding the harms cause by the primary infections by failing to deal with them appropriately.

7.3 He found 18 individuals who had been infected as a result of receiving blood from donors who were subsequently found to be HIV positive. In his evidence to this

[2501] WITN2242001 @ paragraph 2 (Pamela Pennycook)

Inquiry, he suggested that the programme may have missed "one or two" patients who contracted HIV from blood transfusion[2502].

7.4 Of the minimum of 18 people who were infected with HIV by blood transfusions, the Inquiry has certain evidence about the infection of one. It seems likely from the circumstances if her statement (made by her representative her stepson) that she was identified by Dr Gillon's Lookback exercise in 1986.[2503] The circumstances of her finding out meant that she was referred to the City Hospital to be tested and cared for. That hospital dealt with the multiple AIDS cases which emerged in Edinburgh at around that time, mostly in the IVDU and homosexual communities. The patient appears to have received no bespoke handling or counselling other than the care at that hospital. The lack of any bespoke system for explaining how she had come by the infection means that she harboured misapprehension based on press reporting that she had received US blood. This misapprehension and the consequences could have been avoided had a bespoke counselling system for blood transfusion infections been set up at that time.

HCV

7.5 The national look-back exercise to identify recipients of blood that might have been infected with Hepatitis C did not start until April 1995 although a test for Hepatitis C was introduced in September 1991. This was a significant dereliction in the responsibility of the State to identify those whose infections it had caused. Whether treatment was available for the condition or not, patients had a moral right to know that they had been infected and know they had been infected. The State had a corresponding ethical duty to identify these individuals and provide them with support. The failure of the State to institute an effective system before 1995 resulted in the eventual Lookback exercise being inadequate due to the passage of time between the infections and the exercise. It was inevitable that this passage of time, combined with the lack of effective records keeping would render

---

[2502] IBI transcript for 19/01/22: 135 (Dr Jack Gillon)
[2503] WITN2103001, paras 3 and 4 (first statement of Ian Cobbledick)

the exercise far less effective than it might otherwise have been. Dr Jack Gillon, in his evidence to the Inquiry, said that the biggest problem in the Lookback exercise was tracing the hospital record indicating the ultimate fate of the donation.[2504] Delay merely compounded this problem.

7.6 As progress was being made towards the introduction of routine anti-HCV testing for donors in Scotland, in June 1990 Dr Cash asked Dr Gillon to produce operational guidelines for blood transfusion service doctors in the context of counselling donors found to be anti-HCV positive. The final draft included a recommendation that a look-back be carried out. The justification for this was clear - the desirability of informing recipients, the protection of others and so they could receive treatment with Interferon if the benefits of that form of therapy were confirmed.[2505] When the national look-back was ultimately introduced in 1995, much of what was contained in that document was used.[2506]

7.7 Dr Gillon's report was considered by the Medical Scientific Committee (MSC), which advised the SNBTS, at a meeting on 19 February 1991. It was decided that, "in light of national events", a look-back should not be introduced at that time.[2507] It seems that despite the clear impetus for such a Lookback to be undertaken in Scotland the lack of consensus to do this nationally was causing an impediment to Scotland taking its own and clearly the right course. Professor Cash gave evidence to the Penrose Inquiry about these issues.

7.8 Dr Gillon told the Penrose Inquiry he felt strongly that look-back should have been implemented from September 1991. It was the ethical thing to do.[2508] As soon as anti-HCV testing became available in September 1991, he commenced a look-back exercise in the South East Scotland Blood Transfusion Service.[2509] It should be noted that the NHS legal service still appeared to have a role to play, despite this

---

[2504] IBI transcript for 19/01/22; 73 (Dr Gillon)
[2505] PRSE0004689 (21 June 1990); PRSE0004114 (20 September 1990); Penrose Inquiry transcript for 18/01/12 (Day 86): 8(17-22); 12(16) to 13(7) (Dr Gillon) [PRSE0006086_0008; 0012 to 0013]
[2506] Penrose Inquiry transcript for 18/01/12 (Day 86):17(10-13) (Dr Gillon); [PRSE0006086_0017]
[2507] PRSE0003568_0004 @ para 3.14 (19 February 1991 meeting)
[2508] Penrose Inquiry transcript for 18/01/12 (Day 86): 31(7) to 32(15) (Dr Gillon); [PRSE0006086_0031 to 0032]
[2509] Penrose Inquiry transcript for 18/01/12 (Day 86): 32(20-25); 38(17-19); 43(13-14) (Dr Gillon); [PRSE0006086_0032; 0038; 0043]

decision as Dr Gillon sought legal advice about the duty to advise the donor about his donation testing positive for HCV from the NHS CLO.[2510]

7.9 In November 1993 Dr Gillon, together with Dr Ayob, submitted a paper about this look-back exercise, which was accepted for publication in July 1994[2511] and which concluded that look-back was feasible with little in the way of extra resources and justified in terms of outcome.[2512] The failure to extend the so-called pilot study, , those who were identified as receiving a transfusion-transmitted HCV infection were subject to a postcode lottery. The lookback could and should have been instigated across Scotland at the earliest opportunity, in late 1991.

7.10 At this juncture it is important to realise that there was significant political influence in relation to the holding of a Lookback from around 1991. Evidence in this regard was heard by the Inquiry from Dr Aileen Keel. She played an active role both in having been a medical officer shortly after the period when decision making around Lookback took place in 1991 and more directly thereafter (from 1992) and also in reporting elements of the disaster to the then health minister, Susan Deacon in her investigation into elements of the blood contamination disaster which took place in around 2000. The evidence given by Dr Keel in this regard suggests that there were material misunderstandings on her part at the time of her advising the minister about those matters. This is indicative of the fact that at no time did those advising the government (either before or after devolution) have a clear grasp of the material facts relating to the possibility of an HCV Lookback in Scotland, as Dr Keel had the opportunity to represent the sum total of the knowledge of government advisors on the subject over the whole period in which it was under consideration (from 1991 to the investigation in 2000). This means that ministers are likely to have been given the wrong impression about the Lookback from the time of its contemplation from 1991, right up to its analysis in 2000. In her oral evidence when asked about whether instigating a Scottish Lookback in 1991 was something which ought to have been

---

[2510] NHBT0009732

[2511] Penrose Inquiry transcript for 18/01/12 (Day 86): 44(6-10); 48 (20-24) (Dr Gillon); [PRSE0006086_0044; 0048]

[2512] Penrose Inquiry transcript for 18/01/12 (Day 86): 72(7-14) (Dr Gillon); [PRSE0006086_0072]

done, which was the clear position of Dr Gillon, the Lookback architect, she said that hindsight was a wonderful thing.[2513] She was under the impression that the for the Scottish lookback did not happen for logistical reasons.[2514] She was under the impression that the exercise was feasible in Edinburgh due to its close links with the hospital but that in Glasgow, for example, the BTS was remote from the hospitals which would have been a problem. This was tantamount to an admission that the fact that system made a Lookback (the ethical duty of the service according to do Gillon) practically difficult was the reason why it was not done. Even if she was right, this was a breach of the State' ethical duty. In any event, this was also not accurate. Dr Gabra had been part of the transfusion service in the west of Scotland from 1974. In his evidence he described that the director of the service, Dr John Wallace fostered strong links with hospitals in his area and that there was a programme which it involved the going into hospitals and providing advice to clinicians about the use of blood. He even remarked that he had noted an increase in usage, contrary to his advice.[2515] In fact, Dr Gillon's clear evidence was that he could have and would have embarked on the work but for the intervention of Dr Cash telling him that he could no due to "national events".[2516] This is what (as Dr Gillon explained to this Inquiry) lead to his proposed plan for a national Lookback being phased down to what was called the "pilot study". It would be a reasonable inference form this evidence to deduce (a) that Professor Cash was stopping the national project due to a political intervention which he was communicating to Dr Gillon and (b) that by "national events" he is likely to have meant that the UK government was not keen on undertaking the project and so Scotland was being told at political level not to. This was consistent with Dr Keel's evidence that it had been "necessary" for all four parts of the UK to proceed on a uniform basis.[2517] This was also consistent with contemporary evidence.[2518] It is submitted that this resistance to lookback must be construed as being consistent

---

[2513] IBI transcript for 25/07/22; 64 to 65 (Aileen Keel)
[2514] PRSE0001169; IBI transcript for 25/07/22; 62 to 68 (Aileen Keel)
[2515] IBI transcript for 03/02/22; 8 to 10 (Gamal Gabra)
[2516] Witness statement of Dr Jack Gillon (WITN6987001), para 249
[2517] Aileen Keel witness statement WITN5736003 @ para 35(c)
[2518] DHSC0032208_136 – 4 January 1995

with the prevailing civil service attitude to the blood contamination disaster at that time (discussed in more detail below), namely that it was a matter which had been concluded at the time of the settlement of the HIV litigation. Those who had settled that litigation had been forced to sign a waiver precluding action being taken in respect of hepatitis. The disaster had throughout been viewed within the DoH as a matter relating predominantly to the importation of products for the treatment of haemophiliacs. There was no appetite to expand the matter into the transfusion area or to seek to find new potential claimants. This was a breach of the State's ethical duty.

7.11 In any event, the position adopted by Dr Keel as to why it had not happened appear to have made no mention of these political considerations which were the proximate cause of Dr Gillon's otherwise laudable attempts to undertake the project being prevented. This re-writing of history led to inaccurate ministerial briefing which continued for many years. An inaccurate "line to take" about the Lookback being undertaken as soon as testing became available was given to ministers in 2005.[2519] Testing was available at the latest by September 1991.

7.12 Dr Cash told the Penrose Inquiry that after he attended a symposium on 8 October 1993 at which he learned about the latest treatment for Hepatitis C, he took the view that there was reason to start a look-back.[2520] Thereafter further consideration was given was given to the possibility of implementing a look-back exercise in Scotland and by May 1994 a decision had been taken to implement the look-back on 1 June 1994. This was not done and look-back in Scotland was only commenced in April 1995 with the implementation of the UK national look-back.

7.13 Dr Gillon was clearly right that an HCV Lookback should have been undertaken in Scotland in 1991. He considered the suggestion that lookback for HCV should be deferred for some years as "unethical" and contrary to his duty of care to recipients of blood[2521]"; we agree. It was suggested in this area and in others to

---

[2519] Aileen Keel witness statement (WITN5736003) @ para A46; SCGV0000044_024 - briefing to ministers in January 2005

[2520] PRSE0003512; Penrose Inquiry transcript for 17/01/12 (Day 85): 68(9) to 72(11) (Professor Cash) [PRSE0006085_0068 to 0072]

[2521] WITN6987001. Para 251

the Inquiry that the lack of treatment being available justified exercises like the Lookback not being undertaken. Though this is wrong, in our submission, for the reasons given above, in any event, Dr Hayes told the Penrose Inquiry that that Alpha Interferon was introduced into clinical practice in about 1991/1992[2522] and that the first opportunity that patients would have had to receive treatment would have been as part of a clinical trial.[2523] Thus, treatment was available. Indeed, in his article published in 1999 in Transfusion Today, Dr Gillon noted that *"interferon was shown to be beneficial in trials of treatment of non-A, non-B hepatitis before HCV was identified, and the antibody test very quickly established that non-A, non-B equalled C. Though unlicensed, interferon treatment was therefore available. Furthermore, the fact that HIV lookback was instituted from the beginning of routine testing, when no treatment of any kind was available, suggests that in the case of HCV, the treatment issue was a red herring"*[2524].

7.14 By delaying the look-back exercise until 1995 patients were deprived of the opportunity of receiving treatment at the earliest opportunity. Even if treatment were not appropriate or accepted, lifestyle choices could have been made which would have minimised the effects of infection from 1991 and those who had developed symptoms of their infection would at least have the knowledge that this was the cause of those symptoms, rather than living with difficult symptoms which had no apparent explanation. The delay in the roll-out of the programme across Scotland undoubtedly increased the risk that recipients of contaminated blood were lost to follow up, and meant that there was an extended period in which (a) those infected were robbed of the opportunity to take steps to mitigate the effects of their infection and (b) posed a risk of infecting others due to their lack of knowledge of their own infection. Testing could have been offered to their partners and children.

[2522] Penrose Inquiry transcript for 14/12/11 (Day 78): 51(21-25); 53(8) to 54(8) (Professor Hayes); [PRSE0006078_0051; 0053 to 0054]

[2523] Penrose Inquiry transcript for 14/12/11 (Day 78): 54(9) to 55(6) (Professor Hayes); [PRSE0006078_0054 to 0055]

[2524] PRSE0000881

7.15 Funding, it would appear, also played a part in the decision making around carrying out the Lookback. Dr Keel conformed to the Inquiry that the funding for it ultimately came from the existing SNBTS budget.[2525] This would have been restricted due to the need to fund other ongoing work. In any event, the HCV Lookback exercise which was eventually carried out was inadequate, given that it was based on identifying infections only though donors who re-presented for donation, finding them to be positive and testing identifying the recipients of any previous donations.[2526] The SNBTS had to rely on the donors coming back to make a donation for their previous possibly infective donations to be identified. In his evidence to the Penrose Inquiry, Dr Alexander pointed out that one of the problems with this approach was that potential donors who may have donated positive donations previously may not have returned after having been discouraged from coming back to give blood if they had a history of IV drug use. These donors' previous donations would not have been screened for HCV. Anti-HIV screening from October 1985 had resulted in a number of donors being excluded. Given the common infection routes, the previous donations of these donors may also have tested positive for HCV. These donors' previous donations would not have been screened for HCV. Dr Alexander said that for this reason the approach was flawed from the start.[2527] He suggested that an alternative approach might have been to go back through stored samples. Dr Alexander referred to a study by Soldan *et al* which estimated that only 5 per cent of the total number of HCV infections had been identified by the look-back exercise. Dr Alexander confirmed that this was a fair assessment and that the data of the look-back exercise matched up with data on the likely frequency of Hepatitis C infection at that stage.[2528] He explained that the reason for this small percentage was because the look-back exercise was based on donors coming back and being found to be

[2525] IBI transcript for 22/07/22; 108 to 109 (Aileen Keel)
[2526] Penrose Inquiry transcript for 18/01/12 (Day 86): 2(3-21) (Dr Gillon); [PRSE0006086_0002]
[2527] Penrose Inquiry transcript for 17/01/12 (Day 85): 125(2-18) (Dr Alexander); [PRSE0006085_0125]
[2528] Penrose Inquiry transcript for 17/01/12 (Day 85): 136(1-8) (Dr Alexander); [PRSE0006085_0136]

positive, but that donors had stopped coming back because of the steps taken to discourage high risk donors from giving blood.[2529]

7.16 The Inquiry heard about further difficulties with the lookback in terms of being able to match HCV infected donors with the correct recipients. In this regard Dr Alexander indicated that hospital records were needed to check that the blood had been transfused and they needed to know where the patient lived at the time of the Lookback, which could have been 15 or 30 years after the time of the transfusion. He said that this was difficult based on not knowing who the GP was, not knowing the recipient's current address and not even knowing if the hospital records were available. He said that even today hospital records continue to be destroyed not long after the patient has attended.[2530] These were all limitations of the system which in itself was flawed. These issues were clearly compounded by the delay in implementing the process between 1991 and 1995.

7.17 The limitations of the national look-back exercise should have been appreciated at the time that the look-back exercise was implemented. Additional measures such as a public awareness campaign should have implemented to ensure that as many recipients as possible would be traced and tested. In its one recommendation, the Penrose Inquiry recognised that there remains may individuals who had been infected with HCV by blood transfusion who had still not be diagnosed or at least the actual sources of their infection had not been appreciated. The Lookback was deemed to have become static by 1998 and was considered to be closed at that time.[2531] The State's limited appetite to carry out its ethical duty to find those whom it had infected had run out. Its limited ambition to identify "many but not all" of those infected with HCV by blood transfusion had not even been realised.[2532]

7.18 The results of the Scottish HCV lookback in 1998 are difficult to analyse; Dr Gillon in his evidence to this Inquiry was unable to assist with interpretation of them,

---

[2529] Penrose Inquiry transcript for 17/01/12 (Day 85): 135(25) to 136(13) (Dr Alexander); [PRSE0006085_0135 to 0136]
[2530] Penrose Inquiry transcript for 17/01/12 (Day 85): 126(9) to 128(3) (Dr Alexander); [PRSE0006085_0126 to 0128]
[2531] PRSE0003277 – 28 April 1998, Dr Franklin to Dr Keel
[2532] Aileen Keel witness statement (WITN5736003) @ para A38

save to recognise that *"the lookback was always in a state of flux, and there were always things coming in and things going out*[2533]*"*. The 'headline' figures appear to demonstrate that 1656 donations were identified which came from individuals subsequently found to be HCV positive, and it appears that 2022 components were notified to hospitals. The hospitals were able to identify just 878 recipients of those components. It seems that 535 recipients had already died before any follow up under lookback was able to be undertaken. It appears that, of those recipients who were followed up, almost twice as many tested positive for HCV than tested negative (133 as against 70)[2534]. As a matter of logic, it would seem that the prospects of lookback being a success (in terms of identifying as many recipients of blood that may have been contaminated) would have been increased had it been implemented at an earlier date.

7.19 No epidemiological modelling based on the Crawford data (available from 1991) appears to have been done which would have facilitated an assessment of the likely number of positives and so the likely number who were still to be found. An assessment could have been made at that time of the efficacy of the project and hence whether further measures, involving greater advertising[2535] and possibly proactive testing of stored donor samples (which would not have relied on repeat donors testing positive) to identify more cases and offer medical assistance to those who needed it. This did not happen. This was consistent with the unethical and uncaring attitude which the State also adopted to the possibility of infections with hepatitis C amongst those who had received factor IX (DEFIX) for reasons other than bleeding disorders. Despite there being evidence that she was counselled to do so by Professor Ludlam, Dr Keel again said that this would have been logistically difficult and so it was simply not done. In her evidence she said that such treatment would have been given to tens of thousands of patients.[2536] This means that, in particular given the fact that this was a pooled product, many,

---

[2533] IBI transcript for 19/01/22: 124 to 126 (Dr Jack Gillon)
[2534] PRSE0002209
[2535] IBI transcript for 25/07/22; 93 to 94 (Aileen Keel) – Dr Keel did not recall there being any such advertising at that time
[2536] IBI transcript for 26/07/22; 120 to 121 (Aileen Keel)

many more HCV infection could have occurred in Scotland as a result of State treatment before DEFIX was vitally inactivated for HCV from October 1985. That this was a very real possibility was precisely why Professor Ludlam advised as he did.[2537] Dr Keel's response that patients may have been picked up by their clinicians appears unrealistic as many of those who received the treatment would have moved on from being treated by those clinicians.[2538] This was why a population Lookback was necessary. This simple but devastating fact seemed to be lost on Dr Keel.

7.20 In a 1991 article Busche et al suggested that in light of the data showing the very limited efficacy of previous look-backs, an appropriate response to the situation posed by HCV would be an aggressive education campaign for physicians and the lay public about the risks and benefits of transfusions. He suggested that there was a need to disseminate information about the risks of all transfusion-transmitted diseases, both to previous and future transfusion recipients, in a well-orchestrated and long-term education campaign. He also suggested that all physicians should be encouraged to keep detailed transfusion histories from their patients and, on the basis of clinical findings and dates of transfusion, to test their patients for relevant viruses or diseases. He was of the view that the long-term gain of a commitment would outweigh the short-term yield of any specific HCV look-back effort.[2539]

7.21 Dr Gillon told the Penrose Inquiry that the possibility of a public education campaign was something that had been considered by the MSBT and that to some extent this was done in the press conferences when the CMO's letter came out. He also indicated that the letter to doctors had included a statement that any patient with a history of transfusion who expressed any concern about Hepatitis C should receive a test.[2540] Dr Alexander also gave evidence to the effect that at the time of the look-back there had been discussion about the possibility of having a

---

[2537] IBI transcript for 25/07/22; 94 to 95 (Aileen Keel)
[2538] IBI transcript for 26/07/22; 121 (Aileen Keel)
[2539] PRSE0004329
[2540] Penrose Inquiry transcript for transcript 18/01/12 (Day 86): 75(16) to 76(8) (Dr Gillon); [PRSE0006086_0075 to 0076]

television campaign inviting people who had received a transfusion at a certain time to come forward and be tested. He said that what had happened was that most of the people in his profession throughout the UK were invited on to local radio programmes two or three times over a year or two, and sometimes into television programmes, and they would invite people who had had a transfusion to come forward and be tested.[2541] He said that alternative approach was to ask GPs to refer everyone from their practice who had been transfused, but that it turned out that GPs often do not know that a patient has been transfused and that neither do patients. In this regard information about transfusions are not routinely reported back to GPs.[2542] Given that that the Inquiry has heard that there have been recent diagnoses of transfusion-transmitted HCV and in light of the very successful treatment now available, as well as the availability of financial support, additional measures to raise public awareness about Hepatitis C could still be beneficial.

7.22 The government was culpable in its failure properly to engage with the need to identify those whom it had infected. It is submitted that it did so as a result of an institutional fear about the possibility that litigations would ensue as a result of infected individuals being discovered.

7.23 Amongst Thompsons' clients there are only a very small number of transfusion patients who were identified via HCV lookback. Due to the fact that patients were not necessarily informed that they had been traced via lookback, it is impossible to be certain about the precise number of such individuals identified, but it would appear to be less than 10% of those individuals diagnosed with HCV as a result of a transfusion.

7.24 Professor Dillon, in oral evidence, told this Inquiry that, whilst patients who had a bleeding disorder are more likely to be under ongoing follow up, and are accordingly more likely to have been tested for HCV, those who received blood transfusions "are the more challenging group to find". He noted that a review of transfusion books provided very limited information such that it was difficult to

---

[2541] Penrose Inquiry transcript for 17/01/12 (Day 85): 127(2-16) (Dr Alexander); [PRSE0006085_0127]
[2542] Penrose Inquiry transcript for 17/01/12 (Day 85): 127(4) to 128(8) (Dr Alexander); [PRSE0006085_0127 to 0128]

identify whether components had been transfused, and the identity of those who might have in fact received the transfusion[2543].

7.25 A compounding factor of the effect of the failure to instigate a proper lookback programme is the fact that some GPs lacked awareness of the issues surrounding HCV and transfusion. Indeed, it seems that some GPs were mistaken as to the nature of lookback; one witness described her GP explaining to her that he understood that the lookback would involve a check of all blood donated at the time she had received her donation so that she would be contacted if there was an issue. It was not until this witness had blood tests 10 years later in 2005 that she was found to have HCV[2544].

8. The ways in which people learned of their infections

8.1 Although it is not the case for all of the bleeding disorder community, the majority of those infected as a result of their treatment remained under regular care and follow ups in connection with that underlying condition. This is almost invariably not the case for those infected via transfusion. In most of those patients, there was no ongoing follow up connected to the cause of the need for the transfusion in the first instance. Instead, individuals may not have had any acute need to attend medical practitioners for years after their infection, or may have been attending various clinicians for a variety of reasons (some of which were likely unknowingly connected to their underlying infection, but some would perhaps have no ostensible connection). As a result, the way in which people were identified as being infected (mostly with HCV) was something of a lottery. Those treating this community in many cases had no knowledge of the fact of the transfusion (in contradistinction to the bleeding disorder community in which treating doctors were at the very least aware of the possibility that factor concentrates may have formed part of an individual's treatment regime).

[2543] IBI transcript for 17/11/22: 50 to 52 (Professor Dillon)
[2544] WITN2126001

8.2 For some, the medics who were notifying their patients of their infection were often ill-informed and ill-prepared to advise their patients as to the nature of the illness, the risks, the steps that could be taken to mitigate the effects of the infection, to minimize the risks to themselves and others, and as to the most appropriate steps going forwards. This led to considerable uncertainty, fears, and concerns that could have largely been avoided had proper steps been in place to ensure that those informing their patients of a potential infection had been properly educated both in respect of the diseases and how to impart such knowledge.

8.3 There was a lack of understanding amongst clinicians regarding the nature and prognosis of the diseases contracted via blood and blood products. That lack of understanding meant that those who had contracted the diseases were frequently left to fend for themselves, researching their own conditions and seeking support from outside the medical profession. The lack of information was, as recognised by the psychosocial expert group, a *"major source of stress for both infected and affected individuals*[2545]*"*.

8.4 The circumstances in which individuals learned of their infections have variously been described as, "*disgusting*[2546]*"*and "*horrifying*[2547]. Some patients were told of their infection alone, in circumstances where relatives were nearby and would have been in a position to support them when being given potentially life-changing news[2548].

8.5 Some patients were closely questioned about their sexual history and possible drug use, with the possibility of their infections having arisen via blood or blood products being ignored or dismissed. One doctor, Dr Zentler-Munro who was responsible for the diagnosis and treatment of patients in treating the infected who had received transfusions for at least 5 years[2549] (and indeed treated haemophiliac patients at the same time[2550]) was described by some of those

---

[2545] EXPG0000003_0004
[2546] WITN2070001 @ paragraph 10
[2547] WITN2085001 @ paragraph 12
[2548] WITN2103001 @ paragraph 15
[2549] WITN2108001 and WITN2997001 both describe being treated by him in 1990 and 1995 respectively
[2550] WITN2149007 (anonymous witness)

treated by him have described appointments with him feeling like an interview, with intense questioning about sexual history with the result that one person felt that the questions were 'creepy'[2551]. An oral witness who was 'secondarily infected', her husband having contracted HCV as a result of surgery following the traumatic amputation of his thumb in an accident, recalls being 'interrogated' by the consultant who was carrying out biopsies on both her and her husband, noting that he was *"autocratic"*, and *"condescending"* and *"very rude[2552]"*. Despite the fact that the witness' husband advised the gastroenterologist that he had received a plasma transfusion, this was dismissed, the witness and her husband being told that plasma was *"not a blood product"*. Her husband died in 2019 as a result of his infection. In her oral testimony to this Inquiry, the witness gave emotional evidence about the effect of both her and her husband *"being treated like pariahs"*, and the couple's decision not to talk to others about their infections[2553].

8.6 A core participant recalls being told of her transfusion-transmitted infection by her GP who *"simply sent out a letter with just one line saying that I had hepatitis C[2554]"*. Others were told of their infection by the GP's receptionist[2555], or via telephone, with very few people told in the presence of a relative or someone else able to provide support.

8.7 A witness who gave oral testimony to this Inquiry, recalls her treating gastroenterologist, Dr Boulton-Jones, telling her, following 2 years of consultations regarding ongoing bowel problems that he had *"some good and bad news for you. The good news is you don't have cancer. The bad news is that you've got hepatitis C[2556]"*. She further described that he did not give her any information about the infection, and she felt that she had *"little knowledge of precisely what it meant or would mean for me in the future"*. In a lengthy response to her evidence, Dr Boulton-Jones does not deny that he suggested there was 'good news and bad

---

[2551] WITN2108001, para 19
[2552] IBI transcript for 31/10/19: 8(19) to 9(15) (Jryna Batters)
[2553] IBI transcript for 31/10/19: 9(19) to 10(14) (Jryna Batters)
[2554] WITN2074001 @ paragraph 7
[2555] WITN2242001 @ paragraph 3
[2556] WITN2076001 @ paragraph 6

news', noting that it is *"factually accurate*[2557]*"*, but denies that he did not provide her with information about the infection voluntarily. However, he seems to suggest in part at least that the information was provided voluntarily because there were no consultations at which the hospital was aware that the witness was infected when she was not similarly aware. The evidence demonstrates that she had been found to be HCV positive in July 2005[2558] but was not told about the infection until a consultation on 10 October 2005[2559]. She had not been aware that she was being tested for HCV and, accordingly, the diagnosis came out of the blue. She gave striking oral evidence to this Inquiry about how she was told of her infection, including being asked, *"any idea how you could have got it"* and the fact that her doctor was simply looking at his computer screen[2560]. The witness was concerned about the absence of information about what the infection meant or would mean for her in the future. We submit that, although Dr Boulton-Jones seeks to rely on a clinic letter as demonstrating that *"we discussed many aspects of her hepatitis C*[2561]*"*, the letter and Dr Boulton-Jones' own statement in fact shows that the concerns that the witness raised in respect of her future prognosis were not discussed. That her treating doctor is unable to answer these criticisms is, we submit, demonstrative of the lack of care and attention given by some in the medical profession to those in a vulnerable position. She was, like many others, given the news of her infection with HCV in unsupportive ad unsympathetic circumstances, and provided with little or no information or assistance. She wrote in her statement that, *"when [she] got home that evening [she] was in such a state that [she] phoned the Samaritans as [she] was that depressed*[2562]*"*. In oral evidence, the witness gave harrowing evidence about her mental health struggles following her diagnosis.[2563]

[2557] WITN3501001 @ paragraph 9d
[2558] WITN2076007
[2559] WITN3501005
[2560] IBI transcript for 08/07/19: 6(20) to 7(7) (Maria Armour)
[2561] WITN3501001 @ paragraphs 3 – 8
[2562] WITN2076001 @ paragraph 9
[2563] IBI transcript for 08/07/19: 9(4) to 10(6) (Maria Armour)

8.8 An anonymous witness records in her statement that, at the appointment where she was provided with her diagnosis with HCV in 2009, and having told her GP what she did for a living, was told that she would have to stop such work and that she could not work with children if she had hepatitis[2564].

8.9 An affected representative of the only known co-infected transfusion recipient notes that his stepmother was told in 1986 that she required a blood test because she was exhibiting symptoms of anaemia, and that when the tests were returned, that he *"was not qualified to give her these results"*. The GP referred her to the City Hospital in Edinburgh which was the infectious diseases hospital to which Dr Ray Brettle had been recruited in 1983 as an AIDS specialist. By 1986, it was well-known that the City Hospital was where AIDS patients were being treated, and, we submit, is the likely reason why she asked her GP whether the issue that he was unable or unwilling to discuss with her was related to *"that bloody AIDS"*. Her stepson recounts that her GP did not tell her, but following her attendance at the City Hospital and further tests being carried out, she was told that she was in fact HIV positive. She was also told that the hospital knew that she had been infected via blood transfusion, and had identified the donor. In the premises, it is our submission that the GP's suggestion that she undergo blood tests due to 'anaemia' was nothing more than a pretext to obtain confirmatory samples, with the exposure to HIV having been identified via lookback. If that reasonable inference is correct, her GP was in a position to ensure he was sufficiently well-informed to discuss matters with her, but instead sought to mislead her about the nature of the tests being carried out, refer her to a hospital in the knowledge that such a referral was likely to cause terror and panic, and to abrogate his responsibilities to his patient. As a result of these failing, she was told of her diagnosis on the day of her terminally ill son's birthday[2565].

8.10 Some core participants learned of their infection only when seeking to give blood themselves. The Inquiry has heard evidence of the fact that a higher proportion of blood recipients themselves gave blood than the general population before

---

[2564] WITN2085001

[2565] WITN2103001 @ paragraph 3

restrictions were put in place preventing those who have received blood from donating blood. For those who have given blood prior to the introduction of testing, there can be feelings of concern or guilt that they may have inadvertently infected others through their donations[2566]. An oral witness gave evidence to this Inquiry that, despite the fact that she was identified as being HCV positive when trying to give blood in 1994, she received no helpful information from the doctor who she was referred to following her notification, by letter, of her HCV status. She was provided with a leaflet entitled *"Useful advice to blood donors found by chance to be hepatitis C positive"*; it contained no advice regarding possible treatments or steps that could be taken to minimise the risks associated with the disease such as lifestyle advice[2567]. Others have described that at appointments at blood transfusion centres following identification as a result of attempting to give blood, being subjected to questions regarding their sexual activity and drug use[2568], notwithstanding the specific knowledge that such centres had regarding the fact that the transfusions were a potential source of such infections and the fact that such centres had greater experience of counselling patients regarding such matters.

8.11 A relatively small number of core participants were identified via the HCV lookback following transfusions. The issue of individuals being lost to follow up in respect of their bleeding disorder treatment is addressed elsewhere in this submission. Those who were identified via lookback were not provided with greater levels of information regarding the risks associated with the disease or management strategies, notwithstanding the period in which the lookback programme was being implemented and the capacity that should have given those involved in the programme to educate those who might be advising transfusion recipients of their potential infection[2569].

[2566] WITN2997001 @ paragraph 12, WITN4186001 @paragraph 10 and 16,
[2567] WITN2997008
[2568] WITN2109001
[2569] WITN2098001 @ paragraph 6 and 7

9. **Delayed diagnosis**

9.1 Amongst the core participants on whose behalf this submission is presented, there are a number of individuals who have only been diagnosed with HCV in recent years, or after an extended period of ill-health which necessitated repeated appointments and reviews with medics and which, we submit, gave rise to opportunities for the infection to be picked up at a much earlier stage than was in fact the case.

9.2 In one case, an individual who had received blood in both 1986 and 1988, had deteriorating liver function tests in 1988 which prompted his doctor at the Western General to notify the GP of concerns that *"this may be some form of post-transfusion infective hepatitis".* [2570] Despite the individual being followed up for about a year in oncology, it was not until 2016, some 28 years after concern had been raised about symptoms potentially suggestive of post-transfusion hepatitis, that he was tested for HCV. The doctor noted concerns regarding the possibility of there being post-transfusion infective hepatitis in a latter dated 27 May 1988, just 8 days after the announcement of the identification of the virus causing NANBH[2571] but even in those circumstances, it appears that little attempt at follow up was undertaken.

9.3 Another individual, having been advised in 2008 that there was "something wrong with [his] blood work"[2572] (following transfusions in 1971) was only diagnosed with HCV in 2018, despite being closely monitored by his doctor since 2008. This individual notes the longstanding issues he has had at work and home as a result of the symptoms of his unknown HCV status.

[2570] WITN2271003 (anonymous)
[2571] PRSE0003091 (19 May 1988), Ezzell, 'Candidate cause identified of non-A, non-B hepatitis' Nature Vol 333, 19 May 1988
[2572] WITN0831001, witness statement (Anonymous), para 7

9.4 Another witness sets out in her statement that, when she had her second child in 1986, she developed hepatitis, becoming jaundiced. She was initially advised that she might have hepatitis A, but her gynaecologist explained that he thought she had NANBH and advised her that she might have liver disease. He told her that the infection might be related to a blood transfusion she had in 1976, and advised her not to have any more children. The witness underwent a gallbladder removal in 2001, and had a number of issues with her liver (with abnormal LFTs) but was not diagnosed until 2011[2573].

9.5 An anonymous witness provided a statement in which he set out clearly that, following a road traffic accident in 1982 when he was 15 years old, he required a blood transfusion. As an adult, he was a long distance lorry driver, but could not drive for the uninterrupted 4.5 hours permitted under law due to his fatigue. He was diagnosed in 2013; the doctor told him, *"I have good news and bad news for you"*, stating that the 'good news' was that he did not have HIV, but that the 'bad news' was that he did have HCV. The witness states that he had tried to give blood in the 1990s but had been refused because he had himself received blood as a result of his 1982 accident[2574]. In 2001, the witness was found to have significantly abnormal LFTs, but was not followed up. In 2004, he was found again to have elevated LFTs which prompted consideration of a diagnosis of haemochromatosis. It was only in 2013 that he was finally diagnosed with HCV[2575].

9.6 The stepson of a transfusion recipient, who contracted both HIV and HCV from a transfusion of 4 units of blood in 1984 has given evidence to this Inquiry that she was told of her infection with HIV in 1986. Although she was thereafter under the care of Dr Brettle at the City Hospital she was not told of her HCV infection until 1994, shortly before she died in 1995. Given her ongoing care in an infectious disease hospital we say it is striking that either (a) her treating doctors did not think to test her for HCV until 1994, or (b) she was tested for the disease but for some reason was not told of the fact of her infection until shortly before she died.

[2573] WITN3746001 (Carol Craig)
[2574] IBI transcript for 02//07/19: 72 to 73 (anonymous)
[2575] WITN2106001 (anonymous)

9.7 The failure to follow up transfusion patients has exposed not only the recipient of the infected blood to danger, but their families, and even other blood recipients. Some core participants have been 'secondarily' infected, through close contact with a relative who was infected via NHS blood transfusions. Some core participants found themselves to be infected when they themselves tried to give blood after screening was introduced. It is possible that some of these infections could themselves have been avoided had more robust measures been in place to trace recipients of infected blood, or with other measures such as education (including medical and public information campaigns to trace recipients) and to follow up symptoms that were indicative of an HCV infection.

10. Medical records

10.1 Some core participants have found that inaccurate entries were made in their medical records. In some cases, the records failed to note the fact of a transfusion at all. Some had erroneous notes regarding the likely cause of their infection.

10.2 By way of example, the Inquiry heard oral evidence from a witness regarding entries in her medical records suggesting that both she and her former partners had been intravenous drug users. She sought to have that misinformation corrected, and was advised that, although her consultant accepted that his registrar who had written the inaccurate letter was *"simply wrong"*, the letter could not be removed from her files. Instead, a separate letter was provided to 'correct' the error in 2018[2576].

10.3 Although some core participants have been able to have erroneous information about them corrected, many others maintain that their records are inaccurate whether in respect of allegations of other sources of their infection or the absence of reference to a transfusion that they have clear memories of receiving. In some instances, this has meant that individuals have been unable to access any of the support funds. Dr Patricia Hewitt gave evidence to the Inquiry in which she noted that, in the absence of evidence within the medical records of the fact of a

[2576] WITN2076005

transfusion, a description of the procedure or event alleged to have resulted in the need for transfusion was required from the patient. She contended that the advantage of the Skipton appeal panel was that it comprised practitioners who were in practice in the relevant decades and "were aware of what practice was then". That knowledge of practice was applied to the described circumstances of the procedure or event and an assessment, on the balance of probabilities, was made as to whether the procedure or event was likely to have required a blood transfusion. The Inquiry has heard evidence of a broad range of transfusion practices even within single hospitals, across the country, and internationally[2577]. As set out above, there was some guidance in place throughout the period upon which this Inquiry is focussing, but clear evidence of that guidance not being followed. Dr Hewitt confirmed that, in circumstances where a particular procedure would not result in the need for a transfusion in 4 out of 5 incidences of the procedure (so that in 1 out of 5 procedures, a transfusion would be expected to have been required), an applicant without the record of a transfusion in his or her records would be rejected if they alleged that they had received a transfusion when undergoing that procedure[2578].

10.4 Dr Hewitt also gave evidence that, although she was aware of inaccuracies in medical record keeping, where there was reference to other potential causes of infection, such as IVDU, the panel would consider the "counter argument" of the applicant in respect of the claim that the infection was caused by a transfusion. It appears, therefore, that in such cases, where the applicant denies the entry regarding IVDU or the like, he or she is likely to be left with considerable, and perhaps insurmountable, difficulties in persuading the panel of the cause of their infection because it started from the position on appeal as 'a counter argument'. There is no evidence that the panel would take account of the applicant's explanation as to how the misunderstanding might have arisen in the medical records, much less any investigation into how that entry in the medical records

[2577] SBTS0003883_095_0001
[2578] IBI transcript for 10/12/21:67 to 70 (Dr Patricia Hewitt)

came to be made. As set out above, it has been accepted in some cases that entries in medical records can be mistaken.

11. Concerns regarding blood collected from outside Scotland

11.1 A number of transfusion recipients have given evidence that they believe the blood they were given came from America. Although there is no evidence in this Inquiry that whole blood or red cells were ever imported from America, we submit that the conclusions that such individuals have drawn are likely a result of (a) a lack of information being provided to individuals when they were seeking answers and explanations for their infection; (b) the media coverage regarding USA-sourced factor concentrates and the fact that transfusion and factor concentrate treatment were often written about as being one and the same; and (c) the manner in which limited information was provided when the transfusion was initially given. In some cases, there are more 'direct' explanations for individuals believing that they received blood from the USA. An oral witness in this Inquiry gave evidence that, following complications in surgery for an inguinal hernia at the age of 18, he was told he had required a transfusion of three units of blood. In the days thereafter, he and the nurses were having "friendly banter" and he was told that "the blood was from America" and he would "start to speak in a Yankee Doodle accent"[2579]. The evidence suggests that blood may have been collected from USA armed forces bases in Scotland and, for example, during the Edinburgh Festival when increased international travel meant that donors included those travelling from the USA and elsewhere. Therefore, although blood was not 'imported' in blood bags from overseas, it is certainly feasible that blood from American citizens was collected and transfused into Scottish patients.

11.2 In any event, we submit that the conclusions reached by those who believed they received blood sourced from the USA were entirely reasonable having regard to all the circumstances, and, in allowing the vacuum of information to exist and

[2579] IBI transcript for 10/07/19: 2 to 3 (anonymous)

persist regarding this issue, the state has compounded the harms suffered by this community.

12. Conclusions

12.1 Many of the harms visited upon those who had received infected transfusions could and should have been avoided. Some of the transfusions themselves should not have happened. Patients could and should have been better informed regarding the risks occasioned by their treatment, and accurate records should have been kept to ensure that follow up of those who had received transfusions could be properly undertaken.

12.2 The inconsistency of practice regarding when transfusions were administered meant that there was a lottery as to when patients were transfused, with little or no thought being given by clinicians as to whether the transfusion was in the best interests of the patients (almost inevitably, in circumstances where the clinicians were not themselves aware of the risks of transfusion or the reality of blood collection in Scotland). Record keeping was inadequate, with the effect that there was insufficient information passed on to other clinicians that would enable them to be aware of the fact of transfusion, such that assumptions were made as to the cause of subsequently identified infections, and there were frequent delays in even considering the possibility of infection.

12.3 Attempts to introduce audits of blood usage were sporadic and too late. The introduction of Hospital Transfusion Committees and audits of blood usage was recommended over a period of years, with little evidence of impetus to actually act in this regard.

12.4 Those who received transfusions were thus frequently let down by multiple clinicians for extended periods of time. Infections were undiagnosed for years, with risks to those who were infected directly as a result of blood transfusion and risks to their loved ones going unchecked.

J. DOMESTIC PRODUCTION OF BLOOD PRODUCTS

1. Background – the introduction of blood products to the treatment of bleeding disorder patients

1.1 As is explored in some detail above, the steps taken to move towards a system of domestic fractionation in the UK were taken against a background knowledge of (a) the risks of industrialisation of blood products, such as the consequences of viral disease being spread by vaccines which contained human derivatives, such as the yellow fever vaccine and (b) the fatal consequences which could ensue, such as the fatal consequences of HBV infection resulting from the outbreak in the renal unit in Edinburgh and other places which led to the Rosenheim report (see above).

1.2 In the light of the knowledge of those combined risks of pooling which increased the number of potentially infective donors to which recipients were exposed and the risk of fatal disease, it was known from the start of the fractionation project that measures which could be taken for the avoidance of those risks should be. This is shown by the fact that efforts were put into the early development of heat treatment for albumin, which was successful from around 1965.

2. Investment in the production of blood products

Background to the way in which products were provided to patients with bleeding disorders in Scotland

2.1 As is analysed below, the use of ever-increasing amount of factor concentrates, made from large plasma pools in the treatment of patients with bleeding disorders in Scotland vastly increased the risk of them becoming infected with viral infections by increasing the number of donors to whose plasma they were exposed. The Inquiry should have some regard to the history of the way in which decisions were made about the way that blood products would be made and supplied in Scotland. That history is a lengthy and complex one. The important point to realise is that decisions about the way in which blood products would be made in Scotland taken in the 1960s (a) without any apparent consideration of the patient view and (b) without an accurate feel for the likely requirements of bleeding disorder patients in the medium-term future, far less the long term. The investment made in the Scottish PFC (initially the renamed Blood Products Unit or BPU at the RIE and then in the purpose-built facility in Liberton, Edinburgh from 1974) meant that to a significant degree the decisions about the treatment of patients with bleeding disorders equated with the state putting all, or at least most of its eggs in the factor concentrate basket. Though the facility to produce frozen cryoprecipitate remained within regional transfusion centres (as is discussed elsewhere in this submission) the financial commitment to the production of the wide array of blood products which could be made at the PFC included a commitment to factor concentrates as the business of the PFC in that regard was fractionation on a large, industrial scale.

2.2 Initial planning for the construction of the PFC facility at Liberton was taken in the late 1960s. Correspondence from the SHHD to the Treasury in 1968 indicates that the Treasury approval for a new BTS and fractionation facility at the RIE had originally been granted in 1965. By 1968, ironically on the grounds that the fractionation facility needed to be completed before 1974 to keep pace with the proposed development of the English plant at Elstree, a new proposal was made to create the fractionation facility on a separate site.[2580] The accessibility of the

[2580] DHSC0103209_172 (30 May 1968)

Liberton site (in the south of Edinburgh) to the 4 regional transition centres was part of its attraction.[2581] The likely demand for both PPS (albumin) and AHG concentrate were likely to have been too low in the 1965 estimates and were still not clear in that proposal.[2582] This phenomenon of the likely requirement for products being ever elusive would continue to be a phenomenon of the system for decades to come, despite the fact that that the lack of accurate projections for future product need appears to have been flagged up by the Treasury as an initial problem.[2583] That decisions were made on this basis from the start would appear to have been an error which was to render the system forever unfit for the purpose for which it had been designed. As is submitted elsewhere the main reason for this was clinical freedom. The investment in the system at the start of the project needed to have a clear vision as to the parameters within which it could safely operate. Otherwise, those involved in the treatment of patients who needed the products would inevitably wish to push the supply as far as they could. Without such limitations imposed within the system at the start, clinicians treating conditions like haemophilia would seek to make medical advances and by doing so replicate the treatments able to be provided by other systems (like the US) which operated differently from the UK system and hence did not have the same limitations. The failure to make this part of the project from the start was one if its fatal flaws.

2.3 It appears clear that during the time period between the decision making about the commissioning of the new plant, developments meant that the original decisions must have been take at a time when the reality of the blood product market could not have been known. Much changed in the period between the late 1960s and 1974 when the plant at Liberton opened. In 1973, commercial concentrates were licensed for the first time in the UK. Furthermore, it appears that whatever predications were made about the likely demand for blood products in Scotland (and indeed elsewhere in the UK), things had altered

---

[2581] DHSC0103209_172_0002
[2582] DHSC0103209_172_0003
[2583] DHSC0103209_170

considerably as the opening of the PFC plant grew nearer. The developments were discussed at an advisory meeting at which DHSS and SHHD had representatives present on 20 March 1973.[2584] The advice received from experts on the subject of factor VIII concentrate usage appears to have been provided by Dr Biggs and Dr Maycock (the Biggs et al paper referred to below seems to reflect much of the material which is the basis of much of the discussion). No Scottish advisors were appointed to the group, though Mr Watt and the medical director of SHHD were to be seconded after it. The paper shows the background against which planning for future requirements of treatment was being undertaken. Despite the fact that in Scotland the PFC construction project was almost at an end, it appeared clear that the precise number of haemophiliacs in the UK was not known. The number registered with centres was under 60% of the estimated actual number.[2585] The desire for factor concentrates over cryoprecipitate appears to be assumed at the start of the meeting, based on no papers or statistics. There is no suggestion that the patients had been consulted.[2586] The greater risk of hepatitis from pooling is noted 'in theory' but no close assessment of the increased risk is made.[2587] This was on contrast to the position taken by other intimately involved with the project. In a paper of which he was a co-author relating to the production of factor IX concentrate, Professor Cash had complained about the "perennial problem of hepatitis B" which appears never to have gone away.[2588] Of course, the pool size at this time is likely to have been far smaller than the pools used in later years, but this was the basis against which decisions about future use were to be made. The risk of hepatitis infection (HBV) was considered on advice to be not much greater with concentrates than with cryoprecipitate, in practice at that time.[2589] In essence, this seems to be a poor basis for making such decisions – the more effective product seemed to be no more unsafe. The risk of greater transmission is theoretical. No assessment was made of the possible different epidemiological

---

[2584] PRSE0004706
[2585] PRSE0004706_0002
[2586] PRSE0004706_0001
[2587] PRSE0004706_0002
[2588] WITN2235010
[2589] PRSE0004706_0003

risk of future pathogens. The view of the UKHCDO on the matter (in favour of the move to concentrates) was noted and accepted. No virological advice seems to have been taken. It seems hardly surprising that such a cursory view of the pros and cons of future plans for product use was taken. In reality, the decision to opt for concentrates had already been taken by the government. Money had been paid over from the re-development of BPL and the construction of the new PFC facility at Liberton. Licences had been granted for the import of commercial concentrate. The work of this advisory group appears to have been little more than a rubber stamping of a decision which had already been taken. The "theoretical" risks of viral hepatitis are noted but largely ignored. The limiting factors were said to be only production capacity and cost of concentrates.[2590] Against this background the figure used for planning purposes of 400,000 plasma donations for the treatment of all haemophiliacs appears to be a shaky foundation upon which to be planning major projects, especially as at this stage the yield cannot have been easily predicted.[2591]

2.4 The recommendations of this important advisory group at this important time merit close scrutiny in light of how the self-sufficiency project in the UK and in Scotland, in particular, turned out. In the first place, it should be realised that the planning for the increase domestic production of concentrates had already been started some years before, although at this time the expert group was just convened, at this time when goals were being set without any Scottish input. Despite this, it was noted that it was thought to be essential that the production and distribution of the therapeutic agents concerned should be considered as a U.K. exercise and that close co-operation between England (including Wales and Northern Ireland) and Scotland would be required in order to co-ordinate and optimise blood collection and transport, the fractionation processes, distribution of the therapeutic agents, and utilisation of other blood fraction products.[2592] This did not happen in reality. As is set out below, the miscalculations about the likely capacity of the PFC led to the Scottish facility operating independently to meet the

[2590] PRSE0004706_0003
[2591] PRSE0004706_0003
[2592] PRSE0004706_0004

needs of Scotland alone (which it failed to do for many years). In this Scotland gained a huge advantage over the other parts of the UK. It ended up having a fractionation facility of its own which had originally been designed to mee the needs of part of the rest of the UK at least. That Scotland was still not able to achieve self-sufficiency and that it caused so much infection was despite the fact that it had these considerable capital advantages which were not enjoyed elsewhere in the UK.

2.5 Further, it was noted that in any consideration of increased UK production of freeze-dried AHG concentrate, the immediate problems were those of the organisation and cost of increasing donations of either whole blood or plasma (by plasmapheresis) and the difficulties, including cost, of increasing the capacity of the laboratories at present engaged in production. It was recommended that the U.K. should aim to become self-sufficient as soon as possible by increasing home production of freeze dried AHG concentrate, an aim which one might say had already been adopted by the investment in the production facilities some years before. In order to achieve this aim it was recommended that the Regional Transfusion Directors should be consulted about the consequent increased demands upon the Blood Transfusion Services throughout the U.K. It was recommended that discussions should take place between DHSS and the directors about problems of decreasing production of cryoprecipitate and increasing the production of fresh-frozen plasma for fractionation and the possibly increased collection of plasma by plasmapheresis.[2593] The need for more plasma was realised but never properly actioned. Plasmapheresis was never implemented on any great scale and much beyond the collection of high titre plasma for the manufacture of intravenous immunoglobulins. This was despite the fact that the SHHD was aware that there were plans to start or increase plasmapheresis in England and that Scotland may wish to take the same approach in at the latest 1981. In the same memo, on the subject of introducing/ making own HBV RIA, there reference to Scotland having own "devolved" health service which could go its own way.[2594] As

---

[2593] PRSE0004706_0004

[2594] SCGV0000082_041 - 24 February 1981 – Dr Bell (SHHD) note of DHSS meeting

is illustrated in numerous other parts of this submission, this autonomy was little more than theoretical when it came to many matters relating to blood.

2.6 As far as the use of imported concentrate was concerned, it was recommended that the DHSS should give early consideration to the central purchase of freeze-dried AHG concentrate from the firms who had recently been granted product licences and that distribution to other haemophilia centres and hospitals should be through the regional centres, 3 of which would be in Oxford, Manchester and Sheffield in England, 1 in Scotland (Edinburgh or Glasgow) and 1 in London (to be decided). It was recommended that the establishment of such a distribution scheme would be a pre-requisite of the central purchase scheme in order to ensure the most effective use of available material.[2595] Thus, the requirement to control and monitor the use of commercial imports was clearly understood as a prerequisite of maintaining a grip on overall usage and expenditure and also on the success of the domestic scheme. Instead, regional transfusion authorities seemed prepared to write cheques for ever increasing amounts of commercial material to be used in England and Wales and in certain part of Scotland, thus undermining the domestic project and creating an indirect expectation that a similar scheme could be supplied by domestic products in Scotland, with consequences for the safety of that scheme (as explored elsewhere in this submission).

2.7 The planning for the likely future requirements for factor concentrates over this period played a significant part in the designs and planning for the facilities which were to be constructed and set up for domestic production of the UK requirements. A report prepared for the MRC by Dr Biggs and others (including Dr Wallace of Glasgow) which looked at usage in the period between 1969–71 provided an estimate of the future UK requirement for plasma to support domestic treatment (based on an estimate of there being 3,000 patients in the UK) of between 38,327,800 and 53,000,000 units of Factor VIII, requiring 547,540 to 750,000 blood donations per year.[2596] The actual number of haemophiliacs

[2595] PRSE0004706_0004
[2596] PRSE0002359_0018 and _0021

remained unknown, due to the acknowledged limitations of using the numbers registered with centres. This was based on the recognition that that number (around 1,600) did not take account of those treated in non-centre hospitals, to which cryoprecipitate continued to be sent. Further, the calculations appeared to be based on anecdotal evidence about how much more material could be used.[2597] Thus, it could hardly be said that the calculations being done in around 1974 (when this paper appears to have been written based on references in it) were based on any firm scientific grounding at a time when planning for construction of the plants for the manufacture of these very products was well underway. Calculations and planning at that time were based on the then current practice of making freeze dried concentrates from pools of 200 donors which, given the estimate that 1 in 800 donors was HBsAg positive, did not make infection inevitable but was acknowledged as raising the chanced of hepatitis transmission when compared with cryoprecipitate.[2598] The data being looked at was of course already some years out of date. Significantly, it was assumed that home treatment would not generate additional demand would be in substitution for hospital treatment. Prophylactic treatment was thought to be impractical at that stage and so no allowance on the projections was made for it. It is hardly surprising, therefore, that in his evidence to the Inquiry, Dr Peter Foster of the PFC blamed the poor advice given to government at the time of the investment in the domestic facilities in the late 1960s/ early 1970s for the failure of the UK to achieve self-sufficiency.[2599]

2.8 The financial implications of the various means of funding the provision of products for the treatment of bleeding disorders are also apparent in this early documentation which predates the commissioning of PFC in late 1974. The total cost of the building of the PFC facility was £1 million.[2600] The context of this cost needs to be borne in mind. In 1974, planning for the likely projected needs of the bleeding disorder community to be optimally treated (as defined above) were

---

[2597] PRSE0002359_0005
[2598] PRSE0002359_0012
[2599] WITN6914001_0147, para 63.7(ii) – he characterised these failures as having involved an underestimate of the demand for products by a factor of 2 and an overestimate of the yield of factor VIII by a factor of 2
[2600] PRSE0003839_0001 (27 March 1973)

stated by Biggs et al in their paper to the MRC to be £1,800 per annum per patient, which based on the estimated 3,000 patients in the UK would amount to £5.4 million. It is also noted that the planning at that time was based on trying to mitigate this potentially huge commercial cost as it was clearly advised that the production of UK material would be as effective and much cheaper.[2601] In a note of a trip to the PFC while under construction in 1973, it was observed that the reason why investment into domestic production as being made was economic, ie the need to avoid the costs associated with the purchase of commercial products imported from abroad.[2602] The capital costs viewed in the context of the amounts which would otherwise be spent per annum show that the investment was clearly financially wise. Furthermore, the Biggs et al paper gives some important context to assertions that the reasons for investment in UK self-sufficiency were based on safety. They clearly were not. The economic advantages of domestic production were clearly laid out. No comparison of the relative infectivity of the domestic and the imported products appears to have featured in this expert analysis, only their relative cost. In any event, at that time the predictions for the infectivity of domestic concentrates remained gloomy. It was assumed that patients would continue to be exposed to HBV, given the limited likely success which screening tests would have in reducing PT hepatitis.[2603] Thus the drive towards domestic production was based on economic and not safety considerations, as would later be claimed. It is also worthy of note that the perceived economic advantages of home treatment are also relied upon in this analysis. Home treatment is presumed for these purposes to have ended up using the same amount of concentrate as hospital treatment.[2604] The cost of maintaining a patient in hospital for treatment is put at over £100 a week, these patients being described as being "not cheaply maintained by the state".[2605] There was a clear inclination at this stage to get patients out of hospitals and onto home treatment. This was later seen in

---

[2601] PRSE0002359_0021
[2602] DHSC0103209_106 (November 1973)
[2603] PRSE0002359_0013
[2604] PRSE0002359_0018
[2605] PRSE0002359_0021

treatment programmes which vastly increased the amount of factor concentrate to which patients were exposed at home, such as the treatment programme at Yorkhill and the movement and maintenance of children on home treatment programme in Edinburgh during AIDS crisis, despite ana vowed policy that children should be treated with cryoprecipitate at that time due to the risk.[2606]

2.9 Much is made in later commentary on the successes of the PFC of the fact that Scotland was able to achieve self-sufficiency in blood products. The accuracy of this claim is considered elsewhere in this submission but the background to the commissioning of the PFC is instructive in understanding the extent to which this boast is one deserving of credit. In February 1965 planning for a new fractionation facility was discussed at a meeting between the SHHD and the Blood Transfusion Services of England and Wales and of Scotland.[2607] It was estimated at that time that the new facility required in Scotland to manufacture plasma products should be capable of processing up to 1000 litres of plasma per week, including (by implication from a later note) plasma from England. At a similar meeting in May 1968, it was expected that the new PFC would be commissioned in June 1972 with an initial capacity of 1500 litres plasma per week but capable of being increased to 3000 litres per week.[2608] It was agreed that it should be prepared to cope with the requirements of a larger part of England than originally intended, though the precise ambit of this obligation is unclear. By March of 1969, it was agreed at a similar meeting that Elstree should process two-thirds of the plasma from England and Wales with the remainder being processed in Scotland.[2609]

2.10 By 28 March 1973, Mr Watt was reporting nationally that the PFC would have insufficient capacity to fractionate any fresh plasma from England for the production of factor VIII or IX concentrates, its capacity being restricted only to time expired plasma.[2610] Claims for credit that Scotland achieved self-sufficiency

---

[2606] See PRSE0001556_0002 (2 February 1984) in which Professor Ludlam wished to maintain a supply of cryoprecipitate for the treatment of children due to the AIDS risk. Despite this 2 children were maintained on home treatment programmes and infected with HIV in Edinburgh

[2607] PRSE0000808 – "Planning of Plasma Fractionation in Scotland, synopsis by SNBTS of meetings February 1965 – March 1973"

[2608] PRSE0000808_0001

[2609] PRSE0000808_0002

[2610] PRSE0003839_0002 (27 March 1973)

in blood products therefore have to be understood in the context that the facility which was designed to fractionate not only enough plasma to meet Scotland's entire factor concentrate requirements but also fractionate plasma from part of England. That the facility failed even to produce enough factor VIII concentrate to meet Scotland's factor VIII concentrate requirements until around 1984, viewed in the context of what the facility was designed to achieve represents a significant failure in meeting its objectives. The planning for how (which had been undertaken many years before the PFC at Liberton was commissioned in 1974) had already proven to be inadequate. That failure to take account of the true need for fractionated products inevitably led to the need for commercial concentrates to be available to the domestic market in 1973. Planning for the capital investment in the UK facilities had been made in the context of a clear understanding that cost was a major part issue in the drive towards the increased reliance on factor concentrates. Imported concentrates came at an increased cost. Against this background, it is hard to see how the apparently unfettered appetite of haemophilia clinicians for factor concentrates could have been continually fed. The investment having been made in UK production, partly for cost reasons, it is hard to see how that appetite was not controlled to meet the supply which the UK system as able to provide. In effect, the domestic production plan was doomed to failure even before the PFC at Liberton opened its doors. The ongoing failure of the system to adapt to these initial problems and to recognise the fallacy of unrestricted clinical freedom are discussed above.

Freeze-dried cryoprecipitate

2.11 In Scotland, the facilities available historically meant that an option was available for the production of freeze-dried cryoprecipitate at Law Hospital, the based of the WSBTS. At the time of the formation of the factor VIII concentrate group in 1981, it appeared that the options available for consideration for the future of the treatment of those with bleeding disorders included this product as an option.

Information available to the Inquiry shows that this was a product which was used to a far greater extent in European countries, even in 1983 when the AIDS risk was becoming prevalent.[2611] By that time, the UK's unreserved commitment to factor concentrates meant that the Council of Europe recommendation was thought not to refer to them by Dr Gunson in is analysis of it. However, that commitment was precisely the problem. Other countries (see it appears as technologically backward) in fact had safer systems combining the safety of cryoprecipitate with the convenience of the freeze-dried form. They ended up having lower incidence of HIV. HIV has not been proven to have been transmitted by cryoprecipitate (in fact the frozen variety) in Scotland.

2.12 On the basis of this advice, Diana Walford made an assessment of the proposed recommendations to the Council of Europe in 1983, dismissing the main recommendation to rely on small pool products as, in her view, it was possible to avoid concentrates as only 17% of products were cryo (small pool).[2612] Importantly, she ought to change the wording of recommendation 1 (as she was not happy that it would be medically necessary to treat in UK with large pool concentrates) to say that it they should be avoided where reasonably practicable to do so. Her views about availability of even frozen cryoprecipitate contrasted with the position taken about the feasibility of a reversion to cryoprecipitate given by Dr McClelland to the Penrose Inquiry (see above). Again, an English assessment of the recommendation had been taken and adopted without consideration of the different Scottish position. However, such a policy would have been all the more possible, had the safe option of maintaining and indeed increasing the supply of freeze dried cryoprecipitate been taken up 2 years earlier.

2.13 Dr Gabra gave oral evidence to the Inquiry about reports which he had prepared in connection with this possibility.[2613] The reports which he had prepared outlined both the feasibility and the significant advantages of this option, most important

---

[2611] DHSC0001655 at page 2 from May 1983 – this also refers to a virus not being known to be the cause of AIDS but it being regarded as such by the Council of Europe Committee at that time

[2612] DHSC0001659

[2613] BPLL0002088– British Medical Journal , "Factor VIII supply and demand", G.S. Gabra et al, 1980 (11 October 1980); and PRSE0001036 – "Factor VIII Cryoprecipitate and Hepatitis Risk" - The Lancet. Gabra, GS et al, dated 27th November 1982

of which was the safety aspect. The use of this cryoprecipitate would greatly reduce the number of donors to whose plasma those with bleeding disorders would be exposed, hence reducing considerably the risk of viral transmission. The freeze-dried form would have the practical advantages of the factor concentrates, including home treatment. Dr Gabra confirmed that it was use for home treatment of the children at Yorkhill.[2614] For some reason, this treatment is not part of the UKLHCDO records of treatment used there. It could have been a low risk alternative to the commercial concentrates used there. In a 1980 report by Dr Gabra on the use of lyophilised cryo he suggested that the factor VIII C concentration of the production have been improved by improving the technique of production.[2615] The yields achieved had led the NIBSC to state that the product was highly satisfactory in its letter to Dr Mitchell.[2616]

2.14 Dr Gabra confirmed that the results of quality tests were included in the report and confirmed by the National Institute for Biological Standards in 1979.[2617] The production of freeze dried cryo could have been scaled up for wider use.[2618] In his oral evidence he confirmed that other transfusion centres could produce it as it was not a complicated procedure.[2619] There appears to have been no consideration at that time given to producing freeze dried cryo at least for use for certain types of patients only in Scotland due to the lower hepatitis risk such as children or mild/ moderate patients. Evidence confirms that the product was inexpensive to produce and that factor VIII activity could have been raised sufficiently by exposing patients to only 10 - 15 donors.[2620]

2.15 The second 1980 articlsuggested that the factor VIII c yield in normal cryo (made by the rapid 4 degrees C thaw method) was excellent and that the freeze drying did not affect that. In the final paragraph, he advised a reassessment of the method of meeting demand for the treatment of haemophiliacs was undertaken.

[2614] IBI transcript for 03/02/21; 23 (Gamal Garbra)
[2615] PRSE0001701 (1980), page 2
[2616] Ibid page 12
[2617] Para 115 of Dr Gabra statement at WITN5495001
[2618] Ibid page 14
[2619] IBI transcript for 03/02/21; 51 to 52 (Gamal Gabra)
[2620] see EXPG0000044_0058 (fractionation expert group)

This did not happen. The possibility of adopting a mixed model of treatment what he was proposing at that time was simply dismissed. This would have provided a useful safe alternative in the HIV crisis which was just around the corner. It would have made complying with recommendation 1 of the Council of Europe recommendation far more achievable. Holland and Belgium used systems involving freeze dried cryo.[2621] These countries not dissimilar in size and resources to Scotland. In the CBLA commentary on Council of Europe Lisbon conference on 13 June 1983 re AIDS risk by Dr Gunson, he stated, with regard to the Council of Europe recommendation 80(5), number 1 that the recommended move from intermediate concentrate to small pool freeze dried cryo was not warranted as he thought that the regulatory processes in the UK are better than elsewhere. This move would have been feasible at least on a temporary basis if more investment had been made in FD cryo after Dr Gabra's 1980 report. [2622] An opportunity to introduce a safety mechanism into the system was missed at a crucial time. At a meeting of haemophilia directors and transfusion directors as well as SHHD in January 1983, the PFC factor VIII concentrate in use at that time was discussed which was only of intermediate purity.[2623] As the Inquiry knows this purity issue meant that it had have similar problems (such as allergic reactions) to cryoprecipitate. Purity issues were not only known to cause problems like that but also lower purity was associated with a higher viral burden[2624] - this was also the position with the intermediate purity concentrate which drove the work on producing a purer concentrate in later years. The minute mentioned the freeze dried cryoprecipitate experiment in west which had been discontinued due to closure of freeze drying plant at Law. It was thought unnecessary to continue with that due to impending hepatitis free concentrate. Such a product was not forthcoming until April 1987. No consideration was given to the Law project being revived with adequate facilities in 1983 in response to CoE recommendation 80(5).

[2621] Para 155 of Brian McClelland's statement at WITN6666001; see also reference to usage in other countries at references 2 to 4 in PRSE0001701
[2622] DHSC0000335
[2623] PRSE0001736
[2624] see EXPG0000044_0063 (fractionation expert group)

2.16 Professor Lowe said in his statement that the small pool FD cryoprecipitate project "was not progressed, because of the risk of severe anaphylactic reactions which precluded home treatment on safety grounds".[2625] This argument seems hard to sustain based on contemporary evidence and in light of the problems which were in any event experienced with the intermediate purity PFC concentrate.

2.17 A 1983 article reported that freeze-dried cryoprecipitate was used in the treatment of 14 patients with haemophilia A. The in vivo recovery was 91.2% which is comparable to that reported from other parts of Europe. The product was efficacious and **no adverse effects were reported**. Freeze-dried cryoprecipitate is the high yield product of a low technology process and as such may be of value in reducing any possible shortfall in the Factor VIII requirements of the haemophiliac population of the UK. It was also reported that the excellent yield and the simple, low cost technology required for its production make this product suitable for further consideration in the UK if the National Health Service protein fractionation centres are unable to meet the demand for factor VIII with the consequent reliance on commercial, imported sources of factor VIII. Additionally, freeze dried cryoprecipitate would be particularly suitable for developing countries wishing to provide a haemophiliac therapy programme.[2626] Further, it was suggested in 1982 that some paediatric patients were using FD cryo for home treatment, as Dr Gabra confirmed in his oral evidence. [2627] It is interesting to note that even by January 1982 the PFC R&D priorities (presented by Dr Foster) did not include inactivation of viruses.[2628]

2.18 By the time of the Gabra reports there appeared to be a certain artificiality about the discussions relating to the possibility of relying to any extent, far less a considerable extent on freeze-dried cryoprecipitate. The facilities at Law Hospital were old, dating from the second world war. Their quality was brought into question by the Medicines' Inspectorate report. Most importantly, as is narrated

---

[2625] WITN3496013

[2626] WITN4035008 (Hambley H, Davidson JF, Walker ID, Small M, Prentice CRM. Freeze dried cryoprecipitate: a clinical evaluation. Journal of Clinical Pathology 1983; 36: 574-576.

[2627] PRSE0001020 - Minutes of the Factor VIII Study Group, 28 January 1982 @ _0004

[2628] PRSE0001020_0004

above, the PFC had been invested in heavily many years before this. Concentrates were the future, irrespective of what considerations might arise or become more pressing in the assessment of the safety of the products being used. This was despite the fact that only a few years earlier, in 1979, Professor Cash had proposed that production of fresh freeze-dried plasma at Law might be re-considered.[2629] It should be realised that investment in FD cryo in the interests of safety would not have been catastrophic for the PFC operation, however. Many other products were made there, production of which could have continued until heat treatment allowed factor safe concentrate production.

2.19 It is important to note that main reason given by Dr Gabra for the lack of appetite for investment into freeze dried cryoprecipitate was his impression that there were signs were there that safer large-pool virally inactivated products were "just round the corner" at the time of the MI report in 1982.[2630] This is a significant revelation, not just in explaining the demise of the freeze dried cryo but also in explaining the prevailing mood of the time. Whereas scientists like Dr Foster had previously been sceptical about the possibility of successfully applying heat treatment to factor concentrates so as to inactivate their viral content, it would appear that decisions were being made in 1982 based on the assumption that there would be a technological breakthrough soon. This is significant as it means that decision making relating to any possible change in treatment to avoid factor concentrates in light of the AIDS risk by 1983 would have been taken in an environment when such a measure would only have been temporary, pending the arrival of heat treated concentrates.

2.20 This might be appropriately contrasted with the demise of PFC in the face of the vCJD later which could not have been contemplated at this earlier time due to the investment in PFC. Unlike the response to the vCJD threat, economic considerations were put above safety. No reconsideration of the capital investment in the PFC was undertaken in light of the safety implications of the course upon which the State had embarked.

[2629] SBTS0000226_005 – 1 August 1979, Page 3
[2630] Para 120 of Dr Gabra statement at WITN5495001

3. Efforts made to render domestically products blood products safe from infection

3.1 The evidence heard by the Inquiry was that the use of factor concentrates in the UK started to increase significantly from around the early 1970s. From around that time the risks associated with these products based on (a) their pool size and (b) the limitations on what could be done to prevent the spread of infection from them was well known. The dangers of pooling and viral transmission were or should have been realised from the time of the early Cohn fraction I derived product which was made in Scotland from around 1956.[2631] In particular, the limited effectiveness of HBV screening tests combined with the certain knowledge that even the most effective tests would only serve a limited purpose in eradicating the transmission of post transfusion hepatitis (which was known to be caused other than by HAV or HBV) meant that it was imperative that increased reliance on the use of factor concentrates required to have built into it a safety mechanism so that these considerations could be managed and safety maximised.

3.2 John Watt, Director of the Protein Fractionation Centre (PFC), and colleagues presented a paper on plasma fractionation at a Joint Symposium held by the Royal College of Physicians of Edinburgh and the Royal Society of Edinburgh in February 1972. In the discussion on the discovery of the Australia antigen, it was stated that:

"A screening programme which results in identification of HAA carriers among blood donors, even if such identification be less than totally accurate, is bound to reduce the incidence of infection in recipients of whole blood, cellular components and whole plasma. However, it is equally certain that such screen procedures, unless they be absolutely infallible, will not greatly influence the infectivity of plasma products. This must remain the province of the fractionator and the characteristics of his technology until such time as screening systems are capable

[2631] Fractionation expert group report (EXPG0000044_0030)

of identifying HAA presence in dilutions at least six orders of magnitude greater than can presently be detected .... Many commercial fractionators and some state organisations process pools containing as many as 30 000 donations of plasma; one unidentified infected donation would be enough to make the whole of such a pool suspect"[2632]

3.3 The need for solutions beyond the inadequate screening procedures was also emphasised at that time by Professor Cash:

"we must not assume that the elimination of all antigen-positive units will solve the post-transfusion hepatitis dilemma. Current evidence strongly suggests that the present limitations, which have been calculated to represent a detection rate as low as 25 per cent, cannot be entirely explained on insufficient sensitivity of existing methods, and that other agents are responsible for a significant proportion of the problem."[2633]

Professor Cash warned at that time about the risks of transfusion which were yet to be fully defined but made it clear that one thing which could certainly be done would be not to forget about hazards which were already well-defined.[2634] Sarah Middleton co-authored which seemed to work on the premise that even in 1984 there was a considerable residual infectivity of HBV even post routine screening.[2635] This was in addition to the NANBH and HIV risks.

3.4 The fractionation expert group report stated that "the pathogens that may be present in donor blood require that safety is of high interest and of a particular

---

[2632] PRSE0000137_0014 - Watt et al - 'New Developments in Large-scale Plasma Fractionation', Proceedings of the Royal Society of Edinburgh (1972)
[2633] PRSE0002637_0008 - Cash - 'Principles of Effective and Safe Transfusion', Proceedings of the Royal Society of Edinburgh (1972)
[2634] PRSE0002637_0005
[2635] IPSN0000589

focus" in the production of plasma-derived products.[2636] In reality, focus on efficacy in development of heated or purer products and better yield with no consideration whatsoever on safety. The Inquiry heard evidence about the early developments in fractionation technology at the PFC from Sarah Middleton. She worked there as a biochemist between 1969 and 1975. Contemporary materials from 1973 provided some insight into the technology insofar as it was designed to improve safety in the form of early research on factor IX concentrate which was the forerunner to an extent of factor VIII concentrate in Scotland as there was a significant continued use of cryoprecipitate in the treatment of haemophilia A patients.[2637] This article made it clear that the screening which had been instituted in Scotland for HBV in 1971 detected less than 50% of the HBV positive donors and that it should be assumed that factor IX concentrates made in Scotland remained infective for HBV and that the incidence of HBV in the donor population in Scotland was estimated to be 0.07%. Thus the "golden interval" which had been assumed in the general trend throughout the UK for increased concentrate therapy from around 1973 and the increase in home treatment was a fallacy. Further, it was clear that despite this concentrate juggernaut having been given substantial capital funding for the construction of the PFC the juggernaut had been launched with no brakes as there was absolutely no possibility of safety being achieved given the limitations of screening on preventing infection in pooled products, the inevitability of infection by known and new agents and the complete lack of any investment in research and development into any new means of minimising the viral threat. The expert group on fractionation made it clear that the service is now focussed on minimising future viral threats.[2638] It should always have been. It was not until 1981 that any effort was made to try to assemble the knowledge available to the SNBTS to try to find ways of making factor VIII concentrate safe, by the formation of the factor VIII study group.[2639] In his evidence, Dr Perry described

---

[2636] Fractionation expert group report (EXPG0000044_0015)
[2637] PRSE0003648 at _0011
[2638] see EXPG0000044_0067 (fractionation expert group)
[2639] PRSE0001684 - 17 December 1981, Professor Cash wrote to Mr Watt, Dr Perry, Dr Foster, Dr Prowse, Dr Boulton, Dr Pepper and Dr G S Gabra intimating the setting up of the SNBTS Factor VIII Concentrate Study Group (Factor VIII Study Group) and inviting them to be members. The group was to have as its remit the exploration

why that group had been formed. It was based on the premise that they could not sustain a product supply which was transmitting NANB to all of its recipients even measured against the perceived benefits.[2640] By this time, the product was known to be 100% infective. That the safety of the product was only being considered at that point was the whole problems with the system. Dr peery also confirmed that there is no reason why the study group could not have been formed sooner.[2641] Despite this knowledge they operated no plasma quarantine system, like at BPL.[2642]

3.5 Before that time (and even some time after that) experts in the field thought that it would be impossible to apply heat to the factor VIII protein, as had been possible with albumin. In her statement to the Inquiry, Sarah Middleton observed that Factor VIII and Factor IX were regarded as unstable proteins which it was believed would be difficult to heat treat.[2643] Mr Watt's report 'Development of Factor VIII concentrates' in 1973 included no consideration of viral threat or thoughts about what might be done to combat it.[2644] At the start of the concentrate project in Scotland this was not part of the agenda.

3.6 Therefore, the concentrate project had been launched against a background of knowing that the products was infective for HBV and with little scientific prospect of finding a solution to address that. The factor IX research from 1973 indicated that in the period since 1970 factor IX concentrates had been made from donor pools of between 200 and 600 patients.[2645] Despite the absence of any safety measures beyond ineffective screening, that pool size was substantially increased. Pool sizes in the PFC factor concentrates were about 4,000 donations.[2646] Like the need to use every drop of plasma which could be collected, the increase in pool sizes was also part of the price of trying to achieve self-sufficiency as more vials

---

of "new developments in the widest possible sense with regard to the production of factor VIII concentrates and thereby create the opportunity for cross fertilisation and for co-ordinated research within the SNBTS"

[2640] IBI transcript for 31/03/22; 142 (Dr Perry)

[2641] IBI transcript for 01/04/22; 99 (Dr Perry)

[2642] IBI transcript for 31/03/22; 147 (Dr Perry)

[2643] WITN5666001 @ para 7

[2644] PRSE0000678

[2645] PRSE0003648 at _0011

[2646] Penrose Inquiry transcript for 06/09/11 (day 41); 38 - 39; [PRSE0006041 _0038 to PRSE0006041 _0039] (Dr Peter Foster)

could be produced with larger pools.[2647] Sarah Middleton did give some evidence relating to efforts made to achieve clearance of Hepatitis B from Factor IX concentrate using polyethylene glycol precipitation, which were unsuccessful. Against a background of efforts to try to render the products safer which were scientifically unsuccessful, the response was to increases the pool size and the amounts being prescribed. This showed how little regard was paid to the safety of the concentrates. What was needed was investment in the development of technology to stabilise the more labile proteins – it was known that this was what was needed from the early days when albumin was heated in the 1960s.[2648] No such investment came.

3.7 This was despite the fact that there were voices at that time (in addition to Professor Cash) who were advocating the need for advancement in efficacy to me accompanied by similar technological advancement in safety. At the same 1972 Joint Symposium a paper was delivered by Dr John Wallace about the developing fractionation technology.[2649] He talked about the availability at that time of heating of Protein Plasma Solution to eradicate viral hepatitis in an effort to promote the need for these two developments to progress together.[2650] Technology for safety needed to match technology for efficiency.

3.8 The analysis undertaken by Dr John Wallace in his book on transfusion 1977 casts some light on how the efforts to improve the purity of factor concentrates contributed to the diminution of their safety in the late 1970s into the 1980s.[2651] Dr Wallace described the situation in 1977 as being that cryoprecipitate and the then available PFC intermediate purity factor VIII required contained 40% of the factor VIII protein in the original donations, whereas the then available purer commercial concentrates only contained 20% of the factor VIII protein in the original donations. The price for purity appeared therefore to be the need to use larger numbers of donations in the pool in order to produce a comparable amount

---

[2647] IBI transcript for 24/03/2021; 83 (Dr Peter Foster)
[2648] see EXPG0000044_0032 (fractionation expert group)
[2649] PRSE0004564 – "New Approaches to the Supply of Blood and Plasma" By John Wallace
[2650] Ibid at _0008
[2651] PRSE0002052_0020

of international units of factor VIII. This had the effect (a) of increasing the number of donors in the pool but also (b) increase the number of donations of plasma which were required in order to service the process. This must have had the dual effect of exposing the recipient if a single product to a greater number of donors and hence more risk of viral transmission but also requiring an ever-increasing number of donors. In a situation (as Wallace described in 1977) where the main issue in Scotland was no longer fractionation capacity but plasma availability, the drive for greater purity would inevitably place a greater burden on the system for even more plasma and hence the need to be all the more cavalier in its sourcing. Indeed, in his text, Wallace had lamented the fact that warnings given earlier in the decade by Dr Watt and others not to switch more to the use of red cell concentrates for transfusion as opposed to whole blood in order to increase the yield of plasma for the same number of donations had not been heeded.[2652]

3.9 Thus, there was a need to invest sufficiently into domestic production of products. In effect, in the period between the PFC being operational and the emergence of possible heat treatment strategies to minimise the risk of NANBH in the early 1980s (driven not by research and development at the PFC but information gleaned from early commercial developments in that regard) there was little protection against HBV and no protection against new threats such as the potentially lethal NANBH and the emerging threat of HTLV-III. Against this background, blood products manufactured there were described to the patients as "safe". The lack of attention paid to the facility at the PFC is neatly summed up by the results of the MI reports, the first of which dated from 1980. The delays in the commissioning of the PFC until 1975 caused problems with fractionation at the PFC, as represented by Mr Watt.[2653] Problems reported included open processing with free circulation of personnel, components and air, clothing changed next to plasma, control of footwear being inadequate, free circulation of personnel, the plasma thawing tank inadequately protected from contamination, supernatant used in the production of factor IX being left to stand overnight, open to

[2652] PRSE0002052_0019 (1977)
[2653] PRSE0002985_0006

contamination, there being no microbiological monitoring, cryoprecipitate being transported in open container and the microbiological quality of plasma not being monitored. There was no formal staff training.[2654]

3.10 A further MI report was dated October 1981, a paper exercise against the backdrop of assumed Crown immunity (see below). [2655] It stated that:

"The present buildings and facilities continue to fail to reach minimum standards of GMP, and a licence would not be recommended for an industrial equivalent unless agreed upgradings were instituted as a matter of urgency. Possible satisfactory alterations to the buildings and facilities have been discussed, on site, but provision of detailed plans by you is still awaited."[2656]

3.11 It went on to state that "The use of a closed system for plasma stripping, pooling and crushing would substantially upgrade this part of the operation and lead to clearer starting material for extraction of coagulation factors and fractionation product".[2657] This apparent lack of a closed system was not hygienic. Sarah Middleton confirmed in her evidence that the facility at that time was not a particularly clean place to be making a blood products "but it was all we had".[2658] Lord Clarke, who became minister of state for health in 1982, described the blood transfusion service as an "oasis of calm" in his evidence to the Inquiry. The PFC was, in fact, a forgotten wasteland. It was unlicensed, unfunded and unsafe. The products it was producing had the potential to kill. There was no quality assurance scheme before Dr Perry's appointment as QA director after the MI report.[2659] His concerns about the way that the PFC was operating continued into the period after that. He expressed a concern about personal responsibility for operating the PFC

[2654] PRSE0002985, para 5.3.9
[2655] BNOR0000572
[2656] Ibid para 4.1
[2657] Ibid para 4.4
[2658] IBI transcript for 01/10/21; 142 (Sarah Middleton)
[2659] PRSE0004516 page 2

outwith good medical practice/ the minimum standards of the pharmaceutical industry in the interests of self-sufficiency.[2660] This had been the problems with the way that the SNBTS had operated for many years. The system was stretched beyond good practice to meet the unfettered demands of the clinicians.

3.12 The evidence available to the Inquiry also suggests that key decision making relating to product use in Scotland had been taken well in advance of the well-known commitments to self-sufficiency elsewhere in the UK. The decision to invest in national self-sufficiency (meaning in effect for the purposes of the treatment of bleeding disorders, self-sufficiency in factor concentrates) had in fact been taken in the 1960s, when commitments were made to the funding of the new fractionation centre at Liberton in Edinburgh (The PFC). There was a lack of investment in the infrastructure, in particular in considerations of safety.

3.13 Further, the evidence available to the inquiry made clear that there were operational failings in the way that the PFC was run, such that it was not able to run to capacity. This resulted in it being able to produce less than it was designed to produce for the needs of patients. In his witness statement, Dr Foster indicated that the continuous thaw process was not implemented at the PFC until 1975.[2661] This was despite the fact that it had been assumed that the production would be a continuous process from the start, as appears to be the case at the time of the DHSS visit in 1973, before the PFC opened.[2662] It appears that the technique had not been developed until 1975. In fact, the factor VIII production process was not continuous ever as it was overly operated intermittently between 9 and 5 every day due to staffing issues, though it could have been post 1975. [2663] By 1983, Dr Foster had you reached the view that (a) with shift working the fractionation capacity of the PFC could be increased (b) with greater facilities it could be increased 10 fold and (c) that the decision not to use the capacity of the PFC before that point had cost £10 million.[2664]

[2660] PRSE0000712 – 21 December 1987
[2661] page 174 of witness statement at WITN6914001
[2662] DHSC0103209_106_0002
[2663] see ASTM0000039_002_0001 – June 1983
[2664] Ibid

3.14 In addition to these efficiency issues, there appeared to be further operational issues with regard to the achievement of self-sufficiency in Scotland. The PFC appeared to be unaware of the precise requirements of the haemophilia directors. In 1986, Dr Foster referred to such information which he had had you wanted which had not been forthcoming from the haemophilia directors in the past.[2665] It was hardly surprising that such communication difficulties on important issues of supply and demand arose when that only medical (and not scientific) staff would interact with clinicians.[2666]

Heat treatment

3.15 It should be acknowledged that the fractionators across the UK appear to have been aware of and concerned about the risks of viral transmission. Dr Foster's concerns about AIDS based on the two European conferences he attended in 1983 are analysed in detail above. It seems likely that they were aware of the pool sizes and hence the risks which any virus posed to the domestic system. Dr Foster reminded the Inquiry that they always had cryoprecipitate (a small pool product) available where there were concerns. He recalled that in early 1984 an offer was made for more, a substantial amount of cryo to be made available which was refused by the clinicians.[2667] He confirmed that if that offer had been taken up, the PFC could simply have continued to make its other non-factor concentrate products. They did not hide behind the myth that AIDS was an American problem, like the government or the haemophilia clinicians did. An increase in cryo was also contemplated in England. Dr Snape confirmed that the supernatant would just have been passed to BPL by the RTCs for the manufacture of its other products

[2665] HSOC0002690 (18 November 1986, memo from Foster to Perry)
[2666] page 47 of witness statement of Peter Foster at WITN6914001
[2667] IBI transcript for 25/03/22; 33 to 36 (Peter Foster) in the context of PRSE0001556 (2 February 1984) where it was noted that cryo was recommended for the treatment of children only by Professor Ludlam

including factor IX concentrate. That would have been no practical impediment, as had been envisaged might be the case in the evidence of Dr Walford. [2668]

3.16 Efforts were made to try to introduce heat treatment in the early years of the 1980s. The products which were the outcome of these early heat treatment experiments were administered to patients without clinical trial certificates, exemptions or licences. The fact that the licensing authority was kept aware of developments appears to have been the limit of government regulation of these new products. This appears to have been the product of the approach to Crown Immunity being taken at that time (see below). They appear to have been tested initially in rabbits, though were subsequently tested in humans on patients in Edinburgh and Glasgow.[2669] By 2 February 1984, concern was being expressed about the apparent lack of compensation for patients who were taking place in clinical trials who might suffer damage.[2670] Anti-CMV in haemophiliacs also appeared to be a matter which was being tested with their knowledge at that time.

3.17 The haphazard way in which the service had approached the essential need to have a means of making products safe meant that the achievement of heat treated product was largely a matter of chance, based on what information could be gleaned from commercial producers who had invested in such solutions, in the knowledge that a heat treated product would be more valuable in the marketplace. Even in June 1983, it was being maintained that "full and proper funding" was needed for the ongoing heat treatment research, which was not available.[2671] This was despite the fact that information about heat treatment was available to the haemophilia directors which was not shared with PFC as they did not see the UKHCDO minutes.[2672]

3.18 It was often claimed as a great triumph of the PFC operation that it had managed to get a factor VIII concentrate in full circulation which had been heat treated to

---

[2668] CBLA0001691; IBI transcript for 30/03/22; 78 to 79 (Dr Snape)
[2669] PRSE0003851
[2670] PRSE0001556
[2671] ASTM0000039_002_0002, para 5
[2672] HSOC0002690; Dr Foster indicated that information about s technique used by Baxter to enable them to dry heat their product would have helped with planning (IBI transcript for 24/03/21; 90 to 91 (Dr Foster))

inactivate HTLV III by December 1984.[2673] Though this was a positive achievement, this fact in itself needs to be viewed in its proper context. First, the fact that this treatment regime was able to be applied was of scientific good fortune and the existence of a glut of product which had actually put patients at risk and caused infections. The innovation that dry heating the product for 2 hours at 68 degrees was not the result of any scientific discovery in Scotland but as a result of such advances made by others. Information about the possibility that dry heat treatment would eradicate HTLV III had come to the attention of Dr Foster at the Groeningen conference in October 1984 from commercial manufacturers. Though the PFC's efforts towards trying to achieve a heated product had been focussed on pasteurisation in an effort to eradicate the virus which caused NANBH, it was fortunately possible for them to dry heat the products from that point. This was luck rather than design. Further, the reason why all of the Scottish product was able to be heated was due to the fact that by end of 1984, the PFC had built up considerable stocks of factor VIII concentrate. This had been the result of efforts made by Dr Foster which had resulted in better yield being obtained from the plasma collected in 1983. Though this was also a welcome scientific achievement, the system did not adapt accordingly in the interests of safety. The early years of the 1980s had been characterised by every drop of plasma having to be used to meet demand for factor VIII concentrates. This resulted in targets for blood collection being strained and every drop of blood requiring to be collected, meaning that donor exclusion require to be kept to a minimum. The improvement in factor VIII yield offered an opportunity for donor selection practices to be tightened up considerably as it was not the case that every drop of plasma was not needed as more factor VII could be extracted from the plasma. No changed to donor selection policies took place as a result of this. No planning had been out in place – Dr Perry described himself as shocked in November 1983 to have accumulated such stocks.[2674] This missed opportunity to adopt stricter donor selection policies in the key year of 1983 led to this surplus stock. Dangerous donor

[2673] PRSE0001079 (1999) – SNBTS Report to the Scottish Executive on the development of a hepatitis safe factor VIII concentrate by Dr Peter Foster, para 1.3
[2674] IBI transcript for 31/03/22; 126 (Dr Perry); PRSE0001576 – 18 November 1983

collection practices (like going to prisons and military institutions where donations were not given voluntarily) continued. The achievement of the heat treating of this stock allowed old stock to be replaced with new stock. However, the fact that this stock had been allowed to build up was the consequence of the unnecessarily lax donor selection practices being allowed to continue. These had contributed to the causation of many HIV infections in 1983 and 1984. Second, by this time (as it narrated in detail elsewhere in this submission) many patients had already become infected by this time as a result of their treatment with PFC products. Thirdly, the ability to heat the product in such a short time was no great technological achievement. It only needed to be heated for 2 hours and needed no extra equipment beyond an efficient freeze drier associated with an oven or autoclave.[2675] Fourthly, it was not known in December 1984 that the product had been successfully heated to inactivate the virus which caused AIDS. It was merely suspected that this was the case based on what had been gleaned from the scientific discoveries of others.[2676] This is important (as is explored in more detail elsewhere) as it was represented to patients that the product had been treated so as to be safe. This was a misrepresentation which was used to divert attention away from the fact that many had already become infected. Of course, many did not find out about their infections for some time, years on some cases. The conviction with which it had been declared that the new product was safe had played a part in these infected individuals thinking that they were not infected. It would hardly have been of much advantage to them if there was a successfully heated product if they were already infected. The conviction that the product was safely heat treated was also part of the reason why patients in Edinburgh, generally kept in the dark about the precise circumstances of their infections, reasonably inferred that these products must have been tested on them before December 1984, as without human trials it would be impossible to make this claim (as is analysed elsewhere in this submission). This added to the considerable suspicion and harm of the infected group there. Fourthly, a similar heating process

[2675] see EXPG0000044_0088 (fractionation expert group)
[2676] CBLA0001898 (Levy et al, September 1984). This paper (looking at the effects of dry heat treatment on mouse retroviruses) had spiked the product with mouse retrovirus.

was not applied to factor IX concentrate at that time. A heated factor IX product was not available until October 1985. This led to haemophilia B infections in 1985 in Glasgow. Until that time (and until April 1987 in the case of the factor VIII concentrate) both concentrates remained likely to be 100% infective on first infusion for NANBH. The "great achievement" of the PFC, viewed in this context gives a rather different impression. The SNBTS has consistently, when the disaster has been examined in subsequent years focussed on this achievement is one of the cornerstones of the SNBTS's management of transmissible disease from its products. It is one of the key SNBTS "party lines". The Inquiry should take care to take account of the proper facts surrounding this achievement and not the spin out on it in these subsequent years. The lack of attention on these full facts has been a key part of the SNBTS's lack of candour with the infected and affected community in Scotland.

3.19 There was a clear lack of information sharing within the UK services. The evidence heard by the inquiry suggested that no efforts were made by the DoH or the SHHD to ensure a consistency of approach and/ or a sharing of knowledge between the PFC and BPL so that information about the fractionation processes being looked at could be shared, with a view to heat treated concentrates being available to both at the same time and as early as possible. Little occurred other than informal contact between the scientists, which might be described as polite professional conversation based scientific curiosity as opposed to any properly co-ordinated effort. This was despite the fact that sharing of information between the two facilities as early as 1981.[2677]

3.20 Any informal contact between the two was no substitute for a properly co-ordinated effort being made by the two centres towards improving the safety of products. This did not happen, which was a wasted opportunity and symptomatic of the lack of priority given to safety in the continual scaling up of the factor concentrate production in response to unfettered clinical demand. There was a failure to take up opportunities which may have eld to earlier technological advances. At a meeting 17 October 1983, Dr Snape discussed dry heat

[2677] CBLA0001517, para 7

treatment.[2678] Dr Perry explained that this would have involved model viral inactivation data derived from spiking sample with model viruses.[2679]

3.21 This failure to co-ordinate and pool resources, combined with a lack of investment in safety related research led to the anomaly explored elsewhere in this submission that though a safe factor VIII concentrate (8Y) was available in England and Wales from April 1987, a similar product was not available in Scotland until April 1987 (Z8). This caused unnecessary HCV infections, as are explore elsewhere in this submission. The success of the dry heat project at BPL and the move from pasteurisation was discussed in 1984. This did this not prompt a switch at PFC.[2680] Further, the informal contact did not allow the PFC staff to access information about the success of the 8Y clinical trials (which would have benefitted uninfected Scottish patients in 1985 and 1986. The urgency with which Z8 was pursued and the need for these patients to be prioritised is explained by the misunderstanding on the part of Dr Foster that mild and moderate patients were being treated with cryoprecipitate.[2681]

3.22 The delay in the roll out of Z8 was also contributed to by lack of compensation arrangements and was evaluation of Z8 between August 1986 and April 1987 when no such evaluation had taken place on heat treated NY released without such trials in December 1984.[2682]

Loss of self-sufficiency in 1988

3.23 The 1988 failure of the PFC's provision of Z8 led to cases of NANBH due to the need to rely on Alpha's Profilate which was known to carry a risk of infection, described by Dr Forrester as having been appreciated by the licensing authorities but

---

[2678] PRSE0000040 (PFC note)
[2679] IBI transcript for 31/03/22; 156 (Dr Perry)
[2680] PRSE0000428 - 12 January 1984 – Factor VIII study group (SNBTS)
[2681] IBI transcript for 25/03/21; 82 to 83 (Dr Foster))
[2682] 9.1 of PRSE0001709

deemed to be "tolerable"[2683]. Any such infections were probably caused unnecessarily. In any event, the continued failure in the system to achieve self-sufficiency meant that patients were exposed to an unnecessary risk of infection. Profilate transmitted NANBH to 20% of its recipients.[2684]

3.24 This had been caused in part by the requirement to store plasma off site, which apparently caused the dissolving problem with the Z8 in 1988.[2685] The requirement to store the material off site was as a result of storage problems in PFC, which had not been resolved, despite prior warnings.[2686]

Information about products and compensation

3.25 The evidence heard by the inquiry indicated that the relationship between the fractionation service in Scotland and the SNBTS was a close one. This contrasted with the position as regards the BPL in the parts of the UK where its products were used. The evidence heard by the Inquiry was that the BPL was seen by haemophilia clinicians as being just another fractionator, akin to the commercial fractionators from which they sourced their products. The PFC on the other hand was an integral part of the SNBTS operation. Its meetings were attended by the regional transfusion directors but also by representatives of the PFC.

3.26 By contrast, it was always the practice in Scotland that information was shared between the clinicians responsible for the treatment of recipients of PFC products and the SNBTS/ PFC. There was a report of adverse reactions to the PFC intermediate Factor VIII, at a meeting of the SNBTS Directors on 1 July 1976.[2687] At that meeting the practice of informing PFC of adverse reactions to products using specific forms was discussed. Mr Watt stressed the importance of information about factor concentrate use on individual patients being shared with him and the

---

[2683] See PRSE0003962_0001 (30 August 1988 memo by Dr Forrester)
[2684] PRSE0004464 (24 August 1988) – letter from Mr Donald related to Profilate infections in 1988 in Lothian.
[2685] page 96, para (ii) of Peter Foster witness statement at WITN6914001
[2686] see BNOR0000572_003 (MI report in 1981) in this regard - lack of adequate cold storage highlighted
[2687] PRSE0004412_0001

PFC. A particular reaction to a batch of product was reported and discussed in the context of its infectivity with HBV.[2688] There was further investigation of two suspect batches of products was reported at a meeting of the SNBTS Directors on 4 October 1976, using a more sensitive test for HBsAg.[2689] This close relationship continued throughout the period with the Inquiry is concerned.

3.27 By the time that heat treatment trials started in Scotland (as analysed above), efforts were made by haemophilia clinicians to try to ensure that patients who were included within clinical trials of the new products subjected to the experimental treatment methods would have compensation available to them in the event of adverse events.

3.28 In fact, it is hard to see the difference between the position as at the point when viral inactivation studies were underway in Scotland (from around 1983) and the system which had always operated within the Scottish NHS. In Scotland, the State had always benefited from information about the efficacy and safety of its products. Information had always been provided by haemophilia doctors to the SNBTS/ PFC about the products which were used on their patients, as it illustrated above. The evidence heard by the inquiry indicated that the patients generally had no knowledge or involvement in that process. They were unwittingly being used as a means of the State honing the products which it was producing for their treatment as well as the technologies involved in their use. If, as was argued by Professor Ludlam and others from around 1983, there was a moral obligation on the State to provide a system for comprehensive compensation for losses sustained as a result of their involvement in clinical trials in exchange for the, the Inquiry should deem there always to have been such a moral obligation on the State to provide compensation in response to the adverse effects of treatment suffered by the many bleeding disorder patients treated with its products over the years. In essence, such patients had always been involved in clinical trial. The fact that the early products had not been subjected to processes designed to reduce their infectivity was due to the emphasis placed by those involved in producing

[2688] PRSE0004412_0004
[2689] PRSE0000983_0002

the products on features such as yield and purity. In the effort to focus on these features, the patients suffered adverse effects in the form of infection. It seems illogical in the extreme to suggest that the State had a moral obligation to compensate those who may have suffered adverse consequences once fractionators attempted to reduce infectivity but that it has no such moral obligation to compensate those infected by products where no such efforts were being made.

4. Regulatory controls over domestically produced blood products

1. Licensing - the Medicines' Inspectorate

Crown Immunity

4.1 One concept which has acquired almost mythical status amongst those who have sought to understand how the blood contamination disaster in Scotland occurred is that of Crown Immunity. As is discussed in some detail elsewhere in this submission, the licensing authority, in effect the medicines Division within the DoH, issued licenses to the commercial manufacturers of products who wished to sell those products in the UK market. That system is analysed below. There was no such licensing system for products made in the UK by the State, including those manufactured at the PFC in Edinburgh for the Scottish and later the Northern Irish market.

4.2 As is analysed above, in the period when the infections with which this Inquiry is concerned in the bleeding disorder community occurred in Scotland (pre-April 1987), the licensing regime did not apply to state bodies such as the SNBTS because of the doctrine of Crown Immunity. This as deemed to have covered the PFC as well.

4.3 The doctrine of Crown Immunity is a legal one. It represented the immunity for the Crown from action for damages in delict (tort) and meant that the Crown could not be sued in an action for damages arising out of the alleged negligence of one of his servants, or a person for whom it was alleged that the Crown was vicariously liable. The application of the rule in Scotland was not without judicial controversy, though its status as good law was confirmed by the Inner House of the Court of Session in the case of *McGregor* in 1921.[2690] In that case, it was confirmed that the English law principle of the immunity of the Crown had been made part of Scots law at the time of the Treaty of Union in 1707. The Lord Justice Clerk endorsed the words of Gloag on Reparation to the following effect:

"The maxim that the King can do no wrong takes away the ground of an action of damages, and leaves the injured party without a remedy in a Court of law." Then he goes on to say: "This protection extends to public departments, to officers of public departments when their action has been instructed by the State, and to British subjects carrying out the orders of a foreign sovereign in his territory.""[2691]

4.4 The Lord Ordinary, Lord Anderson had cited in his opinion the cases which were the English law principles that though the Crown could be found liable for damages in contract, it could not be found liable in the law of tort.[2692] Interestingly, though agreeing with this interpretation of the law, Lord Salvesen expressed some reservations about the fact that this was the legal position, as follows:

"The present state of the law, as it has been settled in England, does not appear to me to be satisfactory, because it leaves it in the option of a department to accept liability where it pleases, and to repudiate liability where pressure is not

---

[2690] *McGregor v Lord Advocate 1921 SC 847*
[2691] Ibid @ 852 per LJC Scott-Dickson
[2692] Ibid @ 848 per Lord Anderson*; Thomas, (1874) L. R., 10 Q. B. 31;* and *Windsor and Annapolis Railway Co, (1886) 11 App. Cas. 607)*

brought upon it, possibly from political sources, to accept liability. I do not think it is desirable, from the point of view of public policy, that a department should be in that position, and it may well be that the present state of matters ought to be the subject of legislative amendment." [2693]

4.5 Thus, he saw the rule as archaic and logically hard to defend. Why should a public body escape liability in circumstances where another entity would be found liable? These arguments appear to be of relevant to the question of why the blood transfusion services should have enjoyed Crown immunity in Scotland in the period with which the Inquiry is interested. Why should these standards be allowed to drop below the standards of reasonable conduct which were expected as a matter of law of other organisations in the normal course of human affairs?

4.6 The law was changed by the Crown Proceedings Act 1947. The Crown was rendered liable for wrongs committed by its servants or agents, provided that, apart from the provisions of the Act, the act or omission complained of would have rendered the servant or agent liable.[2694] The Crown was also made liable in respect of any breach of those duties which a person owed to his servants and agents as their employer, and in respect of any breach of the duties attaching at common law to the ownership, occupation, possession or control of property.[2695] Where the Crown is bound, whether expressly or by necessary implication, by a statutory duty which is binding also upon persons other than the Crown and its officers, it is liable for breach of such a duty in the same way as if it were a private person.[2696] No proceedings, however, will lie against the Crown in respect of acts or omissions by judicial persons or by public servants, such as policemen, not directly or indirectly appointed by the Crown and paid out of the Consolidated Fund or certain other national sources.[2697]

[2693] Ibid @ 852 - 853 per Lord Salvesen
[2694] Crown Proceedings Act 1947 ("the 1947 Act"), section 2(1)(a), "Agent" is defined as including an independent contractor employed by the Crown (section 38)
[2695] 1947 Act, sections 2(1)(b) and (c); the Crown is bound by the law on occupier's liability by section 4 of the Occupiers' Liability (Scotland) Act 1960
[2696] 1947 Act, sections 2(2)
[2697] 1947 Act, sections 2(5) and (6)

4.7 Section 19 of the National Health Service (Scotland) Act 1972 provided for the constitution of the Common Services Agency for the Scottish Health Service (the CSA) with effect from 1 April 1974. Amongst its several responsibilities was the operational management of the blood services. In Scotland, the advice of Scottish Law Officers from 1979 was that Crown privilege applied to the CSA and Health Boards in Scotland, altering advice previously given. As a result, licences granted prior to 1979 were allowed to become time expired.[2698] It is of interest to note that the advice of the law officers must have been requested at that time. Though not absolutely clear why, it seems unusual that a system of licensing had been in place and that something had triggered the instruction. It seems hard to imagine what could have done so, other than a desire to revisit a legal issue which could get the system off the hook if anyone were ever to question to the quality of its practices. Though the SNBTS maintains that it adhered to a system which adhered to GMP as if it required to be licensed, this is clear not accurate. This is shown by the MI reports from the early 1980s. In any event, the licensing system would not have looked at important elements of safety such as the collection of blood. What had been acquired by the system in 1979 was in the nature of a legal get out of jail free card of and when the system was proven to be unsafe. It can reasonably inferred that the person who sought such advice did do in the knowledge that licenses would not be granted if required as the system was indeed unsafe. Rather than take steps to improve safety at the time when evidence was starting to accumulate that there was a new, potentially dangerous viral threat, the system was seeking to take steps to evade any responsibility.

4.8 The fact that Crown Immunity was deemed to apply to the operation of the PFC and the blood transfusion service more generally in Scotland (and more widely in the UK) was redolent of a system which did not permit accountability and hence had no real driver to ensure safety of its products. This observation clearly applied to quality and efficacy took the complaints of the haemophilia directors as to the purity and efficacy of the PFC intermediate purity factor VIII concentrate manufactured at the PFC (NY) analysed elsewhere in this submission demonstrate.

[2698] PRSE0000985

In any event, the application of the doctrine to a transfusion service which claimed to be a world leader compromised scrutiny and hence ultimately safety. Actions of clinical negligence had competently been taken against Health Boards in Scotland for damages arising from the negligence of NHS staff over this period.[2699]

4.9 In 1982, the Medicines' Inspectorate undertook inspections of SNBTS facilities, including the PFC, outwith the ambit of any formal licensing regime, as due to the 1979 advice licences were no longer required. Particular elements of these inspections and the inadequacies which they revealed relating to the transfusion centres are discussed elsewhere in this submission, As regards the general status of these inspections, on 14 February 1983, a representative of the DHSS wrote to a colleague within SHHD regarding the Medicines' Inspectorate and the policy issues relating to product licences for the UK products, in response to a previous letter of 7 January 1983. In light of the licensing position, the first issue addressed was the basis of the inspections. It seems clear that this had been questioned by the SHHD in light of the absence at that time of any clear licensing system. It seems a logical corollary of that starting point that the authority of the inspectors and the purpose of their inspections might be called into question, no doubt as SHHD was requiring to deal with the multiple problems they had found with the centres and the PFC. That is clarified as being health circular HSC (IS) 144 which means that the inspectors are charged with looking into "activities concerned with preparations of human blood which are medicinal products". It is noteworthy that the ambit of the inspection at that time was the manufacturing processes associated with the production of blood products and not "the source of the raw material" without this is something in which it is said that the Inspectors had an interest. It is suggested that for this to be the focus of the work, an extension of the ambit of the health circular would be required which was not at that time envisaged. Though they had something to say about the practice of collecting blood from prisons, this was not the main focus of the regime under which these non-legally

[2699] See for example Reid v Greater Glasgow Health Board 1976 SLT (Notes) 33; Baxter v Lothian Board 1976 SLT (Notes) 37 (no competency challenge regarding documentary recovery to action based on clinical negligence); Steward v Greater Glasgow Health Board 1976 SLT (Notes) 66; Kay's Tutor v Ayrshire & Arran Health Board 1986 SLT 435

required inspections were being carried out. Thus, what limited inspection as there was did not focus on the safety of the collection of blood but on its processing into a blood product which (at that time) did not involve viral safety mechanisms. The focus of the inspections had therefore been on the "premisses, equipment, procedures and staff" as a basis for future inspections. Therefore, it seems that between these inspections were somewhat preliminary in nature. The start of 1983 was of course a significant moment in time when recipients of blood and blood products might reasonably have expected there to be some system of government inspection which would be designed to protect them from the existing viral threat of AIDS as well as HBV and NANBH. The standards applied were those of GMP to be found in a combination of the "Red" and "Orange" Guides.[2700] The letter refers to a suggestion in the earlier January letter that the fact that the blood/ plasma is being used to make blood products makes biological hazard inevitable. The response refutes the suggestion that because of the biological risks accepted in the product's use that the Inspectorate could ignore the biological standard of the source material and the microbiological standards in which the product is processed.[2701]

4.10 On the issue of licensing, the letter indicated some bemusement at the issue of licensing being raised as it was thought that it had been settled two years before (ie in 1981, presumably in the aftermath of the 1979 change of legal opinion on the issue of Crown Immunity from the Scottish law officers). The letter confirms no product licenses had required for blood transfusion centres Scotland on the basis of legal advice from the Scottish law officers in 1979 to the effect that Crown Immunity did apply in Scotland. This was a change of legal view as the previous view had been that in Scotland, unlike in England, Crown Immunity did not apply to the Scottish transfusion centres. As a result of this previous legal opinion, licences had been issued for the transfusion centres in 1986, which were allowed to lapse after the change in legal position after 1979, when no new licences were issued. It is suggested that SHHD had intended to issue "letters of approval"

[2700] PRSE0000985_0001
[2701] PRSE0000985_0002

indicating that they were satisfied with the centres as would previously have been required for the issue of licences which had been issued in 1976. No indication is given as to whether these letters or what effort was out into their issue or indeed what required to be done for the licences to be issued in 1976. There is no suggestion that inspections occurred in 1979 similar to the later MI inspections. The system was underpinned by a changing legal view of the application of a principle which seems to be in contravention of the provisions of 1947 Act. There would appear to be no good reason why the provisions of the Act should not apply to the transfusion service, which was in essence a branch of the NHS. The confusion around this area seems to have played a part in the inadequate system of government inspection of the safety of the blood products coming from the PFC, though it precise status is not made clear in this correspondence. Whether under the banner of Crown immunity or not, the government system of monitoring the safety of blood and blood products sems to have focussed on process and not the safety of the raw material. In any event, the precise role of that inspection of process remained unclear in a system where licences were not required and no clear sanction could be applied by the inspectors.

4.11 In a paper by Professor Cash, written in January 1984 he set out the position in which the position (after 1979) from his perspective. He set out the aspiration (and it was nothing more than that) that despite the lack of legal requirement for the SNBTS or the PFC to hold manufacturing or product licences, they should strive to conduct themselves as if they did.[2702] It seems that the 1982 MI inspections and the response to them in 1983 had not brought about the kind of licensing regime or adherence to standards which he would have wished. In the words of Dr Perry at the Inquiry, the operation of crown Immunity at the PFC had always been an unsatisfactory arrangement and it had always been a "moor point" as to what licences or inspections meant.[2703] In effect, this meant that the position was poorly understood and there was no real regulation. What remains unclear is why the rest of the NHS was not ever claimed to benefit from this immunity in its dealings

[2702] PRSE0002460_0002, 'Medicines Inspectorate/SNBTS activities: current unresolved problems'
[2703] IBI transcript for 31/03/22; 20 (Dr Perry)

with its patients. The PFC appeared to be accorded a special status. For whatever reason, that status put patients at risk. As Dr perry pointed out, there was no option for the facility to close down, or be closed down.[2704] There was no sanction due to the supply needs.

4.12 In July 1986 a meeting was held relating to the standards applied to the screening of blood used in the production of factor VIII produced at BPL in response to a request for clarification from the DCMO about recent realisation that not all plasma collected for that purpose had been screened for HIV.[2705] The context of the meeting relate to the possibility that the production facility would in future require to be made subject to the provisions of the Medicines Act and apply for product licences but not a manufacturing licence. It was thought to be the position that BPL benefitted from crown Immunity as a "special health authority" and hence had never held not applied for a manufacturing licence, not product licences. The particular issue for consideration was why BPL was allowed to apply lower standards due to Crown immunity as a result of having used unscreened plasma to make 8Y when the commercial companies were required to use screed plasma. Similar to the position of the CSA/ PFC, there seems to be no logic as to why BPL should have benefitted from Crown Immunity when the other NHS trusts in England did not. It was clarified that by that point the NIBSC were checking batches from BPL, implying that that was recent invocation but that it was not known if all batches were so checked.[2706] In paragraph 5 the anomaly which also applied to PFC was set out. It was observed that BPL supplied around half of the UK's factor VIII by that point which would cause problems is licenses were needed as that would cause an intolerable interruption to supply. Supply came before safety. It was noted at paragraph 7 that PFC was still thought to benefit from Crown Immunity, as did other facilities like Porton Down and that the requirement for licensing at BPL would have a knock-on effect at these other facilities. Though licensing was deemed desirable, at paragraph 9 no solution was reached about

[2704] IBI transcript for 31/03/22; 40 (Dr Perry)
[2705] DHSC0001059
[2706] DHSC0001059_0002

what would happen if a currently distributed product failed to reach the inspectorate's safety standards.

4.13 By December of 1986, under reference to the same DCMO who had been referenced in the document above (Dr Harris), Professor Cash had become aware of this debate and expressed his astonishment at learning that having product licence results in loss of Crown immunity, a proposition of which he and the CSA appear not previously to have been aware.[2707] In the same month Dr Ludlam wrote to Professor Cash to urge him to ensure that compensation arrangements are made within SHHD for clinical trials in vivo of the new Z8 product, given that he understood it to be the case that Crown Immunity was to be withdrawn from PFC.[2708]

4.14 By the time that Z8 started to be produced in April 1987 there was still an ongoing debate going on about whether the legal doctrine of Crown Immunity exempted the NHS (and hence the PFC) from the legal requirement to obtain manufacturers' and product licences in respect of products manufactured by them. In his evidence to the Penrose Inquiry, Professor Ludlam initially thought that Z8 had been issued "under Crown Immunity" but later thought that it may not have been and that it was subject to the provisions of the Medicines Art by this time. If the interpretation is correct, given that no product licence or clinical trial certificate had been issued, it appears that Z8 must prescribed to patients on the basis of the 'named patient' exemption in the Medicines Act 1968 (which applied to medicinal products 'specially prepared' for a doctor 'for administration to a particular patient').[2709] In any event, it appears that the product was issued under licensing conditions which were far less stringent then would have applied, had a product been issued subject to licensing requirements today. The doctrine of Crown immunity did not constitute a defence for the NBA in the case of A v NBA, in the opinion of Burton J.

4.15 By 11 May 1987, legal advice was provided within the CSA seeking to summarise the position, it would appear in response to the position being taken by Professor

---

[2707] PRSE0003296
[2708] PRSE0000696
[2709] Medicines Act 1968, sections 7, 9(1) and 31

Cash who asked in the previous year about the consequences of holding a product licence.[2710] A summary of SHHD guidance was provided which had since 1975 remained that product licences need to be applied for. This appeared to be inconsistent with the change in the view of the law officers on that matter. It was suggested that the Lord Advocate appears to have expressed a stronger view on the matter in 1981 but that that had not altered the guidance issued by SHHD from 1975. The position as expressed in the memo was that no Crown Immunity could be pled in a claim of negligence arising from product manufacture, based on the 1975 guidance. At the very least there appeared to be significant lack of clarity about whether and certainly why Crown immunity was said to apply to the PFC/ transfusion service. The narrative does not seem to make out any special a case for the transfusion service or the CSA, the detail relating to the opinion relating to Crown Immunity applying to Health boards. What this spells out was that over the crucial period from the late 1970s into the early to mid 1980s, no product or manufacturing licences were held despite the fact that the SHHD guidance in place since 1975 had stated that they were necessary as Crown immunity did not apply to the NHS in Scotland. Reference was made to a decision by Lord Prosser regarding Crown immunity against interim interdict (interim injunction) which concerned the question of whether the immunity from having such an order pronounced against the Crown applied to Greater Glasgow Health Board. That case was BMA v GGHB [1989] AC 1211, in which the House of Lords eventually decided that such immunity against interim interdict did not extend to GGHB.[2711] The case does not, as it happens, determine the main issue of Crown immunity relating to the NHS in Scotland as the issue was defined more narrowly as only relating to the provisions of section 21 of the 1947 Act which relate to interdict/ injunction:

[2710] PRSE0002909

[2711] Lord Prosser's opinion in the Outer House is reported at 1987 SLT 130

"I consider that they failed to address directly the critical question which is not whether health boards perform functions on behalf of the Crown—a matter which was not disputed by Mr. Bruce for the respondents—nor whether health boards for the purposes of statutory immunity or other purposes fall to be treated as the Crown or as agents so clearly identified with the Crown that they are for all practical purposes indistinguishable therefrom, but whether the respondents' petition amounted to "proceedings against the Crown" within the meaning of section 21(1) of the Crown Proceedings Act 1947. The four authorities to which I have referred were not concerned with this point. That Act, as Mr. Bruce pointed out, is not concerned with Crown immunity and who qualifies therefor, but in the words of the long title with "the civil liabilities and rights of the Crown" and "civil proceedings by and against the Crown." Indeed, section 40(2)(f) specifically provides that the presumption of Crown immunity from statutory liability is not to be affected. The two primary objects of the Act were (1) to enable a plaintiff in England to proceed against the Crown as of right instead of by petition of right, and (2) to subject the Crown in both England and Scotland to actions founded in tort and delict in the same way as other defendants and defenders."[2712]

4.16 Lord Jauncey also stated in his speech that the Inner House of the Court of Session had decided the case on other grounds which he did not think necessary but did not disagree with, as follows:

"All three judges in the Second Division, 1988 S.L.T. 538 concluded that, although a health board performed certain functions on behalf of the Secretary of State, it was not the Crown and therefore not entitled to protection under the Crown Proceedings Act 1947. I do not in any way criticise these conclusions, but I do not find it necessary to decide this case on so broad a basis, preferring to rely on a construction of the sections above referred to."[2713]

[2712] 1225D per Lord Jauncey
[2713] 1227E per Lord Jauncey

4.17 In the Inner House, the Lord Justice Clerk Ross had said:

> *"In my opinion what Lord Diplock states regarding English public law is also true of Scottish public law. In Scotland as in England I am of opinion that "the Crown" covers ministers of the Crown and members of the civil service acting under the direction of ministers. However, I see no justification for holding that "the Crown" also covers bodies such as health boards which exercise some of the functions which have been delegated to them by the Secretary of State. In my opinion, for the purpose of determining who are included in the expression "the Crown" it is important to draw a distinction between government departments on the one hand and bodies like health boards on the other. Counsel for the respondents expressly stated that they were not contending that a health board was a government department or part of a government department. The Crown and a minister who requires to discharge statutory duties can only act through servants or agents, but I see no justification in principle for holding that every agent or servant of the Crown falls to be equiparated with the Crown itself. As Lord Diplock pointed out in Town Investments v. Department of the Environment, the Crown will embrace certain civil servants employed in various government departments, but I see no justification for holding that every body or person who is a servant or agent of a Secretary of State should be held to have Crown status."*[2714]

4.18 Thus, it was held in Scotland that the concept of Crown immunity should not in a more general sense be applied to Health boards, which was consistent with the position which had been advanced in the 1975 SHHD circular. Immunity would not in any event have prevented the boards from being sued in negligence due to the provisions of the 1947 Act. Despite this, the impression in the day to day activities of the transfusion service in Scotland was that it die in fact have the benefit of Crown Immunity. It was not subjected to official inspections. It faced no sanctions

---

[2714] Per LJC Ross @ 541G

when unofficial inspections occurred in 1981/ 82. Licences were allowed to lapse. There was no official, formal control of the system of blood collection or the production of blood products in Scotland. There was thus no effective system of oversight of the service based on an erroneous impression of the law and a failure to appreciate that the 1975 guidance did not change after the law officers' opinion in 1979.

4.19 The confusion about the need for licences at Scottish SHHD and within the transfusion services appears to have continued. At a meeting on 26 October 1986, it was thought that there was or was about to be a new culture post "removal of Crown immunity. It was suggested by representatives of SHHD that the new consumer protection legislation would remove Crown Immunity in the sense that it would not protect the service from actions based on breaches of the new Act's provisions but that other aspects of Crown Immunity would remain the same.[2715] The possibility of the SNBTS applying for a manufacturing licence was discussed, indicating that there was still none in place. In any event, it was made clear that certain activities of the transfusion centres could not be covered a manufacturing licence anyway, as they were not covered by the provisions of the Medicines Act. This indicates that even if certain elements of the transfusion centres' work (presumably related to the manufacture of blood products) could in theory be covered by a licence, not all could and thus these activities (presumably related to the collection of blood) could never be regulated under the existing regime.[2716] Products licenses were discussed and it was stated again by SHHD (contrary to the guidance document From 1975) that there was no need for there to be product licenses due to Crown Immunity. SHHD suggested that the SNBTS might apply for product licences "for purely presentational purposes" as to their safety and in order to remove the temptation from clinicians to buy commercial products at a greater cost to the NHS. It was therefore agreed that licences would be applied for where there was a clear presentational purpose in doing so subject to the recognition that the licence actually provided no greater assurance of safety and

[2715] PRSE0004722
[2716] PRSE0004722_0001 to _0002

was, in effect, a meaningless gesture.[2717] The minutes of this meeting are annotated with a series of exclamatory and question marks. This seems hardly surprising, given the frankly ridiculous content of the text. It is clear that the erroneous interpretation of the legal position within SHHD had resulted in there being no effective means by which the government undertook any regulatory control of blood or blood products collected or produced by the NHS in Scotland.

4.20 This meeting was followed up by a further letter from the SHHD to the CSA seeking to clarify the government's position, dated 16 November 1987.[2718] The position of the SHHD on the matter appeared to be as follows:

- The SHHD thought that Crown Immunity did apply to the operations of the transfusion service and that the provisions of the 1968 Act did not apply to the production of products as acting as servants of the Crown;
- The SHHD was not overly worried by the BMA vase as it would turn on a narrow point of construction about section 21 as opposed to a wider legal point about the application of Crown Immunity. As is analysed above, thought this was ultimately the way that the case was disposed of in the Lords, the Inner House's determination of the case on the wider point of principle stood as good law and determined that the legal interpretation of the department about the crown Immunity of the transfusion service was wrong;
- It was noted that the 1975 guidance circular which the SHHD had issued (and had not been changed) contradicted the legal interpretation being presented in the letter. In any event it seemed to be of concern that the 1975 guidance (which worked on the basis that there was no Crown Immunity) was not being adhered to by the transfusion service. [2719] This appears to make little sense based on the expressed opinion that Crown Immunity did apply but, in any event, it shows that the service was not complying with the requirements imposed when it was thought not to; and

---

[2717] PRSE0004722_0002
[2718] PRSE0003017
[2719] PRSE0003017_0004

- The specific issue is raised about the fact that the holder of a product licence would need to provide a data sheet as a condition of the licence being issued with details about the product, including its safety.[2720] It is of significance to note that product information leaflets issue with products produced by the PFC were misleading or at least incomplete as they did not contain warnings to patients such as there being no warning about the possibility of HIV transmission on the pre-December 1984 factor concentrate. This makes clear that they were unregulated based on the erroneous impression that there was no need for regulation, as Crown Immunity applied.

4.21 The context in which these letters were being written is important. The correspondence relating to whether Crown Immunity existed spans the period over which blood products were infective (pre heat treatment) and over which important blood safety measures such as anti-HCV and anti-HCV testing as well as the possibility of surrogate testing for NANBH or HTLV-III were being discussed. The resistant attitude of the SHHD to measures being taken to promote safety over this period is discussed in detail elsewhere in this submission. However, these measures were all being considered (and rejected or at least not implemented with urgency) against a background where SHHD erroneously believed that the transfusion service enjoyed immunity and thus there was no pressure to act. Even when the provisions of the 1987 Act came into force in March 1988, a culture existed whereby matters of blood and blood product safety were not accorded adequate priority within SHHD, even though it was accepted that Crown Immunity did not accord statutory immunity under the 1987 Act. Crown Immunity appears to have played a prominent part in SHHD's thinking about and approach to these matters. It did so based on an erroneous understanding of the law and in contravention of its own guidance from 1975.

4.22 The claimed policy of the NHS in Scotland at the time was to aim to comply with good manufacturing practice, as if Crown Immunity did not apply. However, the erroneous understanding regarding the existence of the doctrine meant that there

---

[2720] PRSE0003017_0002

was no sanction which could be applied. The absence of sanction meant that there was no real impetus to ensure that standards of good manufacturing practice were adhered to at the PFC, that safety was put at the forefront of practice of that funding was maintained to ensure that these aims were met. In reality, the system of treatment for bleeding disorders meant that the NHS was almost entirely dependent on the PFC for its factor concentrates. The system could not tolerate the machines simply being switched off. This, there was no real control where the system was so dependent on the PFC and there was no real sanction which could be applied when there were departures from GMP.

Conclusion

4.23 The PFC was operated under the nebulous concept of "good manufacturing practice", which was poorly defined and could not really be enforced. The problem with the commitment to self-sufficiency was that it was a noble aspiration at a time when the brakes should have been applied at the start of the PFC project in the 1960s but without any such brakes the project quickly an out of control. When the risks of the products were known, the "concentrate juggernaut" was launched in Scotland where (i) safety considerations could have been prioritised such that they were invested in and incorporated at the start of widespread concentrate use in Scotland and/ or (ii) the use of imported concentrate could have been prohibited from the start. The problem was that the tail (the haemophilia clinicians) was wagging the dog (the system responsible for the production and provision of blood and blood products). The haemophilia clinicians able to insist on a supply of products where they were deemed to be unsafe. That this was the system indicates a complete failure of any regulatory step in the inception or development of the system of blood and blood products in Scotland.

2. Information about the risks of products provided to medical practitioners and patients

4.24 From 1977, under reference to the recommendations made in the British Pharmacopoeia in 1973, it was noted by Dr John Wallace that simple instruction on labels were effective in conveying important information to laboratory workers and clinical users of blood products.[2721] It had always been part of the system of the production of blood products that warnings were included with or on the products as to the risks associated with that product. The ultimate potential victim of any such risk manifesting itself was the patient. The patient required to make decisions about the use of the product in consultation with his doctor, who had an obligation to advise the patient about the risks and benefits of the product under consideration. It is clear that the manufacturer was always deemed to have a role in that and the assist both the doctor and the patient in that important decision making process. In an analysis of the events surrounding the infection of haemophiliacs with HIV in Edinburgh prepared for a litigation, Dr Robert Perry of the PFC clarified that though hepatitis warnings had always been included with the PFC products, no HTLV III warning was ever included with the unheated factor concentrates produced there on the basis that "there was no firm scientific evidence to support or justify such a warning".[2722] This is simply a manifestation of the conclusive proof fallacy which is examined in detail elsewhere in this submission. As it was well known at the PFC that the products were being used at home, it ought to have been considered that the package insets were an important means of information being conveyed to the patients and their families.– why was the Though information was included in PFC concentrates about the hepatitis risk, this was limited to a reference under "side effects" to the words "apart from the general complications of hepatitis and...".[2723] This was hardly explicit given that it was 100% infective.

[2721] PRSE0002052_0010 (1977)
[2722] PRSE0001885_0003 - _0004 - 14 March 1988
[2723] PRSE0001885_0013

4.25 The FDA issued regulations to try to control the transmission of AIDS by blood and blood products, dated 24 March 1983. In Scotland, consideration was given within the SNBTS to the extent to which it was thought appropriate that the FDA regulations should be followed. In correspondence with Dr Perry at the PFC, Dr McClelland questioned whether the FDA regulations about labelling products which were derived from the plasma of donors who may be at risk of AIDS should be followed in Scotland.[2724] It is clear from this letter (a) that the SNBTS was well aware of the content of the FDA advice which had been sent to blood banks and plasma producers by the FDA on 24 March 1983 and (b) that Scotland continued to have (and apparently be able to identify) donors who were thought to be at a risk of having AIDS. Though steps were apparently being taken to use the plasma for the these donors in the production of plasma protein solution (albumin) and immunoglobulins (which would be thought to have no consequent risk of viral transmission), there was a failure at this stage appropriately to realise that the donors should be excluded from donation completely due to the risk of their donations entering the donor pool for transfusion and/ or in the use of factor concentrates which could not be rendered safe. Further, the PFC product concentrates (factor VII and IX) did not include any AIDS warning by way of product insert or leaflet, despite these recognised risks. This was the consequence of Crown Immunity. US products were subject to FDA regulation and licensing requirements in the UK and consequently had product inserts giving some information about the AIDS risk. No such requirements applied to the unlicensed PFC products. As was shown by the MI inspection in 1981, the assertion that despite this GMP was adhered to was not accurate. Had this risk been communicated to clinicians and patients via a product insert, infections could have been avoided and lives saved.

5. Conclusions

[2724] SBTS0000104_076 (15 November 1983)

5.1 The assertions made to patients by haemophilia clinicians that PFC products were safe was simply not true. Systemic failures involving to poor planning, lack of investment, a lack of focus on safety and a lack of proper licensing control led to factor concentrates being produced which were unsafe, despite the significant capital investment which Scotland had enjoyed in what became its own fractionation facility, which had originally been designed to fractionate plasma for part of England as well.

K. THE PROCUREMENT OF BLOOD PRODUCTS FROM BEYOND THE UNITED KINGDOM

1. Knowledge about the particular risks associated with imported products

1.1 By 1975, the World in Action programme revealed clearly that there was an increased risk of hepatitis from imported concentrates. Despite the large increase in usage of concentrates over this period, Dr Winter's "golden interval" was allowed to run unabated in accordance with the anarchic principle of "clinical freedom". In addition to other factor VIII concentrates which had been licensed earlier in the decade the Armour Factorate product was licensed in 1976. The government and its Medicines' Division was positively encouraging use of a products known to carry a materially higher risk. But for that, HIV in Scotland caused by these products (in particular the infections of the boys at Yorkill) would have been avoided.

1.2 In fact, the use of imported products also made no economic sense. Arguments about government budgets and cost limitations (so often resorted to by ministers like Lord Clark and Lord Fowler in their evidence) therefore to not apply. An extract from pleadings for the HIV litigation contains a list of documents/ other sources

which support the proposition that there was a good economic case for these products to be avoided in the UK, as well as a medical one.[2725] These include:

a) 1974 – report of the MRC blood transfusion committee recommending that efforts should be made to achieve self-sufficiency and that it would be very substantially cheaper in the long run
b) End of 1975 – World in Action – Mr Watt stated that UK concentrate would be half or third of cost of commercial concentrate
c) 21 August 1976 – BMJ – Carter et al – domestic concentrates would be very substantially cheaper in the long run
d) 18 September 1976 – BMJ – Professor Cash stated that reliance on commercial concentrate as opposed to SS would be extremely costly
e) 11 August 1979 – Mr Watt in the Lancet stated that SNBTS concentrate was 7.5p per unit and lowest commercial was 9.5p and so NHS had achieved handsome return on investment

1.3 Another important element in the analysis of the clearly higher risks of imported products was letter dated 6 January 1975 written by Dr J Garrott Allen to Dr William Maycock. In that letter, clear concern about obtaining blood from paid and prison donors. The risk from US sources was this made clear on these two separate grounds. Although one (paid donors) was not a part of the Scottish system, the other (prison collections) would remain one for almost a decade after the letter was written. It was also clear from the letter that agents other than HAV and HBV at were causing disease.[2726]

2. Self-sufficiency in Scotland

[2725] DHSC0000324
[2726] CBLA0000249

2.1 The question of when Scotland could have achieved self-sufficiency is a difficult one to answer. Answering it is an important element of the Inquiry's determination of when Scotland ought to have been self-sufficient in blood products. It should be realised at the outset that Scotland was for the entirety of the period which the Inquiry is concerned, self-sufficient in blood and blood components. Thus, the driver for the way that blood was collected was the massive demand for plasma for fractionation into other products. More restrictive collection practices could have been adopted had the need for blood or blood components been the driver for the system. It was the need for plasma for fractionated products which was the driver for how all blood was collected. The result of this was that the recipients of all blood and blood products were subject to the risks of the riskiest donors being allowed to donate. They were allowed to donate due to the need for plasma for fractionated products. As a result, the usage of fractionated products set the level of risk for all recipients of blood and blood products. As a result of the demand imposed upon the system for factor concentrates produced from domestic sources, the transfusion directors continued to rely on high-risk sources such as prisons and the military (see above). Had that demand been kept under greater control with proper regard for the interests of the safety of the end users of both blood and blood products, the result would have been that (a) imported blood products would not have been required at all (ie self-sufficiency would have been a constant) and (b) the safety of domestically produced blood and blood products could have been maintained for all at a reasonably acceptable level.

2.2 Furthermore, the evidence available to the Inquiry demonstrates that due to the lower number of sufferers from haemophilia B, the yield of fractionated factor VIII from blood collected in Scotland also meant that Scotland was self-sufficient in factor IX over the entirety of the relevant period.[2727] No other fractionated product (ie those not used in the treatment of patients with bleeding disorders but for

[2727] Usage of imported factor IX in Scotland for particular reasons is considered below

other medical purposes) seems to have driven demand. A combination of these factors leads to the conclusion that the real driver of entire system was the requirement for plasma to make factor VIII concentrate, for the treatment of patient with haemophilia A. It should, of course, be borne in mind that the PFC manufactured other products beyond factor concentrates, such as albumin and fibrinogen. Thus planning around the construction and operation of the PFC will have involved considerations of those products and the requirement for them as well.

The definition of self-sufficiency

2.3 Answering the question as to when Scotland did indeed become self-sufficient in blood products is dependent, in the first place, upon the definition which is applied to the term. The evidence heard by the Inquiry demonstrates clearly that there was a lack of understanding as to what the term meant throughout the United Kingdom.[2728] The definitions given by various witnesses varied from one to the next. The lack of a clearly defined goal clearly hampered its achievement. This may have been less of an issue elsewhere in the UK, where self-sufficiency was always a distant goal over the relevant period (for multiple reasons on which the Inquiry will reach conclusions but which are not directly relevant to the infection of patients in Scotland), clarity around the definition was much more important in the nation where self-sufficiency in safely sources and manufactured blood and blood products was attainable due to Scotland having its own fractionation facility.

2.4 Self-sufficiency in Scotland was always, as elsewhere in the UK deemed to be a goal. However, it was not always a goal as it had been the starting point. Until the licensing of imported concentrates in 1973, Scotland was self-sufficient on blood and blood products. It had to be as there was no option but to be. The demand had to fit the supply. The unchallenged concept of clinical freedom and the

[2728] IBI transcript for 29/03/22; 126 to 128 (Dr Terry Snape)

modelling of haemophilia care on a system which faced a (ie the rest of the UK) meant that that changed. In effect, demand increased on the part of the haemophilia clinicians with little regard for safety, only for the achieving the maximum treatment available for their patients in particular their haemophilia a patients whom were driving that demand. Rather than the demand having to be tailored to the domestic supply, the availability of an apparently unlimited about of imported concentrate (without professional or financial resolution, it would appear) meant that the demand started to drive the supply. The availability of commercial concentrate was even used as a threat by the likes of Professor Ludlam to fuel his insatiable demand for a domestic supply. He also purchased commercial products (at vast expense to Lothian Health Board) and swapped them with Northern Ireland for PFC manufactured concentrate[2729] and sought to undertake similar swaps internally.[2730] From the late 1970s in Scotland (or 1980 in Edinburgh) the availability of the US products (or in Edinburgh the threat of resorting to them) was the basis upon which the demand was allowed to dictate and control the supply. It was only at the point that the supply was able to meet the demand that self-sufficiency was attained. However, self-sufficiency had been the starting point. In the decade between 1973 and 1983, countless infections had been caused by the demand being allowed to rule over the supply. These infections were caused by the facility of resorting to the use of dangerous commercial products and the constant need for the supply to be stretched beyond safe limits domestically. The self-sufficiency position which exited until 1973 (or in fact later in Scotland as commercial concentrates did not penetrate the market until around 1974 in Glasgow[2731] and later in other centres) ought to have been the norm throughout. The expansion of treatment programmes could have been facilitated when they could be expanded safely.

[2729] See the correspondence referred to above regarding the product swaps with Dr Mayne
[2730] See the Boulton correspondence regarding this proposal between Edinburgh and Glasgow from 1982
[2731] PRSE0002887 _0020

The achievement of self-sufficiency in Scotland

2.5 In a government Memo dated 6 May 1983, it was suggested that Scotland was virtually self-sufficient in factor VIII. [2732] This was disputed by Professor Forbes in his evidence to the Penrose Inquiry who said that he did not think that Scotland was ever self-sufficient in quality factor VIII at that time.[2733] The qualification which he added about quality appears to suggest that it was due to concerns about the quality of the domestic concentrates that the goal of self-sufficiency was not achieved. Dr McClelland gave some detail in his Penrose evidence on the concept of self-sufficiency over this period. There is a distinct lack of evidence about contemporaneous discussions between the producers of the domestic product within the PFC/ SNBTS and the users about demand and awareness of what types of treatment programmes could be satisfied with domestic products. Dr McClelland stated that the SNBTS would never have been confident at this time of meeting "open ended" demand.[2734] The constant demand for more concentrates meant that the target was always moving upwards over this period.[2735] This was also the experience of Dr Foster.[2736] He pointed out that the use of factor VIII in Scotland doubled in 1980.[2737] In our submission, the constantly increasing use of concentrates over this period was (a) contrary to the increasing risk of contracting a fatal disease from those concentrates (initially NANBH and subsequently both NANBH and AIDS) and (b) due to the fact that clinicians always knew that they had the option to purchase commercial products if the SNBTS could not satisfy their demands. This was a recipe for disaster. What was needed was a clear policy that foreign products would not be used and that concentrate use would be curtailed both for reasons of safety and so that demand could be met from locally produced products. Further, Dr Foster made it clear that it was not predicted how the

---

[2732] PRSE0004037
[2733] Penrose Inquiry transcript for 28/04/11 (day 17); 13 (4 to 6) (Professor Forbes); [PRSE0006017_0013]
[2734] Penrose Inquiry transcript for 06/05/11 (day 21); 145 (12 to 15) (Dr McClelland); [PRSE0006021_0145]
[2735] Penrose Inquiry transcript for 06/05/11 (day 21); 144 (24 to 25) (Dr McClelland); [PRSE0006021_0144]
[2736] Penrose Inquiry transcript for 10/05/11 (day 22); 43 (22) to 44 (4) (Dr Peter Foster)
[2737] Penrose Inquiry transcript for 10/05/11 (day 22); 52 (7 to 10) (Dr Peter Foster)

success of concentrates would breed further demand.[2738] This suggests poor co-ordination between the producers and the clinicians to square demand and supply.

2.6 In a Memo from Dr Perry to others at the PFC dated 18 November 1983 he provided an estimation of the current stocks (based primarily on material held at RTCs or in production at the PFC rather than elsewhere) and balanced them against expected demand.[2739] He pointed out that it appeared that the current stocks might indicate that demand would be less than supply, meaning that some of the stock which had been produced would go out of date. This may be taken as an indication that Scotland was self-sufficient at that stage, if that term is understood as meaning that supply outstripped demand. However, this does not mean that the demand was for 100% of the products used to be met by SNBTS concentrates on the basis that other products were still being used. Further, as Dr Perry points out, this would soon be complicated by the fact that any declaration of self-sufficiency would require to be re-assessed once new products were released, such as heat treated products. What is striking is (a) the relatively unsophisticated way in which current stocks were calculated (with no consideration of home therapy stocks or "peripheral" blood banks) (b) the similarly rough and ready method of calculation of demand (based on an assumption that the current year's demand would be this same as that of the previous year) and (c) the apparently nonchalant mention of the possibility of over-stocking resulting in products going out of date, which presumably would have resulted in enormous wasted expenditure. In our submission, this Memo is illustrative of what appears to be an unstructured system for (a) matching supply and demand and (b) achieving the stated goal of self-sufficiency in blood products in Scotland.

2.7 In fact, as was confirmed by Dr Perry in his evidence to this Inquiry, the position was that the PFC had been able to build up large surplus stocks during 1983, predominantly due to an improved technique pioneered by Dr Foster which resulted in a far better yield for factor VIII from plasma.[2740] The main problems

---

[2738] Penrose Inquiry transcript for 10/05/11 (day 22); 37 (6 to 12) (Dr Peter Foster)
[2739] PRSE0001576
[2740] See references to the evidence of Dr Perry in this regard

appeared to be that there was no reaction to this innovation. Collections continued in prisons, for example (as is explored elsewhere in this submission). In addition, clinicians still enjoyed the freedom to prescribe the clearly more dangerous commercial products. The licensing of these products had been granted on the basis that they were necessary in England to meet demand. That became the case in Scotland but their licensing and hence availability to clinicians was not reviewed in Scotland at the point where the supply of domestic factor VIII concentrates met demand, ie at some point in 1983. At that point, treatment with commercial concentrates ought to have stopped on the grounds of safety, except in the most extreme of cases, such where there was an inhibitor to the domestic concentrate.

2.8 At a joint meeting on 2 February 1984, it was noted that over the last 5 years stock levels of PFC factor VIII concentrate held by RTDs indicated that a surplus amount of factor VIII may have been produced by the PFC beyond the usage in Scotland. There was discussion of the possibility of surpluses being given to centres in England. Dr Cash raised the query of whether commercial product was required at all in light of production levels.[2741] This is a clear indication that by this time, Scotland had for some time been self-sufficient.

2.9 It is interesting to note that, by 1990, the meaning of self-sufficiency appears to have changed from all products used being produced in Scotland to meeting all products asked for by the clinicians from domestic supply (irrespective of the amount of foreign products used in accordance with their preference). This was spoken to by Dr Foster in his Penrose evidence, who indicated that this change in definition was something that Professor Cash had not been happy about on the basis that it would make it impossible to predict how much domestic products would be needed as this would depend on how much foreign product was being used, according to the unpredictable preferences of the clinicians.[2742]

[2741] PRSE0001556_0002

[2742] Penrose Inquiry transcript for 10/05/11 (day 22); 31 to 33 (Dr Peter Foster)

3. Reasons given for the use of commercial blood products in Scotland

3.1 As is set out above, it appears clear that there were divergences in clinical practice regarding the use of commercial concentrates in Scotland over this period. One of the given reasons for this appears to have been (i) the higher purity (which also affected solubility)[2743] (ii) greater accuracy in terms of the factor VIII content and (iii) superior user-friendliness of the commercial product, according to some clinicians. In the context of addressing the relative user-friendliness of the packaging of the commercial products, Dr Foster pointed out in his Penrose evidence that he and his colleagues at the PFC were reliant on clinicians pointing out what they wanted from the products which they were producing. He indicated that they would have tried to oblige but that such approaches did not happen.[2744] It is hardly surprising that was being done by the producers of the domestic product to address these concerns of the clinicians if they did not know about them. The complete freedom of the clinicians to obtain commercial products when the domestic product was not quite suitable was not conducive to such a dialogue, nor to the achievement of self-sufficiency.

3.2 Dr Foster also addressed the criticism of the domestic concentrates over this period that it took longer to dissolve. He suggested that this may simply have been because it was not being warmed up enough (as per the instructions) after being taken out of the fridge.[2745] Again, this would tend to suggest that this was not as great an issue as might be suggested.

3.3 The fact that the bulk of the treatment with factor concentrates in Scotland in the late 1970s and early 1980s was with domestically produced concentrates suggests that these apparent issues with the were far from insuperable. It is submitted that the principal reason for the use of commercial products over this period was predominantly to do with availability to fuel the treatment regimes selected by haemophilia clinicians. In any event, apparently non-material considerations of

---

[2743] PRSE0001556_0003
[2744] Penrose Inquiry transcript for 10/05/11 (day 22); 36 (21 to 23) (Dr Peter Foster)
[2745] Penrose Inquiry transcript for 10/05/11 (day 22); 103 (16 to 22) (Dr Foster)

practicality ought not to have been allowed to be dominate safety considerations which should have remained the main priority.

4. Licensing of imported blood products

4.1 The evidence available to the Inquiry shows that the licensing regime focused on efficacy as opposed to safety. It was obviously a broken system where the risks and the comparative risks of commercial products were so well known. It provided a false crutch for government ministers and indeed clinicians to rely on. They wrongly assume that the products must be fine or else they would not have acquired a licence. As is stated above, the main risk the system was the risks posed by the donors. Donor selection was not part of the licensing system. Assessments were mas bases j what worked (factor activity and useability predominantly) and what was need for the English market. The fact that the licensing system was "reserved" to the Medicines Division under the administrative devolution arrangements meant that the Scottish need for commercial products was not considered on its own merits. This led to poorly informed haemophilia directors like Dr Willoughby and Professor Forbes seeing no real difference, on the assumption that the licence meant it could be used with impunity.

4.2 At a meeting of the SHHD and the BTSs of Scotland and England and Wales respectively in July 1971 about planning for the domestic production of fractionated products, it was agreed that discussions on central processing of factor VIII and factor IX concentrates was imperative because of major effects on production planning.[2746] Such central control would have been able to have enabled better planning for the domestic market but also a centralised control over access to commercial products and their use.

[2746] PRSE0000808_0002

L. THE RESPONSE TO THE DISASTER

1. General

1.1 To the extent that the State response to the disaster is not covered elsewhere in this submission, the response of the state to the occurrence of infections as a result of NHS treatment with blood, blood components or blood products is addressed in this section of the submission. The campaign for government recognition and support was based on the assertion that the State, having caused the infections and all of the direct and indirect consequences of it had moral responsibility to engage with the infected and affected. The focus was on HIV infection in the early stages of the campaign due to the fact that it was the infection which caused the most immediate effects. Engagement with the circumstances of the disaster and the consequences of it had huge potential implications for the State. Those huge implications included the need to engage with what had happened, including the almost unimaginable scale of the harm, caused in many cases as a result of a voluntary blood collection service which was one of the cornerstones of the national health service and in others as a result of the importation of blood products which many, including journalists, had been warning was fraught with danger for a decade at least. The possibility that mistakes may have been made which would expose the government to liability to pay reparation for the consequences of the disaster or at least provide financial support almost immediately drove the government response. The focus of government in the 1980s was on the prevention of further infections with the deadly disease. Public information campaigns were designed to scare the public into prevention, without consideration of the stigmatising effects of those campaigns on those who had become infected already. In fact, little, if any, attention was paid to those who were already infected, including those who had been innocently infected by the State. The hope which appears to have dominated

the initial government response was that that the short life expectancy of the infected with HIV would mean that the problem would go away before the State had to deal with the potential implications. Avoidance and denial came to characterise the way that the government dealt with legitimate calls for answers or support. This would continue to characterise the government response in the decades which followed, fixed by an internal civil service mantra of "no compensation, no public inquiry", reflective of the wilful blindness of the State to what had happened and what was to happen as a result.

1.2 The government's attitude over the decades to follow was characterised by:

(a) A lack of recognition of the depth of the many and varied physical, mental, social, financial impacts of the disaster on the infected community. This resulted in a failure to engage with the real needs. Even by the time of the new schemes being set up, no assessment of the effects of the disaster on the infected or their needs had been undertaken.[2747] Still none has been undertaken to this day. The scale of the disaster as any moral obligation to provide financial support would be so huge that sticking plasters were all that could be provided. Even the most recent support schemes were set up without any understanding on the part of government as to what the government considered that it had a moral obligation to address and hence what the schemes were meant to cover.[2748];

(b) The consistent mantra of the State to those looking for support and answers that their only option was to resort to litigation in order to avoid the financial responsibility for the State having caused the disaster in the first place (addressed below);

(c) A lack of recognition of the breadth of the effects of the disaster and the needs of the affected community, in particular widows but also others. This resulted in an apparent desire to cut out the affected as to do otherwise and engage with their needs would carry the financial obligation to support the community onto

[2747] IBI transcript for 18/05/2021; 20 (14 to 25) (Sam Baker)
[2748] IBI transcript for 18/05/2021; 112 (4 to 11) (Mairi Gougeon)

another generation, meaning that the State would not enjoy the benefit of the infected dying out/ the disaster becoming a problem of the past; and

(d) An unwillingness to look at the circumstances as to what had happened which would have revealed the extent to which the State had a moral responsibility for what had resulted. This approach has legitimately led the infected and affected to conclude that the State had something to hide. This manifested itself in a general refusal to consider there being a public inquiry into the disaster, a failure when any investigations were undertaken for them to be fair or thorough and a consequent denial of truth and justice to the victims, which is irreparably and exponentially compounded the harm which they have suffered.

1.3 As time went on, the disaster started to be looked at as problem of a former government, a matter of the past. The survival of some of those with HIV, the emergence of the consequences of the HCV infections and the realisation that there were also those who had been affected by the disaster as well as infected meant that the unresolved issues of the disaster lingered and required resolution. Rather than seeking to do so, the State simply adopted the same line as had been adopted before. This was based on (a) an institutional wilful blindness and resultant adherence to an outdated and incomplete line formulated by civil servants and never reviewed (b) the erroneous impression that the implications of the disaster had been settled by the HIV litigation and (c) a failure to realise that (i) the moral obligation of the State to repair the harm done never disappears and (ii) the very real needs and loss of the infected and affected communities were very much problem of the present. Both the responsibility of the State and the needs of the community were consistently ignored and underestimated by successive governments.

Calls for a public Inquiry - general

1.4 Although not enacted until 2005, it would be reasonable to assume that the criteria to be applied my Ministers in section 1 of the Inquiries Act 2005 are broadly the criteria which would be applied to the determination as to whether a public Inquiry would be merited. Thus, it was incumbent upon ministers (within the UK government, including the Scottish Office before devolution and in the Scotland Office/ Scottish Executive/ Government after it to seek to apply their minds to whether the disaster merited publica examination. It is submitted that the scale of the disaster merited a public Inquiry as judged by this or any criteria at all times from the occurrence of infections in at least the early 1980s. This was due to (a) the number of people who were clearly infected and affected and the severity of the consequences, including death (b) the lack of answers which had been provided to those who had been affected by the medical profession or the government at whose hands the infections had occurred (c) the lengthy of the period of time over which these systems responsible for the occurrence of infections had apparently failed (d) the significance of the blood supply to the health of the nation (e) the clear systemic issues within government and the NHS which fell to be scrutinised by a public Inquiry and the significance of those systems to the public health. The failure by governments to order a full public Inquiry into the matters which fall within the remit of this Inquiry until the announcement of the Penrose Inquiry by the Scottish Government in 2008 constituted a major, inexcusable dereliction of responsibility on the part of those governments to the infected and affected community but also to the public at large.

The way that the campaign for justice for the infected and affected was treated

1.5 As time went on the importance of not engaging with/ recognising the rights of campaigners became an important aspect of the evidence heard by the Inquiry. they were generally dismissed as troublemakers. Their legitimate calls for justice

were discounted and ignored in the same way as the patients had been by the medical profession at the time when the infections occurred.

1.6 The financial needs and the State response to those are addressed in the section below, though the political element of the decision-making around the government trusts and schemes is discussed in this section. The focus in this part of the submission is on the government response and not on the medical profession but it is clear from the evidence which has been heard by the Inquiry that the medical response was also conditioned by the same need to cover-up the full extent of what had happened.

1.7 It is thus important for the Inquiry to recognise that neither the medical nor the political response happened in isolation. The whole response (medical and political) requires to be considered as a whole to understand the extent to which the response of the State to a disaster which it had caused has reinforced and compounded the harms of the victims. Though these failures constituted separate failures of responsibility towards the citizens affected, their effect as cumulative. These failures have led to the overall outcome becoming exponentially worse than it otherwise would, could and should have been.

2. The initial response of government to the blood contamination disaster

2.1 The campaign for justice for the victims of the blood contamination disaster was mounted in the aftermath of the infections in the 1980s. The evidence herd by the Inquiry showed that there was a complete lack of engagement at Westminster by the campaigners who sought to fight for their righteous cause. Many victims, in particular those who had been infected with HIV, had died or would die of AIDS in the period between that point and the mid 1990s. Those who were sick and dying had, of course, generally been left in the dark as a result of the domino effect of misinformation emanating from the medical profession, which is detailed above. They naturally turned to the government for support and explanation as to how this had happened to them. The evidence available to the Inquiry demonstrates

that there was a lack of recognition of responsibility for the disaster or its impact/ extent, and a lack of engagement.

2.2 Calls for a public Inquiry were part of the campaign for justice fought on behalf of the infected and affected from its inception. The calls for such an Inquiry were legitimately based on the scale of the disaster and the fact that (as narrated previously in this submission), those affected had been the victims of the "domino effect" of secrecy and misinformation which had stemmed from their lack of involvement in decision-making about their care and had been fuelled by the need of the medical profession to minimise its exposure to criticism in the HIV litigation and beyond. In his evidence to the Inquiry, Lord Clarke (speaking in connection with his time as Secretary of State for Health) attempted to justify the lack of announcement of a public Inquiry into the blood contamination disaster in the UK as being based on the fact that public Inquiries were not done at that time. This, of course, is simply untrue, as was put to Lord Clarke. At around the same time, a public Inquiry into the Piper Alpha disaster was announced by the Secretary of State for Energy.[2749] This evidence showed the different attitude towards a national disaster involving thousands of ordinary people who might had a legitimate grievance against the government and a national disaster involving significant commercial interests within the oil industry. The circumstances and effects of the blood contamination disaster were not viewed in the same way. Lord Clarke specifically wished to draw a distinction in hie evidence between events such as a hypothetical bridge collapsing and the massive human tragedy caused by the blood contamination disaster. His view was that the former would merit an inquiry but the latter did not. In a confused passage of evidence, he seemed on the one hand to be trying to suggest that nobody was asking for a public inquiry at that time (which is demonstrably untrue) and on the other to be suggesting that nothing could be added by way of an inquiry to the facts which were already known about the disaster. The facts uncovered even at this remove in time by this Inquiry show this latter explanation to be unjustified. Key questions remained unanswered even when this Inquiry was instigated. This was an excuse with no

[2749] IBI transcript for 29/07/2021; 86 (21) to 88 (17) (Lord Clarke)

proper basis – there is no evidence that Lord Clarke took the time to understand what questions remained and what evidence there was to answer them. The approach to the HIV litigation (analysed in more detail below) showed that the government approach lacked any real compassion, lacked any real understanding of the circumstances of the infections and sought above all to stifle as opposed to encourage light being shone on what had happened, at least temporarily until those infected had died.

2.3 No clear explanation was forthcoming as to why this policy of refusing a public Inquiry was instituted in the first place (at some point in the 1980s, it would appear), nor separately why it was adhered to, other than the result of an inveterate system, which simply trotted out the same mantras without considering whether there had been any change of circumstances or the policy merited looking at afresh, despite the ongoing legitimate need in the infected and affected community for answers and financial support, the fact that not all of those infected with HIV died as anticipated, the fact that the affected community also emerged as needing booth answers and support, the fact that the transfusion infected community started to become part of the story (who had never properly been considered by government before) and indeed the emergence of the effects of HCV. It is submitted that the culture of secrecy which pervaded the government's response to the HIV litigation – the thought that its settlement brought an end to the "issue" of the disaster – informed the clear government approach to its "no compensation, no public inquiry" line.

2.4 A clear government "line to take" emerged based on not paying out for the consequences of what was deemed to be non-negligent conduct and the need to go to the courts. The government's focus had stemmed from the HIV litigation. Thus a focus developed on the matter being one connected to the law relating to compensation rather than the moral duty of the State to look after those in need, the case being made stronger where the harms which had caused the need had been at the hand of the State. This led to an adversarial approach between government/ the medical profession and the infected/ affected community which became a model of how not to deal with medical disaster of this scale. Individuals became the victims of the scale of the disaster in which they had been involved.

No individual could be given anything, for fear that it would be a concession to the whole, vast community. This informed the government's approach to litigation (which was fought mercilessly even in deserving cases) and to legitimate claims for answers and/ or support. As is discussed in detail below, there was a lack of realism in the government's approach. For all sorts of reasons, the infected and affected were simply not able to turn to courts including litigation funding issues, and the fact that expert evidence would be required in situations where experts would invariably be drawn from the very community which caused the disaster in the first place.

2.5 This government approach was insisted on, despite the fact that the real need for support for the infected community was recognised even by those medics (including amongst others Professor Ludlam) who were living with the daily consequences of the disaster. Lord Clarke said in his evidence to the Inquiry that as Secretary of State, he thought he had not even seen correspondence addressed to him by Professor Ludlam to that end.[2750] Even their pleas for support for the infected community went unheeded. This was despite the fact that government continued to make payments of ex gratia sums to certain groups but not to those infected and affected by the blood contamination disaster (for example under the Criminal Injuries Compensation Act, the Pneumoconiosis etc (Workers' Compensation) Act 1979, the Vaccine Damage Payments Act 1979). The government had claimed to have followed the medical advice when it needed a scapegoat for decision making around the emergence of the disaster. The advice which they followed from the like of Professor Bloom was convenient in that it was to the effect that that nothing needed to be done, no extra money or initiative was required to respond to the emerging threat of HIV. Consistently with the government's approach to medical advice to the opposite effect – ie that action or money was justified, such as in connection with the earlier introduction of anti-HIV or anti-HCV or the introduction of surrogate testing – such medical advice which would require money or action was ignored, without justification. Lord

[2750] LOTH0000069_022 (29 November 1989) – Dr Ludlam letter to Lord Clarke re compensation; para 32.3 of Lord Clarke statement at WITN0758012

Clarke claimed that he did not think the prospect of litigation played a role in his decision making in relation to the payments and the MFT.[2751] However, he accepted that it would be 'desirable' in light of the pending litigation to avoid any concession of moral or legal liability.[2752] It is submitted that the desire to avoid making payments, whether by way of court award, settlement or otherwise was at the core of the government's approach. This approach would continue to be the bedrock of that approach for years to come. This is why assessment of the losses and needs of the community never occurred. It is also why Lord Clarke was not prepared to contemplate any consideration of moral responsibility. Hence, he deliberately and erroneously conflated accepting a moral obligation with legal liability, when saying that acceptance of a moral duty would have been portrayed as an admission of fault.[2753]

2.6 Actions which were taken, such as the setting up of the Macfarlane Trust and subsequent trusts and schemes were merely sticking plasters, applied to a wound the extent of which was never measured or appreciated. No assessment of the damage to and hence the needs or losses of the infected, far less the affected community has ever been undertaken by the State. The sticking plasters were simply based on what could be afforded as opposed to what was measured to be needed or anything approximating it. There was a complete failure on the part of the State to engage with and hence realise the scale of the disaster; it was thought that the problem would go away with the death of the infected, and there was no consideration of the affected who would be left behind.

2.7 The structure of governments within the UK meant that limited, if any time, was spent by the relevant minister in Westminster liaising with relevant ministers in the Scottish Office in respect of the matters within the remit of this Inquiry, notwithstanding the enormity of the catastrophe. David Mellor, despite apparently taking a keen interest and a leading role in the response to HIV in Westminster thought it "unlikely" that he would have any personal interactions

---

[2751] para 43.4 of Lord Clarke statement at WITN0758012
[2752] para 31.11 of Lord Clarke statement at WITN0758012
[2753] para 31.11 of Lord Clarke statement at WITN0758012

with the SHHD[2754]. Decisions were made in Westminster that had considerable impact on the community in Scotland, with little or no regard to the fact that their circumstances may be different. A 'one size fits all' approach appears to have been the order of the day without any assessment as to whether that was realistic.

2.8 Even when there was some engagement with the community (in the first instance, the bleeding disorder community who had contracted HIV/AIDS), this was limited and caveated, although those involved in announcing those limited support schemes announced them with great fanfare and self-acclaim. Attempts were made to distinguish haemophiliacs with HIV from transfusion recipients with the same illness and from anyone who had contracted HCV via blood or blood products.

The HIV litigation and the government's response

2.9 David Mellor, giving evidence to this Inquiry, said that he was *"always very keen"* to settle the HIV litigation, because he *"thought it would awful to force people to go to court over getting proper compensation"*[2755], but it does not seem his colleagues agreed. The settlement he appears to have been so proud of came about long after the HIV litigation had been launched, and only after Ognall J sent a note to the parties to urge settlement, and that the settlement involved no assessment of the losses and needs of those infected and eligible to claim under the scheme. Indeed, as explored below, when David Mellor was a minister for health, he was involved in the oversight of the first stage of the MacFarlane Trust (ie prior to the settlement of the HIV litigation) and was aware of concerns regarding the management of the Trust.

2.10 Prior to settlement, the government defence explored myriad defences, including technical matters regarding the class action itself, and the existence of duty of

---

[2754] WITN7068001, para 2.6 (First statement of David Mellor)

[2755] IBI transcript for 19/05/22: 16(4) to (13) (David Mellor)

care. The concerns throughout the response by the government appear to have been in respect of 'opening the floodgates' and undermining their opposition to no-fault compensation in the NHS. Very limited thought appears to have been given as to the government's moral duty to support those who had been infected with fatal diseases at the hands of the state. Even in circumstances where political pressure was being brought to bear, and, as Mr Mellor said in evidence, *"there was no constituency out there for being difficult with people who were going through what these poor people were going through"*[2756], there was considerable delay in dealing with the litigation. The MacFarlane Trust, which started to make payments in 1988 was inadequate to deal with the losses and needs of those infected with HIV via blood products.

2.11 Mr Mellor appears to have taken the lead in dealing with the HIV litigation as a result of his interest and responsibility for HIV/AIDS within his portfolio until he left the post in October 1989, to be replaced by Virginia Bottomley. He did not have responsibility for blood services or the use of blood and blood products. He received briefings that included statements such as *"officials involved at the time are satisfied that every possible effort was made to introduce the screening test as soon as possible"* but which were silent on issues such as surrogate testing and the effectiveness (or otherwise) of the AIDS leaflet and other attempts to exclude high-risk donors. He was not aware of the fact that there were individuals with bleeding disorders who had been infected with HIV from domestic products[2757].

2.12 It seems any review of the litigation strategy was prompted by media coverage rather than the minister in charge of managing the litigation being closely involved on a more regular basis[2758], and when Mr Mellor was replaced by Virginia Bottomley following a cabinet reshuffle, there was no discussion or handover regarding the litigation. Yet again, the government's response to the disaster was subject to shifting political sands, and whilst Mr Mellor gave evidence to this

---

[2756] IBI transcript for 19/05/22: 92(2) to (4), (David Mellor)

[2757] Ibid, 210

[2758] Ibid, 100

Inquiry regarding his own views about how the matter should be handled, the official government position remained that the case was being fought on multiple defences and points of law[2759].

2.13 Indeed, it does not appear that there was any inclination on the part of the UK government to consider settlement until such time as lawyers advising them suggested that the prospects of successfully defending the claims, whilst still favourable, had reduced[2760] and there were greater concerns about adverse publicity regarding the government's stance[2761]; notwithstanding the evidence of Mr Mellor that the legal position had remained the same, the documents suggest that at least some of the change in stance came about as a result of the legal advice.

2.14 When settlement of the HIV litigation was mooted, it became apparent that those involved had given no thought whatsoever to the claims of those living in Scotland. There were approximately 80 such claims, but there was no representation on the Steering Committee of plaintiffs' lawyers from Scotland, and those claims were less advanced and had not yet been investigated. A review of the Scottish claimants' cases is set out elsewhere in our submission. It appears that the resolution of the Scottish claims was no more than an afterthought of the Westminster government.

2.15 Notwithstanding Mr Mellor's apparent enthusiasm for increasing assistance for those with bleeding disorders with HIV, it appears he was more reluctant to consider the effects on those who had contracted the same disease via blood transfusions. He supported the position taken by the minister for health, Virginia Bottomley in an adjournment debate in December 1991 which sought to distinguish the position between the bleeding disorder and the transfusion recipient communities[2762]. At this time, the Scottish Office were involved in

---

[2759] DHSC0002536_079

[2760] HMTR0000002_011

[2761] IBI transcript for 19/05/22: 164 to 165

[2762] HMTR0000003_051

matters, and, along with Lord Waldegrave, were advocating for payments to be made to transfusion recipients who had contracted HIV. At least part of Mr Mellor's rationale for refusing payments to the community appeared to be that the DoH had overspent its budget significantly in other areas; in other words, issues elsewhere meant that those who had contracted HIV were a cost that the government did not want to have to meet. Mr Mellor, in his oral evidence to this Inquiry, described the discussions between the Treasury and the DoH as 'playing a game'[2763] and the need to give the DoH a "bit of grief"[2764]..

2.16 It is our submission that, whilst it was a common theme of those who gave evidence at this Inquiry that they were supportive of the needs for payments to be made to those who contracted HIV as a result of treatment under the NHS, there was little tangible progress seen towards settlement until the government's hands were forced by the media, public opinion, and the intervention of Ognall J on 26 June 1990.

2.17 In the meantime, transfusion patients who had contracted HIV as a result of the disaster were left without any recognition of their losses or needs. After payments were made to those with bleeding disorders, attention did turn to those who had received blood transfusions. Virginia Bottomley, in her evidence to the Inquiry, said that the attempt to distinguish between those with bleeding disorders and those who had required transfusions, which, by 1990 was relying heavily on the fact that bleeding disorders were hereditary, and as such "*already suffering from a serious disorder which affected their employment prospects and insurance status*[2765]*"* was "*the most defensible line that could be conceived on the basis that we had already established a precedent*"[2766]. This suggests that the attempt to distinguish between the communities was, in fact, an 'ex post facto' one; the

---

[2763] IBI transcript for 19/05/22: 189 (David Mellor)

[2764] Ibid, 190

[2765] DHSC0002859_002

[2766] IBI transcript for 28/06/22: 124 (Virginia Bottomley)

reality is that transfusion recipients had not really been considered in the first instance.

2.18 Ultimately, payments for transfusion recipients were announced in February 1992, and it took over a year, until March 1993, before the declaration of the trust deed for the Eileen Trust took place permitting payments to those individuals. Again, efforts seemed to be focussed on the perceived 'need' to ringfence the decision regarding payments to those with haemophilia, without any meaningful consideration of the needs and/ or losses of those infected via transfusion with a disease which, at the time, was very likely to be fatal.

2.19 We submit that the lack of consideration of the transfusion community arose at least in part because there was a lack of understanding that domestic blood system was contaminated with HIV. The media portrayals of the disaster focussed on imported 'blood' from the USA. The lack of recognition of the fact of domestic breaches of the blood collection system, with ensuing infections amongst both the bleeding disorder and transfusion recipient communities meant that there was no recognition of the fact that the infections in Scotland largely arose from a very different factual background and ought to have been considered in light of that background.

3. Political engagement in Scotland after the MFT settlement

3.1 The emergence of HCV infections amongst populations in Scotland (not then accounted for in any financial arrangements) became the predominant driving force behind further campaigning in Scotland. Though this campaigning involved those who had been infected from both the bleeding disorder and the transfusion communities, the emergence of the severity of that disease and its relative prevalence in Scottish patients led to campaigning in Scotland, particularly involving the bleeding disorder group who were able to achieve some level of cohesion due to their common infection route and engagement at haemophilia centres. This was particularly the case at the time of the advent of the Scottish

Parliament in 1999, whose petitions committee provided a route to justice for the campaigners. These factors all led to Scotland being at the forefront of the fight for justice in the form of (a) a full public examination of the circumstances of the blood contamination disaster in Scotland and (b) financial support and compensation for the infected and affected.

The period pre-devolution

3.2 It is submitted that the position adopted by the UK government in response to the blood contamination disaster was fixed largely by the defensiveness of the State to the English HIV litigation. This is explored in some detail below, where it is submitted that the response was limited and showed a lack of appreciation for the needs and losses of the affected communities but also that it paid little if any heed to the different position of those who had become infected in Scotland, where litigations relating to HIV and subsequently HCV infection were approached and disposed of as if there were no differences in the position in Scotland. The evidence heard by the Inquiry was to the effect that from the period during which infections were still regularly occurring (the mid 1980s until 1991) the power of the Scottish Office and particularly the Scottish Home and Health Department to exercise its own judgement under the administrative devolution arrangements for Scotland's own independent health system was in fact an illusion, at least insofar as the blood contamination disaster was concerned. The position of the Scottish Office in the period before the Scotland Act is exemplified in a letter from Gary Wildridge of the health department of the Scottish Office to the lead solicitor (Mr Donald) of the Scottish HCV litigation group, comprising at least some of those pursuing actions in the Scottish courts in respect of their HCV infections dated 24 July 1996.[2767] This letter is analysed in some detail below and trotted out many of the mantras which were commonplace in responses to pleas to Westminster for

[2767] BNOR0000130_036 (24 July 1996)

support and answers. Despite the fact that the circumstances of the occurrence of the infections had been different, and the needs and losses of the Scottish infected and affected communities were different, the Inquiry consistently heard evidence to the effect that as the Scottish Office was part of the UK government, a consistent line was adopted. No independent assessment was done by the SHHD of the circumstances of those infections or the needs or losses of the Scottish community was ever undertaken. The non-responsive approach of the DoH was convenient to the SHHD in that it permitted it to turn a blind eye to the harm which had been caused.

3.3 The position over this period was spoken to by Lord Forsyth and Duncan MacNiven, a prominent civil servant, the latter of whom had also given evidence to the Penrose Inquiry and whose evidence at that time is analysed above. One key feature of the evidence heard from both of these witnesses was that over this period, issues relating to blood contamination (either relating to the possibility of prevention of transmission in the period from 1985 to 1991 or in response to the occurrence of infection in the period from 1991 to the advent of devolution in 1999) were rarely elevated to the minister, far less the Secretary of State for Scotland. When they were (such as in connection with the handling of the litigations which appear to have involved Ian Lang to a limited extent) the outcome was that no independent assessment was made of the Scottish position or an appropriate response to it. The line which was adopted was simply the same as was adopted at UK level, however inappropriate, either in a general sense or as regards its application to Scotland. The evidence heard by the Inquiry was to the effect that the set-up of the Scottish office at the time was that ministers were few and spread very thin. Lord Forsyth was the junior minister responsible for the SHHD at the start of the 1990s, which required him to be involved in home affairs (including justice, prisons, the police etc) as well as health. The result of that and the geographical distance between Westminster and Scotland was that the minister had little involvement in anything other than the most prominent matters. Decision making around matters like the blood contamination disaster and its aftermath fell almost exclusively to unelected and unaccountable civil servants. In effect, the evidence heard by the Inquiry about this period was to the

effect that the justified pleas made by the infected and affected were little more than an inconvenience to those civil servants. They simply neglected their responsibilities under administrative devolution of health matters to consider these important Scottish issues independently and used the UK line to adopt a wilful blindness to the pleas of the community. Like in the DoH, this was by this period seen as yesterday's problem, despite the pressing current need of the community for answers and support.

3.4 This was a convenient line for the SHHD to be able to take, though they could and should have adopted a different line, as the Scottish government did many years later in developing the SIBSS, after an attempt at reviewing the position of the infected and affected through the Clinical and Financial reviews (see below). Lord Forsyth was not involved in decision making around these matters when Secretary of State for Scotland. His attitude to these matters appears to have been fixed by a similar view to the civil servants about the need to toe the UK line. When minister within the SHHD earlier in the decade he had been of the view that the matter of anti-HCV testing was one which "should be approached on a UK basis".[2768] Despite formal devolution of health matters in the intervening period, the Scottish Office had the power to take the initiative in relation to the requests of the infected and affected. The funding position would have meant finding money for an inquiry and/ or financial support as no such funding would have come to them via the Barnett formula via the prevailing financial arrangements whereby funding was provided as a proportion of the annual budget allocated to the UK government departments.[2769] This funding arrangement made the avoidance of independent thinking on the issue all the more convenient. It remained the broad funding position in 2017, however, which showed that it was not an impediment to an independent approach.

3.5 The approach in this period was not only dictated to by the need to continue conformity with the UK approach but also the fact that the cost needed to be limited. Efforts made to try to get the issue of financial support for the infected

[2768] Lord Forsyth witness statement (WITN7126001) @ para 44.1
[2769] Lord Forsyth witness statement (WITN7126001) @ para 19.4

onto the political agenda at Westminster simply fell on deaf ears.[2770] This position had become fixed and set the tone for the years which followed. In expressing the view that there was no logic to the position that payments, once made to haemophiliacs should not also be made to those who had contracted HIV from blood transfusions, Lord Forsyth admitted that the whole approach was based on cost considerations as opposed to the arguments about not creating a precedent for "medical accidents".[2771] As such, there seemed to be little prospect that the government of the 1990s would engage with the issue as one of need or moral duty. The matter was simply one of economics. The policy in that regard was fixed for Scotland as elsewhere by the Treasury and the DoH. He accepted also that the approach to urge those who had been infected by transfusions to go to court was unreasonable as the claimants would never stand a chance of proving causation based on the fact that information about the donor would be kept private from them by the State.[2772] That lack of logic and fairness did not prevent the State from adopting that position in response to claims for compensation. Decisions about the amounts to be provided for the MFT and the additional funds being out into the MFT were taken by the Treasury and the DoH without the Scottish Office being consulted.[2773]

3.6 Consideration of the possibility of a support scheme for HCV seems to have been undertaken from as early as 1995 involving the Scottish Office. Plans to have compensation scheme for HCV were under consideration at that time. Ian Snedden wrote to say that there is much legal complexity and the would need to be discussed with the minister.[2774] There is no evidence that the matter was discussed with the minister at that time, of which we are aware. It seems that these discussions did not get very far. There was a Scottish office briefing by Ian Snedden about possible HCV compensation scheme consultation with Scotland, Northern Ireland and Wales about a possible scheme.[2775] It appears to have been

---

[2770] DHSC0004428_097 – Notice of Motion dated 8 June 1995
[2771] IBI transcript for 20/07/22; 53 (11 to 14) (Lord Forsyth)
[2772] IBI transcript for 20/07/22; 54 (18 to 22) (Lord Forsyth)
[2773] SCGV0000230_145 – 1 February 1990 minute.
[2774] SCGV0000165_046 – 25 May 1995
[2775] SCGV0000165_035 – 1 June 1995

clear from that stage that there was no new money for any scheme. It was stated that there would need to be found from health funds and would thus be taken from patient care.[2776] The case for HIV payments being treated differently was also set out. These meetings set the tone for what was to happen next. There was no need for monies to be taken from health budgets and hence patient care. HIV was not different but this seemed to be a sufficient reason for consideration of the matter not to be taken any further.

3.7 These documents show that the likes of Dr Keel were involved in this initial thinking. A memo shows her clarifying her view that anti-HCV testing was not introduced prior to September 1991 due to poor sensitivity and specificity in the tests.[2777] A further memo from Dr Young in the Scottish Office inter alios to Dr Keel sets out the apparent need to let ministers know on the subject of compensation for HCV sufferers that other diseases have been transmitted by organ transplantation as well. This tends to suggest that the "thin end of the wedge" argument was being adopted regarding the possible financial consequences for other diseases.[2778] In a further memo to which Dr Keel was copied, Mr Snedden suggested that no fault compensation would possibly lead to malpractice.[2779] In her evidence Dr Keel confirmed that this was not something which ought to have caused significant concern about such a proposal amongst clinicians, though it was part of the argument against the proposal.[2780]

3.8 By October 1995, in an NHS Executive reply to Ian Snedden, they clarified that they thought that the issues about the difficulties in working such a scheme which he had pointed out had been well made, due to the variable effects of the disease. Their current view was against a no-fault compensation scheme in principle, despite MFT. Irish representatives were coming over to talk about their scheme. It was stated that it would be unlikely to be helpful.[2781] The animus was clearly to focus on perceived practical and funding difficulties with the proposal, as opposed

---

[2776] Ibid, para 19
[2777] SCGV0000165_029 – 22 June 1995
[2778] SCGV0000165_024 – 14 July 1995
[2779] SCGV0000165_035 – June 1995
[2780] IBI transcript for 25/07/22; 115 (Aileen Keel)
[2781] SCGV0000166_054 - 13 October 1995

to the moral case or the needs of the infected community. By September 1998, the line had clearly become no compensation for HCV. HIV was deemed to be different due to stigma and the fact that those with HIV could have infected their partners.[2782] It seems that the matter had by that point become a "line to take" without any real or meaningful consideration of the full case or any engagement with the infected community. This attitude appeared prevalent in the Scottish Office and amongst those civil servants who moved from there to the new Parliament. Dr Keel, for example, agreed with the view that the circumstances surrounding the infection of patients through blood transfusion with HIV were very different from those relating to transmission of HCV. She expressed the view that "at that point, a diagnosis of HIV infection was a death sentence, as well as being associated with considerable social stigma. Neither of these factors applied to HCV infection." [2783] No evidence was presented that any assessment has been done either of the likely prognosis for HCV or the stigma associated with the disease at around that time. There can be no doubt on the evidence that those, like Dr Keel in positions of considerable influence and responsibility approached the matter with a close mind based on little if any real evidence. The assertion that "rigorous examinations" on the issue had been undertaken within the Department of Health in recent years, by 1999 appeared not to be borne out by the evidence.[2784] As health had been administratively devolved to the SHHD before devolution, any such investigation could not have included Scotland.

The impact of devolution

3.9 Devolution in 1999 after the enactment of the Scotland Act 1998 presented the opportunity for a fresh approach to be taken by those who were charged with

---

[2782] SCGV0000045_172 – 22 September 1998 letter from Sandra Falconer
[2783] Aileen Keel witness statement WITN5736003 @ para A71(c)
[2784] Aileen Keel witness statement WITN5736003 @ para A77

responsibility for the health service in Scotland, as well as the needs and losses of those in the infected and affected community.

3.10 The circumstances in which petitions came to be presented to the Scottish Parliament in connection with these matters, the experience of the campaigners and relevant underlying documents are narrated in campaign statements presented to the Inquiry on behalf of prominent campaigners. These efforts led to the presentation to the parliament petitions committee of petitions PE45 and PE185, which sought a public inquiry and financial compensation for both the bleeding disorder patients infected with HCV and also those infected with HCV via transfusion. These were the result of a fresh approach to the ability of those with a legitimate grievance to gain access to the Parliament.

3.11 The minister for health in the Labour government which was in charge in the period after devolution, Susan Deacon, gave evidence to the Inquiry to the effect that she and her government had been responsive to the claims of the campaigning community. It is submitted that, though the mechanisms of the Scottish Parliament which allowed such important matters at least to come to her attention as the relevant minister were indeed welcome, her characterisation of the efforts made by the Scottish Executive to advance matters were not an accurate representation of what happened or its effects on the infected and affected community. The efforts made by the Executive need to be understood in their context. The campaign which had given rise to the petitions had arisen from the growing impact of the infections, not only as a result of the deaths and ill health caused by HIV in the 1990s but also as a result of the increasingly bleak picture coming to light as regards the future for those who were infected with HCV. The situation called for a clear assessment of the needs of the infected and affected communities – this did not occur. In fact, as is analysed below, none of these pressing matters was addressed by the Executive. The lack of information being provided from the NHS in most if not all cases and the inadequacy of the State examining what had happened through the litigations which had been launched (see below) meant that many legitimate questions remained unanswered about how the infections had occurred, whose responsibility they were and whether they could or should have been avoided. This is why the

petitions had called for a public inquiry. The nature and extent of such an inquiry required engagement with the infected and affected community so that the legitimacy of their calls could be fully understood. No such consultation took place. This led to an inevitable sense of greater frustration and alienation at the hands of the State amongst the infected and affected community in Scotland. The community on whose behalf the campaign had been led and on whose behalf the petitions had been presented left feeling unbelieved and let down again. Though the system had allowed the door to be opened, it had been immediately been slammed in their face. Despite the terms of the petitions, the minister thought that it would be best to have an internal investigation as opposed to a public Inquiry into the allegations made by the campaigners.[2785]

The Scottish Executive investigation

3.12 The Scottish investigation into which was undertaken on the instruction of Susan Deacon MSP was directed and controlled by medical advisor to the Scottish Executive, Dr Aileen Keel. Dr Keel confirmed in her evidence that it was Ms Deacon who had determined that there should be an internal investigation, as opposed to ordering the public inquiry which had been called for in the extant petition.[2786] Both of these individuals gave evidence to the Inquiry about the nature of the investigation which, in our submission, demonstrate why it failed. There are a number for reasons for this, which are explored and set out below. In the first instance, it was clear that the newly formed Scottish Parliament had no existing procedures for carrying out an investigation of this nature. Though the petition procedures had provided a pathway for campaigners to access the decision-makers, the lack of proper investigative systems meant that what followed was limited, chaotic, not independent and ultimately did more harm than good. Concerns about the release of the report and the way in it which it had been

[2785] Aileen Keel witness statement (WITN5736003) @ para A77
[2786] Aileen Keel witness statement (WITN5736003) @ para A77

conducted ultimately led Nicola Sturgeon MSP, the about-to-be appointed shadow health minister, to brand it a whitewash, relating in large part to the fact that it was not an external investigation which was mandated, in her view, by the structural set up of the Executive health department and NHS Scotland.[2787]

3.13 As was demonstrated by the evidence of Susan Deacon to the Inquiry, the instigation of the investigation was politically motivated, not motivated by any genuine understanding of or particular concern for the infected and affected community. It appeared from what she said that her main motivation was to show that the new parliament could flex its independent muscle as opposed to flexing it in a way which was helpful or productive. An alternative course could and should have been taken. Proper engagement with the scale of the disaster and the scale of the issues which would have been a meaningful demonstration of the independence of thought and deed of the new parliament could have been achieved by ordering a public inquiry. Instead, by appointing Dr Keel and other administrative civil servants who had been part of providing government advice within the Scottish office pre-devolution to undertake the investigation on her behalf, Ms Deacon showed that her professed desire for the new parliament to be able to take a fresh approach to matters was unrealistic. She made a great show of rejecting the initial advice proffered to her about the pre-devolution policy relating to the disaster. She was keen to take the opportunity to make a political point, using causes such as this to be able to flex the muscle of the new Parliament and Executive. The fact that she appeared not to realise that the very same civil servants who had provided the advice upon which that old policy was based were then out in charge of the investigation into matters which they had previously advised were not worthy of further investigation demonstrated why the process was destined to failure and also that the knowledge of and concern for this cause was of no real substance and designed simply as a means of trying to signal a fresh approach.

3.14 There was a failure to engage with the issues which were involved in disaster which stemmed from a failure properly to engage with the infected and affected

---

[2787] HSOC0020387_009; Nicola Sturgeon first witness statement (WITN7299001) @ paras 14 and 15

community. What had prompted the internal investigation was a petition for a public Inquiry and compensation. Yet, the investigation from the outset seemed be devilled with confusion as to its remit. The evidence heard by the Inquiry suggested that there was a lack of clarity in the investigation's remit. Many important aspects of the disaster including the whole subject of HIV infection and how that had occurred in Scotland appeared never to form part of the remit of the investigation. Although the subsequent investigation was directed towards HCV infections, it seems that from the start, the briefings which had been given to the minister sought to emphasise the distinctions which had been created in the aftermath of the HIV litigation between HCV and HIV. HIV wad characterised from the start as different due to stigma and the fact that the infected could have infected their partners.[2788] The stigma associated with HCV was underestimated. As narrated above, there were many instances of the infected being assumed to be IV drug users, abusers of alcohol or prostitutes. Haemophiliacs with HCV were often assumed to have AIDS. Much of this stigma was meted out by the medical profession or made worse by patients being told by their doctors to keep their infection(s) secret. HCV could of course be transmitted sexually. In particular due to the way that patients were tested without their knowledge (in the bleeding disorder community) or left infected without having been traced (in either community but most commonly in the transfusion community), those infected may unwittingly have infected their loved ones, by bleeding or otherwise. At the very least, the starting point involved a distinction being part of the assumption upon which the investigation was predicated, which meant that it was carried out with a closed mind. This was determined not to be as serious is significant as the HIV infections from the outset. This was a hangover of the post-HIV litigation civil service mantra. It is submitted that there was a lack of proper engagement with the campaigners who could have explained with clarity the nature of the issues involved and the matters which required resolution. Even amongst matters which were expressly part of the remit (such as infections which occurred in the period between 1985 and 1987) the Inquiry has evidence that those who were involved

[2788] SCGV0000045_172 – 22 September 1998 letter from Sandra Falconer

lacked a basic understanding. One prominent campaigner expressed the view that at a meeting with the SNBTS on that subject, those in attendance were surprised that he could have been infected in May 1986.[2789]

3.15 The evidence shows that the scale of the disaster was underestimated from the start, explaining perhaps why it was a matter which was thought to merit a weak internal investigation only and not a public inquiry. A 2000 paper reveals that the context of the investigation was the thinking at least 168 bleeding disorder patients were known to have or have had HCV in the bleeding disorder community in Scotland.[2790] It is far from clear what the methodology was which used to reach this number. The number reached by the Penrose Inquiry of HCV infected bleeding disorder patients was 455. [2791] The statistics group in the current inquiry reached a figure of a similar order. This was not to mention the many, many more who had been infected with HCV from blood transfusions or indeed the many HIV victims. The scale of the disaster was underestimated and hence its significance.

3.16 The standard to be applied to the investigation applied to the assessment of the allegations was, according to the minister, whether "negligence" had occurred and whether "compensation" was payable.[2792] The investigation culminated in a press release which announced that that SNBTS were not negligent in 1980s regarding the eradication of HCV, showing the limitation in standard and scope of the investigation.[2793] Despite her background in social policy, she seems to set the standard at what could be determined by a court and not whether other obligations owed to the patients by the State may be said to have been breached and a moral duty to pay compensation arise. Had the campaigners been consulted, this would have been the question which they wanted the ultimate public inquiry to address. The application of the standard of negligence meant that (a) the investigation served no purpose which could not have been served in a court

---

[2789] WITN2287019 @ para 2.6, though not minuted at WITN2287021
[2790] PRSE0003715 - 10 February 2000
[2791] See para 3.59 of Penrose Inquiry final report
[2792] Susan Deacon witness statement (WITN4436001) @ para 27; PRSE0000978 (1 September 1999), para 1 – though the possibility that the ambit was into negligence within the NHS more generally than the 1985 to 1987 period also appears to have been thought to be the investigation's remit - PRSE0000978 (1 September 1999), para 6
[2793] SCGV0000172_111 – 27 June 2000

action (b) the investigation was doomed to failure as it was conducted in accordance with legal standards by non-lawyers and (c) was always likely to find that there had been no wrongdoing, given the high standard to be applied.

3.17 As had been the case throughout the 1980s and 1990s in the pre-devolution era, there was a complete reliance by the health minister, Susan Deacon, on the information provided to her by her by her medical advisors. There was a lack of any challenge as to the basis of certain matters communicated as fact to the minister. Consistently with the approach of ministers in the previous two decades, information was led to the conclusion that no further action was mandated was accepted without question as the path of least resistance. In fact, the Inquiry which was undertaken and the factual report upon which advice was provided to the minister about how to proceed was not independent. The evidence available to the Inquiry is to the following effect:

(a) Dr Keel came from a haemophilia background. She had professional contact with the key protagonists of the disaster in Scotland. She had herself been involved in treating haemophiliacs in Scottish hospitals over the period during which the infections were occurring. She had been a Leukaemia Research Fund Fellow at Yorkhill Hospital from January 1981 until January 1983. Many of the patients in the hospital who were infected with HIV were infected over that period. She treated those patients at that time and prescribed factor VIII to them.[2794] She had also worked in similar roles at the GRI and in Aberdeen. She confirmed in her evidence that the prevailing view in Scotland was that the commercial concentrates used at Yorkhill were thought to be less safe.[2795] Despite this, she prescribed them. She was an honorary consultant haematologist in NHS Lothian from 1995 at the RIE, where Professor Ludlam was the lead consultant in haemophilia. She regularly attended meetings of the coagulation factor working party from at least 1994 which was also attended by most of the key figures in

[2794] Aileen Keel witness statement WITN5736003 @ para A6(b); IBI transcript for 25/06/22; 8 (Dr Aileen Keel)
[2795] IBI transcript for 25/06/22; 8 to 9 (Dr Aileen Keel)

haemophilia and transfusion.[2796] It seems likely based on her CV that she must have prescribed or injected infected products into patients. There is simply no way in which she was in a position to provide the independent analysis which the situation required. It had been clear from the outset to Ms Deacon that the civil service was pushing the advice formerly given by the UK government Scottish health minister.[2797] Despite that, the very people who had attempted to advise her to maintain the same line were given the power to undertake the investigation;

(b) Factual matters were discussed with the very people whose actions were said to have caused or contributed to the disaster in the first place. Though the remit of the investigation was focussed on the processes within SNBTS for the viral inactivation of factor concentrates, Dr Keel immediately turned to haemophilia clinicians for answers.[2798] There was no reason to have done so given the headline ambit of the investigation. In the same way as the UK government had turned predominantly to Professor Bloom in 1983 for situations as to how to deal with emerging AIDS crisis, the Scottish Executive turned to those with a vested interest in the outcome for answers. When matters which were part of the investigation were put to these individuals, their position on them was simply accepted. She accepted in her evidence that their evidence about whether patients knew of testing and on other matters was taken at face value.[2799] For example, when asked about whether commercial products were used in Glasgow in the period between 1985 and 1987, Dr Lowe said that they had not been. Other materials show this to be inaccurate.[2800] It was suggested at this meeting that the heat treatment strategies of BPL and PFC were developed so as to be complimentary.[2801] Other evidence shows this to be inaccurate. By the time of her evidence, Professor Keel could not remember if

---

[2796] LOTH0000051_027
[2797] Susan Deacon witness statement (WITN4436001) @ para 20; Briefing of 15 July 1999 - SCGV0000176_118
[2798] PRSE0000978 (1 September 1999) – meeting with Dr Ludlam and Dr Lowe
[2799] IBI transcript for 26/07/22; 39 (Aileen Keel)
[2800] PRSE0002887 _0022 – Glasgow had used Immuno factor IX (heated) for a period in 1985 when the SNBTS product was not heated; and the Inquiry had heard evidence Dr Foster about use of Armour Factorate HT at Yorkhill in 1986 (see analysis above)
[2801] PRSE0000978 (1 September 1999), para 4

this had been serendipitous or planned. Further, the materials show that campaigners had alleged that patients were not informed of the risks, had been tested for viral disease without their knowledge or consent and that there were delays in them being told about their diagnosis. These matters were also taken to Drs Ludlam and Lowe for their comment. Their partial answers were inaccurate, though they were accepted as true without further investigation.[2802] This deference to the medical profession's testimony has been a feature of investigations undertaken into the circumstances of the blood contamination disaster in Scotland – see the submissions regarding the Penrose Inquiry and the GMC below. Such an approach carried with it the implication that the patients are not to be believed, their testimony a mere irrelevance to the State. Such an attitude has delayed and prolonged the suffering of the infected and affected community. It has immeasurably compounded their harm. It is worthy of note that a meeting minute from early 2000 shows that a government legal advisor (Mrs Towers) appears to have been keen to limit the investigation to policies.[2803] It is unclear why this approach to the investigation was taken as opposed to simply investigating the facts;

(c) The result of this was that it was far from clear what capacity Dr Keel was acting in in the investigation, in particular whether she was a factual witness using her own limited, non-consultant experience or as a gatherer of evidence. For example, she seemed to be under the impression that there was no evidence that HCV might cause serious disease (in 2005 advice) or that HCV was anything other than a benign condition before 1985.[2804] As we argue elsewhere this was inaccurate. An examination of the medical literature available at the time would have shown that. In her oral evidence she confirmed that this was in part due to her recollections of the attitude towards the condition when she worked in haematology before becoming a government medical advisor in 1992. Thus, the advice given to the minister was based on her incomplete recollection from her time in practice, informed not by looking at medical journals or seeking

[2802] PRSE0003715 (10 February 2000), paras 3, 4 and 7
[2803] PRSE0003715 (10 February 2000)
[2804] SCGV0000044_024

independent expert input but by the partial views of those who might be criticised. [2805] She has a recollection of 8Y not being available to meet the needs of all of the patients as she had worked at the Middlesex hospital, again working on the basis of some limited personal involvement. This was not really the question which the 2000 inquiry should have been looking at. What mattered was the possibility of a supply only for those who would benefit from it – those likely to be uninfected already. The culmination of this was that she said in her evidence that she believed the material to have been placed before the minister to have been accurate.[2806] In relation to the subject to anti-HCV testing she maintained that the position she advanced was accurate (that there was no negligence) based largely on the fact that that the blood transfusion services preferred to wait, despite the decision in A v NBA (the detailed analysis on which did not seem to be part of the report to the minister).[2807] She had based her views in this regard on papers supplied to her by the Inquiry and colleagues with whom she had come into contact from 1992.[2808] Whether this is accurate or not, it was unbalanced and not actually correct in places;

(d) The fact that the investigation was undertaken by Dr Keel and others in an unbalanced fashion is further shown by the fact that she was aware that decisions regarding elements of the investigation were taken by the Scottish Office. When Duncan Macniven gave evidence to the Inquiry he was quite adamant that though he was still employed by government at the time of the Executive investigation, he was not consulted about how or why decisions were reached in the 1980s when he played a prominent role in this area.[2809] In Dr Keel's view the department was not directly involved in the operation of SNBTS.[2810] This contrasted with the evidence of Mr MacNiven who stated that, in fact (including him and others from the SHHD) who were in charge of SNBTS as he said that they could do the necessary and resolve matters within SNBTS by

---

[2805] IBI transcript for 25/07/22; 47 (14) to 48 (22) (Aileen Keel)
[2806] IBI transcript for 25/07/22; 54 (Aileen Keel)
[2807] Ibid
[2808] IBI transcript for 25/07/22; 55 (Aileen Keel)
[2809] IBI transcript for 19/07/22; 147 to 148 (Duncan Macniven)
[2810] SCGV0000170_164; IBI transcript for 26/07/22; 23 (Aileen Keel)

gathering together a small number of people. These were tripartite meetings with 7 people from the SHHD, SNBTS and CSA.[2811] Further, when John Reid gave evidence to the Inquiry, he confirmed that he was not aware of the Executive investigation at the time, despite the fact that he was the Secretary of State for Scotland. It clearly did not feature in the investigation that answers to issues which had arisen in Scotland may lie at Westminster, with which Mr Reid may have been able to lend assistance. This is despite the fact that civil servants like Dr Keel and others had worked in the Scottish office pre-devolution and must have been very aware of the fact that (as the Inquiry itself has found) many Scottish issues were directly or indirectly determined at the time by decisions taken elsewhere in Westminster, such as at the DoH or in the Treasury;

(e) When engagement with campaigners took place, it did not take place with the person with the political responsibility for the investigation (ie the minister) but with the SNBTS, whose "party lines" had been well developed by this point, as is discussed elsewhere in this submission.[2812] The investigation was dominated by these voices who appear to have been seen as independent advisors as opposed to factual witnesses, who may have been subject to criticism for their acts and/ or omissions themselves;

(f) Even when the medics came up with areas for legitimate investigation, these were not pursued, apparently on legal and not medical advice. The tracing of the haemophiliacs who may have been lost to follow up (most likely mild haemophiliacs) was raised as a matter for investigation by the then current haemophilia directors.[2813] The context of this matter being raised was a national recognition that there were haemophiliacs who may be infected who may not have been traced.[2814] Thus, advice was received that this was a genuine issue and those responsible for the medical treatment of such patients considered such an investigation to have been merited in the interests of those patients.

[2811] IBI transcript for 19/07/22; 32 (Duncan Macniven)
[2812] See for example the meeting with the Haemophilia Society on 25 November 1999 at the Western General Hospital, Edinburgh (WITN2287021)
[2813] PRSE0003715 - 10 February 2000, para 9
[2814] GGCL0000074_001 – 1999 – Christine Lee reporting that undiagnosed bleeding disorder patients still presenting with HCV

This matter was not investigated at that time, despite this advice. The minute from this meeting shows that the matter was referred to the Central Legal office (the legal advisors to the NHS) for consideration. The approach clearly shows that the tracing of potentially infected individuals was thought of not as a medical matter but a legal one. As had been the approach to the HCV Lookback, the principal consideration appears to have been the possible legal ramifications of tracing the infected as opposed to the well-being of those who may benefit from treatment, support or advice. Later evidence available to the Inquiry outlines the work carried out to identify and trace patients at risk of HCV since the Penrose Inquiry. This now shows that there were, in fact, haemophiliacs who required to be traced, who were not (the 145 unknowns who had been lost to follow up as at 2013 which were subsequently followed up during the course of the Penrose Inquiry or, for 69, subsequently in 2018, many of whom had died by that time).[2815] It is likely that the failure to attempt to trace the patients in 2000 led to some these not being traced, despite the advice given by the consultants;

(g) As is addressed elsewhere, the patient/ family communities were not or hardly consulted as to the ambit of the matters which might be investigated and why or their position as to what had happened. Indeed, the preliminary conclusions had been made before hearing the case of the Haemophilia Society at all[2816]. Ms Deacon herself identified this as part of a civil service policy not to allow ministers to speak to "folk and make up their own minds".[2817] The result of this (as is discussed below) was a lack of clarity about what the case for investigation was from the outset and civil service "capture" of the process based on pre-existing prejudice about the outcome. As Ms Deacon herself identified, she was consistently being advised by officials that there was nothing further to discover. The investigation was a whitewash from the start.[2818]; and

---

[2815] GRAM0000060_005 (29 March 2018) Note titled "Scottish Bleeding Disorder Patients HCV (Hepatitis C) update March 2018", written by R Campbell Tait

[2816] SCGV0000043_047 – 9 September 2000

[2817] IBI transcript for 29/07/2022; 42 (11 to 16) (Susan Deacon)

[2818] IBI transcript for 29/07/2022; 56 (18 to 25) (Susan Deacon)

(h) There is considerable evidence available to the inquiry from which an inference might reasonably be drawn that, despite the claims made by Ms Deacon to the contrary, a significant influence over the Scottish Executive investigation and position on the matters was still being wielded by the UK government. The influence by civil servants who had previously been versed in the UK government line is discussed elsewhere. The DoH was clearly nervous about compensation being paid in the UK.[2819] Susan Deacon wrote to request a meeting on the related issue of the HCV litigations in mid 2000. The DHSS clearly had a view on the need to co-ordinate the approach on HCV compensation more generally. Lord Hunt was encouraged to promote the adoption of a 'state of the art' case in respect of heat-treated products produced between 1985 and 1987 in Scotland.[2820] Funding would clearly have been an issue with compensation or any other form of support. An 'options' paper relating to the outcomes which may have eventuated after the HCCC report in Scotland was sent to Yvette Cooper on 2 July 2001.[2821]

3.18 Though it is submitted on this basis that it was clear that the investigation which was undertaken was not independent, it is certainly the case that it did not have the appearance of independence, such that justice was at least not seen to be done in the investigation. Ms Deacon's clear expressed wish was that there should be a break with the past and that the previous disappointment of the infected and affected community based on the inadequacy of their previous attempts at government engagement should be remedied. This could never have been achieved by a process in which the key investigator was or had been a professional colleague of those whose actions required to be investigated, where the investigators were the very advisors whose responsibility it had been to provide advice which led to that previously inadequate government engagement, when fact finding was based on interviews with those whom the campaigners deemed to be responsible, when those interviews took place in secret, when the

[2819] SCGV0000171_053 – 25 March 2000, para 5
[2820] DHSC0046972_070
[2821] SCGV0000243_051

community asking for the petitions to be accepted were hardly consulted and when no clear explanation was given as to why the process ended in failure. This was evidence in Scotland of the State closing ranks around a lie, as Jeremy Hunt described the process in his evidence to the Inquiry.

3.19 Dr Keel was asked a number of questions in her oral evidence by Inquiry Counsel about various other matters relating to the contamination disaster. In her answers she again showed that she subscribed very much to the "party lines" adopted by the medical establishment which, we have shown in other parts of this submission, to have been inaccurate or misguided.[2822] In this passage she gave confused evidence about the assertion that it was factor concentrates which had significantly improved life expectancy, contrasting the position with when only bed rest was available. This showed that this assertion was not soundly based as the safer cryoprecipitate was not considered to have been an alternative which significantly improved life expectancy without the extra risk of pooled concentrates. This repeated the oft heard mantra that concentrates were necessary. As is argued elsewhere this was untrue as the evidence does not show that it was concentrates by the factor VIII content of cryoprecipitate which improves life expectancy of severe haemophilia A patients. The possibility of treatment with FFP was also not considered by her, nor was the fact that cranial haemorrhage was not a risk for mild or moderate patients who tended not to have spontaneous bleeds. She asserted that concentrates had transformed the management of the condition which would have been an accurate assertion about convenience not life expectancy.[2823] In addition, she repeated the mantra that 8Y was only known to have been heat treated against HCV in 1988. As discussed elsewhere this confuses conclusive proof with reliable scientific evidence of non-infectivity which was available from 1985 or at the latest 1986 from the clinical trials. She accepted that informed consent (based on information about risks and alternatives) was important but that she did not remember that being the focus

---

[2822] IBI transcript for 25/07/22; 117 to 149 (Aileen Keel)

[2823] The advice at the time of subsequent investigation was summed up in SCGV0000176_118 – 15 (July 1999) from Mr Bell to the minister regarding the continuing campaign for compensation. He asserted that patients received best treatment which was **essential for their survival**.

of the SHHD examination of compensation in the 1990s. She expressed the views that NANBH was thought to be relatively benign, a view which formed part of the "party lines" but not one supported by the evidence. Again, this was part of the "conclusive proof" defence that nothing needed to be done until things were absolutely known to be the case. She stated that she had seen patients with raised liver enzymes but that it would have been very difficult to tell the patient what that meant, which appeared to mean that it could not be said conclusively. In any event, she seemed to think it was not necessary as the patient was not complaining about that ordinarily but about their joints. It would have been hard for the patient to complain about something he did not know was happening and about which his doctor had not informed him. When a test became available, all patients would have been tested and they would have been given their results. This was an assumption not backed up by the evidence the Inquiry has heard. She accepted that too much blood was given in transfusions and explained that that was the catalyst to getting the Better Blood Transfusion programme underway. She accepted that this unnecessary use of blood was not the best available treatment. In response to a suggestion that the best available product might have been surrogate tested blood, she spoke about the unreliability of ALT testing as ALT elevations could possibly be due to alcohol, "not least all the other viruses that can affect the liver".[2824] This runs contrary to the analysis of surrogate testing given elsewhere and was not an answer to the question. It does not mention anti-HBc testing. One might also have thought that the eradication of donations which contained viruses which were harmful to the liver would be a good and not a bad thing. She was equivocal on the accuracy of the suggestion that HCV did not attract stigma. Importantly, she was asked by the Chair about what advice she would have given the minister if she had been the DCMO in 1980, if it had been thought that HCV was a potentially fatal disease and whether she would have advised that concentrates were the best treatment available. She replied that if it had been known then HCV was indeed a serious infection which could lead to death, yes

[2824] IBI transcript for 25/07/22; 123 (Aileen Keel)

that would have changed the advice given and the political perception about the need to do something. As is argued elsewhere in this submission, this was the situation based on the then available evidence and indeed was the position of Dr Walford in 1979/ 80, as described above. A different course should have been take then as this was known or at least there was a clear basis for suspecting it. It does not seem on these matters that Dr Keel was providing the minister with the full available evidence but her gloss on it, influenced by her exposure to the party lines.

3.20 Similarly, to the way that the DoH was structured, Dr Keel had responsibility for advising in relation to matter about blood but not infectious diseases.[2825] Structurally, the two did not go together. As a haematologist who did not deal primarily with infectious diseases, it was always likely that Dr Keel would only see the perspective of her colleagues. In response to a suggestion that she had a role in stopping a public inquiry in Scotland, Dr Keel stated that that it could never be in her power in her roles to prevent the holding of a public inquiry.[2826] Though this may have been technically true, she played a pivotal role in providing the advice upon which Ms Deacon require to act. As was the case with other civil servants who gave evidence to the Inquiry, Dr Keel was keen to downplay her role as merely advisory. As ministers like Ms Deacon required to rely heavily on her advice, she in fact had a pivotal role at this time. In any event, it did not appear clear that Dr Keel had a clear grasp on the key facts and issues which ought to have informed the minister's decision-making, either at the time or at the time of her evidence. This meant that decisions were taken on the basis of information which was accepted as comprehensive and accurate but which was not. In her evidence to the Inquiry, Dr Keel appeared to be unaware of certain simple facts relating to the subject-matter under discussion, both at the time and during the course of her evidence to the Inquiry. She appeared to be under the impression that the HCV virus had been discovered in 1989. This was incorrect. The Chiron Corporation

---

[2825] IBI transcript for 25/06/22; 17 (Dr Aileen Keel)

[2826] Response of Aileen Keel to Bruce Norval (WITN5736001) (response to campaign statement @ WITN2235003 at paragraph 18.3)

announced the isolation of the virus on 19 May 1988.[2827] Scientific details of the discovery were published in 1989.[2828] Though this may appear on the face of it to be a relatively trivial inaccuracy, in this context it was not. It was a material error, which demonstrates the flaws in the system. Dr Keel (given her prominent role as a government medical officer and her background in haematology) was significantly relied upon to provide advice to the Scottish Government over this period. Her advice (derived in large part from other haematologists whom she had consulted, as is discussed elsewhere in this submission) was highly material in informing government decisions about the appropriate response to the disaster and those affected by it. One key element of the mishandling of the disaster had been the delay in the introduction of routine anti-HCV testing which had been found to have been in breach of the State's obligations under the CPA 1987 in A v NBA. The error in the information about then the virus was discovered made the delay in the introduction of routine anti-HCV testing seem less than it actually was. Her witness statement to this Inquiry indicated that she was under the impression that knowledge of the risk of HIV and HCV dated only from the date of discovery of the viruses.[2829] As the analysis presented above shows, this not accurate. Again, this is a considerable issue. Further, Dr Keel appeared to be misinformed in relation to various key elements of the HCV Lookback, as is discussed in detail above. The minister was materially misinformed on these regards.

3.21 This was in addition to matters on which the position of the consulted medics was simply accepted as true which also led to an inaccurate or at least partial view of events being the basis upon which decisions were taken by the minister (see above). These were the "relevant networks" through which she obtained information about issues pertaining to infected blood.[2830]

[2827] PRSE0004410 (19 May 1988) - Ezzell, 'Candidate Cause Identified of Non-A, Non-B Hepatitis', Nature; 19 May 1988

[2828] PRSE0001337 Choo et al, 'Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B viral Hepatitis Genome', Science; 1989, 244: 359-362

[2829] Aileen Keel witness statement WITN5736003 @ para A.5

[2830] Aileen Keel witness statement WITN5736003 @ para A10(a)

3.22 There were other matters on which it appeared that the minister was given inaccurate or incomplete evidence. A paper was submitted on behalf of SNBTS which was prepared by Peter Foster.[2831] Various claims were made, including:

(a) Para 1.1 – neither cryoprecipitate nor DDAVP was listed as amongst the most significant advances in the treatment of haemophilia A. This gave the inaccurate impression that factor VIII concentrate was the only treatment available for the condition.

(b) Para 1.3 – it was stated that say that Scotland was believed to have been the first country in the world to have provided an HIV safe factor VIII concentrate for its whole haemophilia population. The context of this claim is discussed in detail above. In any event, the papers omitted to mention the fact that some countries, like Finland, chose not to use factor concentrates, instead preferring products like cryoprecipitate on safety grounds.

(c) It was claimed that all the factor VIII stocks which were issued from January 1985 were dry heat treated at 68 degrees for 24 hours. Whilst this may be true, it is not the whole story with regard to unheated stock still being in circulation. In a statement made to the Inquiry, one widow of an Edinburgh cohort patient gave evidence of receiving unheated factor VIII for his treatment in about 1985/ 86. Though she noticed the mistake and swapped the product for a heated one, this suggests that any assertion to the Inquiry that all factor VIII product issued after December 1984 was heat treated to eradicate and all stocks were so heated is not true. The system was not as efficient as some would have the Inquiry accept. She also mentioned that this had happened to others in the unit and therefore this was not an isolated incident.[2832] It is submitted that this particular statement is a detailed and compelling one written by a lady who took much action on the part of her husband in the aftermath of his death in 1988. Her statement is detailed and rings true. There is no reason to doubt its accuracy about the

[2831] PRSE0001079 (1999) – SNBTS Report to the Scottish Executive on the development of a hepatitis safe factor VIII concentrate by Dr Peter Foster
[2832] WITN2665001, para 44 (first statement of Linda Grigor)

unheated factor which could have exposed her husband and may have exposed others to the risk of HIV infection after the notional date of heat treatment in December 1984.

(d) Para 1.4 – it was said that Scotland was believed to have been the first country in the world to have provided a hepatitis safe factor VIII concentrate for its whole haemophilia A population. This was a misleading statement in the sense that at the time it was so introduced (April 1987) most treated haemophiliacs were already infected with HCV. The whole truth would have been that the target group (the non-infected) were let down by the fact that the English timetable had not been met. The report did not mention (i) The evidence suggesting that NANBH could be a chronic condition with serious consequences such as the 1978 Preston biopsy research (see para 3.2) (ii) the 100% NANBH infectivity rate of PFC intermediate factor VIII concentrate (iii) the reason why heat treatment was introduced in December 1984 being that PFC products had multiply infected haemophilia patients in Scotland with a fatal disease (AIDS) (iv) the fact that the heat treatment technology which was discovered to inactivate HTLV III was inadvertently found to have been effective in that regard as a result of scientific study by others (vi) the information shared between Scottish hospitals and the PFC about the quality and infectivity of their products and the lack of efforts made by the PFC to ensure that patients were aware that information about them was being so shared (vii) the number of batches of PFC factor VIII or IX which had been found to be infective with HIV and had infected and subsequently killed peopled as a result (viii) the numbers infected with HBV, HCV or HIV by PFC products or (ix) The numbers who had died as a result.

3.23 No information was conveyed about matters arising in correspondence written by Professor Cash about the production of products at the PFC. [2833] This included assertions that PFC products had endangered the lives of patients and that he had

[2833] See PRSE0000462 (letter to Mr Donald, CSA, 20 July 1988) and Dr Foster's response about it to the Penrose Inquiry (PRSE0001919) (See page 173, para 81.2.4 of Peter Foster witness statement at WITN6914001)

authorised the release of products which did not meet specification over the heads of senior staff at the PFC, the PFC did not have a manufacturing licence (as would be required of a commercial operator providing products to the UK market) and if had it required to hold one, it would not have been given one at the time of the second MI report due to breaches of GMP.

3.24 Even in the area of the heat treatment processes between 1985 and 1987, it appeared to have been the official position that it had not been proven until 1988 that the BPL heat treatment process was safe for HCV until 1988.[2834] This was one of the SNBTS party lines. As is discussed in detail elsewhere in this submission, there was strong evidence that it did not transmit to PuPs by 1985 from the Craske research/ clinical trial of 8Y. This had not permeated the thinking of the Scottish medical community until a supply of 8Y in late 1986 was procured. That very act shows that the explanation of the position which was current in the thinking of Dr Keel and hence the minister was at best incomplete as it shows that 8Y was known to be safer at that time in Scotland. This line was another example of the familiar "conclusive proof" technique adopted by the medical profession to evade responsibility which (once again) had been a predominant issue in the government's advice about the emerging AIDS crisis almost 2 decades before. The investigation appeared to contain no reference to the failure to procure a supply of 8Y for virgin or minimally treated patients before late in 1986. It does not appear that the minister was made aware of the clear evidence that the pre-April 1987 PFC factor VIII concentrate (NY) was 100% infective for HCV on first infusion, matters which never featured in the SNBTS party lines. As their position was to be about possibly having to appear before the Lindsay tribunal, the SNBTS were at best reluctant to be forthcoming with the whole truth about the disaster and their role in it.[2835]

3.25 There appeared to be significant confusion around the ambit of the investigation from the start. This appears to have arisen part from the high number of issues

---

[2834] Aileen Keel witness statement (WITN5736003) @ para A80(d)

[2835] WITN3431004 (2000) – Dr Perry's concerns to be about possible inconsistencies between the positions of the PFC and BPL which might require discussion before Dr Terry Snape's appearance before the Lindsay tribunal as an expert witness

which arose from the blood contamination disaster in Scotland and their complexity. The very fact that so many issues were involved was reason in itself for the public inquiry to be ordered into them, as opposed to this preliminary examination of whether one should be contemplated which was, as the evidence showed, simply deemed to be a "PR exercise" within the Scottish Executive as opposed to a genuine attempt to get the bottom of the matter. The inaccurate and confusing briefing provided to the minister at the outset on 5th August 1999 constituted an inaccurate starting point to the investigation and a misleading direction to the minister. The briefing set out that the transfusion related issues arising from the disaster were limited to the allegations raised by the CPA claims (which were under consideration by the DoH at the time).[2836] This was inaccurate. Issues relating to the occurrence of transfusion transmitted infection are addressed throughout this submission. Despite being told about transfusions being part of the picture in the August briefing, the minister was allowed to meet only with the Haemophilia Society which clearly did not represent victims of this element of the disaster at all.[2837]

3.26 There is further evidence of the ambit of the investigation being both confused and limited. The investigation purports to be about the SNBTS's production of a heat-treated factor concentrate in the period 1985 – 1987, during which period the 8Y product had been available from BPL. This of course related only to blood products and not transfusions and associated matters such as anti-HCV testing, surrogate testing, transfusion practice and issues of consent all of which arose over that period. The Health Committee questioned why the investigation is limited to the period between 1985 and 1987.[2838] Clearly, its members understood that the issues for resolution went far wider than that. Despite the apparent limitation to then ambit, even within the bleeding disorders areas, issues such as non-consensual testing were clearly mentioned in reports. Research played no part, nor did HIV infection at all, at any time. There appeared to be no capacity for evidence to be gathered about the context in which any infections with HCV or HIV

[2836] Susan Deacon witness statement (WITN4436001) @ para 29
[2837] Susan Deacon witness statement (WITN4436001) @ para 34
[2838] SCGV0000173_130 – 14 July 2000

occurred, including HBV, emerging knowledge of NANBH or HIV infection. There appears to have been no consultation with the campaign groups or the HCCC about the ambit of the investigation, what the ambit was eventually decided to be or why. It is worthy of note that the clear position of Nicola Sturgeon, shadow health minister and HCCC member throughout this period was that compensation was payable as a matter of simple justice irrespective of the issue of culpability. She saw the payment made in respect of HIV to constitute a precedent which meant that HCV payments should automatically follow.[2839]

3.27 Other matters which were known to be of significance to the infected community but which appear to have been deliberately omitted from the ambit of the investigation included the subject of surrogate testing for NANBH. The lines which had been taken in this regard were identified as being important and also potentially subject to criticism, as it was only with a "dollop of hindsight" that the SNBTS's official position on ALT testing could be deemed to be justifiable. [2840] The whole tone of this email shows the real essence of the investigation. Its purpose was to exonerate the State and not to look at them independently. Its goal was to seek to limit the matters under consideration and not to investigate them fully. The bid to come up with a line to take for any argument which might be made shows that that was the way that the investigation worked in reality. The proposed line about heat treatment being used to justify the decision not to implement surrogate testing was a complete fabrication. Heat treatment was not available until long after surrogate testing was contemplated in Scotland (by Dr McClelland from 1981) and internationally, when it had been done in other countries from the 1960s. It paid no heed to the fact that those receiving transfusions received no benefit from heat treatment. The proposed line was in fact a proposed lie. The email was sent to Dr Keel and Mrs Towers. Its object was to seek medical justification to avoid litigation risk. It paid no regard to the infected or the duty of the State to them. The fact that there was discussion around whether

---

[2839] Nicola Sturgeon first witness statement (WITN7299001) @ paras 25 to 28

[2840] SCGV0000171_052 (28 March 2000)

correspondence involving Professor Cash which was critical of the government should be published also makes clear that the inclination was to supress and defend by whatever means.

3.28 Despite the fact that the underlying petitions sought not only a public inquiry but also compensation, there was no assessment undertaken of the needs or losses of the infected (far less the affected) community. As is pointed out in our assessment below of the Sir Robert Francis evidence to the Inquiry, the assessment of the extent to which the State should be deemed to owe a moral duty to compensate the infected and affected is based on an assessment of both the State's culpability for the occurrence of the disaster and the nature and extent of the harms caused, in exercise of its obligations as having caused the disaster and its obligations to look after injured citizens. The fact that the State did not undertake any such assessment at any stage means that at all points (up to the current Inquiry) the State failed to look at the shole picture relating to the issues arising from the disaster. In her statement about the aftermath of the investigation, Ms Deacon referred in her evidence to confusions that documents were missing and the multiplicity of the questions which arose.[2841] Rather than detracting from the need for a proper judicial inquiry, these issues merely reflected the need for one. That that was not realised shows that there had never been any intention to have one at all. Further, by restricting the investigation to issues of negligence, Ms Deacon had in fact done nothing more than adopt the policy of the previous governments which was to the effect that redress could only be sought via the courts where questions of negligence could be settled. This policy was of course, the very policy to which she had initially sought so vehemently to distance herself in order to show the strength of the new Parliament. It is clear from correspondence seen by the Inquiry that there was never any intention to conduct anything more than a "PR exercise" and that, as correspondence relating to the attitude of the then first Minister shows, the appearance of an open mind was one thing but that the main priority was to ensure that there would be no open cheque book.[2842] Ms Deacon

[2841] Susan Deacon witness statement (WITN4436001) @ para 62
[2842] SCGV0000170_152 - 23 September 1999

had deemed the Inquiry to have found no new evidence. That was hardly surprising given the way in which it was conducted, as explored above.[2843]

3.29 The investigation, as Ms Deacon accepted in her evidence was tainted by group think derived from civil servants whose mission was to minimize investigation and exposure. The minister herself went along with that due to concerns about where a more extensive investigation might lead, in particular the cost of a possible compensation scheme.[2844]

Subsequent events leading to the formation of the Ross Committee

3.30 Due to the tenacity of campaigners and the continued interest of the HCCC in the matters in the petitions, the issues relating to the blood contamination disaster in Scotland did not disappear from the political agenda, despite the failure of the internal investigation and the apparent continued insistence of those advising the government that that should be the result. The issue of compensation which had been sought in the petitions was still on the agenda and was still being resisted by those advising the Scottish government based on medical party lines and the previous government policy. Ministerial briefing paper from April 2001 set out all the lines for the minister to take at the SNP debate on the issue of HCV compensation.[2845] Numerous erroneous or at least questionable party lines were again set out, including conclusive proof (consensus about the potential severity of the condition before there was an obligation on the State to take action[2846]) . Also included was the SNBTS party line that it was the first country to be able to produce an HCV safe for all haemophiliacs.[2847] Of course, by this time this was not the correct goal as most were already infected. The question of producing or procuring safe products for those likely to have been uninfected was not

[2843] Susan Deacon witness statement (WITN4436001) @ para 95
[2844] IBI transcript for 29/07/22; 86 (17) to 87 (6) (Susan Deacon)
[2845] SCGV0000242_077 – 23 April 2001
[2846] Ibid, page 3
[2847] Ibid, page 6

addressed. Issues of moral duty, or possible breach of the CPA 1987, the 100% infectivity of factor VIII concentrate produced in Scotland prior to April 1987, the infections of patients in Scotland between 1985 and 1987 which did not occur in England did not feature in the briefing. The suggestion that it was not possible to test for agents which were not yet known[2848] was inaccurate as surrogate testing was available. No evidence was presented to the minister about surrogate testing having been introduced in other countries. It was suggested that campaigners had been able to present new evidence. In fact, the minister had refused to meet with them in case they did in December 2000. They (unfunded and often ill) had relied upon the government to uncover evidence and present an objective assessment of what had happened. In circumstances where their whole position was predicated upon not knowing the truth, to have expected them to have proven what happened seems startlingly unrealistic and unfair.

3.31 The Health and Community Care Committee Report on Hepatitis C dated 3 October 2001 made various proposals about moving matters forward with compensation.[2849] It appears to have been largely ignored, the old policy of "no compensation, no public inquiry" having been re-adopted. The Haemophilia Society had strongly argued that it was unfair that people who contracted one type of virus should have recourse to financial assistance on a no-fault basis but those who contracted Hepatitis C in the same way did not. The committee agreed with that assessment in their report.[2850] The report recommended a financial support mechanism should come into force within 12 months and should be determined on the basis of need (having regard to physical and psychological loss individually suffered). The report recommended that the financial scheme should include redress for practical difficulties, for example the inability to obtain affordable mortgage or life assurance, and should consult with Hepatitis C sufferers. The report recommended the adoption of a protocol between the Committee and the Executive that, wherever practicable, the Executive consults with the Committee before deciding upon the terms of an internal inquiry and membership of the

[2848] Ibid, page 7
[2849] MACK0001929_001
[2850] Shona Robison statement (WITN6648001), para 6

Inquiry team, to increase publish confidence in the process. None of these matters was taken up at that time.

3.32 On 2 October 2001, the Scottish Health Committee called for financial support for all Hepatitis C blood transfusion sufferers.[2851] The Committee said that it was persuaded by the 'moral' case for providing practical and financial assistance. This was not taken up. It is important to note that this was a second investigation into the blood contamination disaster, after the Executive's own investigation. Prior to event the Ross committee report (addressed below) this Committee recommended that the level of financial assistance awarded to any claimant should be determined on the basis of need, having regard to the physical or psychological loss individually suffered, and should include redress for practical difficulties such as the inability to obtain an affordable mortgage or life assurance. Thus, the report recommended that there required to be an assessment of individual need based on the losses in the form of injury (physical or psychological) which had been suffered. This was an early recommendation for an assessment based compensation scheme, which was not taken up. Of course, the HCCC was a cross party committee. The recommendation enjoyed cross party support. Despite this, ministers feared making payouts because they thought that "it would create a precedent for compensation and lead to immense future difficulties".[2852] Initial indications were that this issue was to be raised by Susan Deacon at the Joint Ministerial Meeting of UK Health Ministers on 22 October 2001.[2853] Though it appears that this did not occur, the inclination to require to enter into discussions at a UK level on this matter in the face of increasing political pressure appears to show the reality of the situation. Consultation was either required at a political level with the UK Labour government and/ or the possibility of funding any compensation scheme required to be authorised at Westminster. Either way, the impression given to campaigners that there was a genuine desire in Scotland to take the matter forward independently appears to have been inaccurate, as subsequent events were to prove. By 22 November 2001, a full analysis of the

[2851] ARCH0003326/ MACK0001929_001
[2852] WITN2287029
[2853] DHSC6262783; WITN6942012

government position reached in response to the 2 petitions was set out.[2854] A financial support scheme ought to have been implemented at this stage in light of the clear HCCC recommendations. That Committee had taken the time to listen to the campaigners and consider the matter fully. Instead, as is discussed below. The matter was sent to an independent committee. It is submitted that this happened in order to buy time in light of the increasing political pressure (a) to square the position with the contrary UK policy on the matter, despite the asserted intention of the Executive to look at the mater independently and (b) to work of how any such scheme might be funded, a matter which appeared to have been given little real consideration by this point.

3.33 Susan Deacon was replaced as health minister by her deputy, Malcolm Chisholm MSP in late 2001. He of course had had a background relating to the matter. He had been a member of the HCCC Committee who spoke up in favour of the "no negligence" line at the committee meeting when Susan Deacon was questioned about the petitions on 25 October 1999.[2855] He accepted that in April 2001, he continued to think that the generally held government line about "no negligence, no payments" should be held.[2856] This was despite the decision that there was legal liability in the CPA cases resulting for the failures on the part of the State to introduce testing regimes in A v NBA. This continued attitude was held by him was despite the fact that as an MP he had raise the issue of compensation (unsuccessfully) with then Scottish health minister Sam Galbraith on behalf of a constituent.[2857]

3.34 Malcolm Chisholm became Ms Deacon's deputy in the month the following the HCCC meeting in October 1999. He became health minister in November 2001, having held a fixed view about maintaining the UK government line which had been committed to by frank Dobson from 1997 as recently as April 2001. Again, his involvement in the issues which remained after Ms Deacon left the role was

---

[2854] SCGV0000247_030
[2855] MACK0001929_021
[2856] Malcolm Chisholm witness statement (WITN0794001) @ para 16
[2857] SCGV0000022_013 – Memo to PS/Mr Galbraith dated 30 September 1998 regarding representations made by Mr Chisholm on behalf of a constituent with Hepatitis C, attaching copy of the letter he sent on behalf of constituent

not consistent with him approaching the matter with an open mind. He had already expressed a view on the matter publicly and was thus not independent in the debate. The desire to draw a line under the incomplete investigation is clearly demonstrated by the fact that the minister was advised not to meet with the campaigners after the report was published.[2858] This was merely a reversion to the old government policy that this was a matter for the past. The position was a clear rejection of there being any possibility of this matter being looked at further.[2859]

4. The Ross Committee and its aftermath

4.1 The political pressure on the Executive continued to be applied via the HCCC during 2002. They democracy process refused to let the issue lie. The commentary on the position which had been reached was summed up in evidence available to the Inquiry from the UK perspective.[2860] It was noted by the start of 2002 that the Scottish Executive Ministers had rejected the recommendations of their Health Committee, but that the issue was due to be debated in the Scottish Parliament on 10 January 2002. The UK briefing note stated that "This was the first time that Scottish Ministers had rejected such a recommendation and Malcolm Chisholm (Minister for Health and Community Care in the Scottish government) was apparently concerned that the Executive would lose the vote". This was an unprecedented action on the part of the Scottish Executive. Their determination not to look at the matter further or consider the matter for the first time in light of any sort of assessment of the needs of the community or any fair assessment of the facts remained resolute. However, they had been backed into a political corner.

[2858] SCGV0000180_088 – 23 November 2000 (advice from Dr Keel based on the emergence of new allegations which merely demonstrated that the existing investigation had been insufficient and was in fact a good reason to meet, not to refuse a meeting)

[2859] SCGV0000044_012 (11 December 2001) – Scottish Executive response to Health Committee report on HCV

[2860] Witness statement of Alan Milburn (WITN6942001) @ para 9.1 and Note briefing Yvette Cooper, dated 7 January 2002

4.2 The political pressure which was able to applied to the Scottish Executive led to the formation of the Ross Committee, under the chairmanship of former senior Scottish judge, Lord Ross. The context is important, in our submission, in understanding the reasons why this steps was taken. There was growing political pressure from the HCCC in the Scottish Parliament to adopt a line which was inconsistent with the position which had been adopted nationally to this point. The Scottish Executive had portrayed its investigation, erroneously, as an open investigation into the issues, in response to the calls for a public inquiry and compensation made by campaigners. The inadequacy of that investigation had been demonstrated by the re-examination of the issues by the HCCC. The pressure to do something was becoming irresistible, in particular if the reality of the lack of real concern for needs and wishes of the campaigners was not to be exposed. Time was needed to work out how to reconcile that pressure with the national line which continued to be held by the UK government – also a Labour administration, as was the position in the Scottish Parliament. The answer was to try to buy time by announcing a limited Committee investigation into the issue of compensation, given a wider remit than just the blood contamination disaster to lend it greater legitimacy. Such a committee required to be independent, given the abject failures and lack of independent which had by this point been exposed in the Executive investigation.

4.3 As it happened, the Ross Committee development had a number of features which created the possibility that it would lead to a positive solution for the infected and affected. In the first instance (unlike the Executive investigation), it accorded a voice to the infected community, which meant that the Committee stood a chance of recognising the actual needs and losses of that community. Secondly, unlike the Executive investigation, it was independent and had a well-respected Chair. Thirdly, it appointed members of the infected community from both the haemophilia and blood transfusion communities, for the first time engaging with the fact that infections had occurred in the latter community. The recognition of HCV led to the need to understand the scale of the disaster, in particular in the HCV infected, transfusion community. Fourthly, by being a Scottish committee, it provided the opportunity for a break from the dominance of the UK-derived civil

service line on the disaster nationally which had continued to dominate the thinking within the Executive.

4.4 Against this background, the Inquiry should be clear in marking the opportunity which the Ross Committee presented and which was not taken. A useful summary of the matters which were recommended by the Ross Committee which were not implemented at the time was prepared by Haemophilia Scotland, some years later.[2861] This document neatly demonstrates not only the factual shortcomings of the Skipton Fund but also that the failure to implement the Ross recommendations still had significant effects on the infected and affected community many years later. The harms caused as a result of this failure were all entirely avoidable. The main failures of the resultant system were:

(a) A recognition that all of those who were exposed to HCV will have suffered some loss and deserved some element of compensation. This included natural clearers who would have received awards under the way that the recommendations. In his evidence to the Inquiry, Malcolm Chisholm tried to characterise the resultant outcome as an increase for those who received the lowest payments (from £10,000 to £20,000). In the case of natural clearers, this is, in fact, inaccurate as they received nothing at all. It is submitted that this was an attempt to divert attention away from the main failings of the Skipton Fund (see below);

(b) What might be described as the main failure to recognise that there should be a damages-based solution, at least for the "stage 2" sufferers for whom it was recommended by Lord Ross's committee that there should be full compensation damages payable at common law without the need to prove negligence. In fact, there was no compensatory element at all in final Skipton Fund and no regular payments [2862];

[2861] WITN2287031

[2862] *"those who subsequently suffer serious deterioration in physical condition because of their Hepatitis C infection e.g. cirrhosis, liver cancer or other similar serious condition(s), should be entitled to* ***full compensation****. This compensation should be calculated on the same basis as common law damages taking account of the payments made under A and B above"*

(c) A further failure of the eventual Skipton Fund was a failure to recognise the affected. In cases where death had been caused by the infection, the Ross Committee recommendations included a recommendation that fatal damages should be paid in accordance with the Damages (Scotland) Act 1976.[2863] This would have meant that payment would have been made to what the Act defined as immediate family for loss of society, as well as claims being available to a wider class of relatives for loss of support. Necessary and personal services claims would also have been available. It is important also to recognise that the recommendations would have permitted estate claims for payments which would have been made to infected persons in life as well. These compensatory measures would have significantly alleviated the suffering of widows, widowers and partners but also a wider class of relatives who have to this point continued to receive no support or compensation from the State at all; and

(d) There was a failure in the aftermath of the Ross committee for there to be a re-assessment of a number of the government lines which had so informed the approach to the disaster since the time of the HIV litigation. For example, despite the fact that the Ross group had formed the view that HCV caused similar consequences to HIV and the lack of financial support represented an inequity[2864], the line that there was a difference in this regard between the two infections continue to be a prevalent part of ministerial briefing. This continued to be the position of Alan Milburn as to why ex gratia payments had been made to HIV infected haemophiliacs.[2865] Having commissioned the report, there appears to have been little time spent considering its gathered evidence or its conclusions, the immediate and apparently only concern being about affordability any subsequent payments which might now require to be made. At the very least, the Ross report showed by its evidence-based (though crude)

[2863] *"where people who would have been beneficiaries of these arrangements are deceased and their death was not due to the Hepatitis C virus, the above payments should pass to their Executors. Where their death was due to the Hepatitis C virus, the compensation should be paid to their Executor and relatives in the same way as relatives are entitled at common law in terms of the Damages (Scotland) Act 1976 and in addition same sex partners – both to be assessed on the same basis as common law damages."*

[2864] DHSC0042275_133

[2865] Alan Milburn witness statement (WITN6942001) @ para 20.7

classification of infections based on the stage of disease that the passage of time had meant that the consequences for those infected had become far worse and this the current policy towards needed to be revisited. The report was a warning that further deterioration could be expected in the future. The failure to take stock of matters like this and the consequent continuation of unfounded lines which had so harmed the infected and affected community meant that these harms were unnecessarily perpetuated and compounded.

The developments leading to the formation of the Skipton Fund

4.5 Despite the value of the Ross recommendations, its conclusions were not respected. In the aftermath of the Ross committee producing its interim report, Malcolm Chisholm (who was clearly aware of the political issues which would be caused over the issue) turned to speak to health ministers in the UK government about how to approach the recommendations.[2866] The then extant agreement was that the matter would be approached uniformly throughout the UK.[2867] This goes to show that the earlier investigation which gave rise to the possibility of a separate Scottish solution had indeed been a PR exercise. The eventual outcome was based on what money happened to be available at the time, not on considerations of need or moral duty.[2868] Since the Ross committee report, no such assessment has been undertaken until the report of Robert Francis QC, addressed in detail below.

4.6 It is correct to say that the genesis of the Skipton Fund came in the Ross Committee and the announcement by Malcolm Chisholm in January 2003 that certain sums would be paid to the HCV infected victims of the disaster. However, at the time the that that announcement was made, the clear intention was that the fund would be a Scottish one – the announcement was made by the Scottish health

[2866] DHSC0042275_132 (31 July 2002 email report from Charles Lister about the imminent publication of the Ross report) showing that Malcolm Chisholm was keen to speal with Hazel Blears
[2867] Ibid, page 2
[2868] Malcolm Chisholm witness statement (WITN0794001) @ para 32

minister in a devolved government in the aftermath of a Scottish committee having investigated the matter. No national scheme had been contemplated. The rUK policy remained against the possibility. Yet, in the final outcome no such Scottish scheme was set up. Despite the Scottish genesis and the commitment to a Scottish scheme, the final scheme was a national one, with no local accountability. At the time of the announcement, the minister was still in the process of reporting on progress to the HCCC. The scheme in contemplation was being devised under the gaze of democratic accountability. The mechanisms of Skipton Fund were set up as a result of and the mysterious "plenary sessions" referred to in the evidence of then MFT Chair Peter Stevens. The scheme announced was a *fait accompli*. There had been no democracy accountability at all to anyone, in particular those Scottish campaigners whose persistence had led to this point. Clearly, the sums which were allocated to the Fund were not as Lord Ross's Committee had recommended, as is discussed above. The evidence of how the Skipton Fund came to be set up the way it was bears close scrutiny in order to ascertain how exactly the outcome was as it was.

4.7 The Inquiry heard extensive evidence from a number of those involved over this period about how it was that the Skipton Fund came into being as it did. One thing which was clear was that it was ultimately set up based on what could be afforded, not what had been recommended by Ross to have been reasonable or necessary. This approach demonstrated, once again, that the State had not learned any lessons from the occurrence of the disaster in the first place. The period of the infections occurring up to September 1991 had been characterised by short term economic thinking based on the civil service system of annual budgets. The path of least resistance was simply to base the plan for next year on what was done last year. Short term thinking predominated as a result as opposed to long term-strategy. Such a system was contributed to by frequent changes of government and of ministers which did not allow long term thinking, even when it was thought preferable (such as Lord Owen's policy commitment to self-sufficiency in 1975). The fallacy of lack of investment in measures designed to improve safety was now being realised. The failures of the past to protect those receiving blood or blood products properly were now manifesting themselves in the bill for the medical and

other consequences. Yet, there was no State engagement with that problem. The same mistakes were made.

4.8 The driving force behind change was the Scottish committee report and the political mandate which it had created (in particular as a result of the work of the HCCC) to provide some form of payment for the HCV infections. As is stated above, the setting up of the Ross Committee was not an act of compassion towards the victims. Had it been, the minister could simply have announced payments at that time. In fact, it was a ruse to try to deal with the awkward political realities with which he was presented, both with regard to the inconsistency with national policy and the lack of proper assessment of what cost would be involved. The announcement made by Malcolm Chisholm in January 2003 was merely the extension of that political imperative. This is shown that once again, the payments were to made at that point but, instead, further delay ensued. No assessment had ever really been undertaken in Scotland of the likely cost or affordability of any scheme from the Scottish health budget, though at the time of the announcement there was no issue that any payments would require to be dealt with by the Scottish Executive as being part of their devolved responsibility for health matters. After all, the investigations into the possibility had merely been a "PR exercise" as is discussed above. Seeking money from the UK Treasury would inevitably involve the issue of having to justify the position and also deal with the uncomfortable schism in the position being taken on the issue by Labour governments north and south of the border. This is precisely what then happened.

4.9 The evidence relating to the exchanges between Alan Milburn and Malcolm Chisholm is limited, as is much of the evidence relating to this period relates to conversations taking place between ministers which were either not recorded or imperfectly recorded. This should in itself be criticised by the Inquiry in light of the evidence referred to below from Lord Forsyth about the importance of records being kept of government action and the requirement to achieve that in the civil service code. The Inquiry is, however, able on the basis of available evidence to put together a reasonable assessment of what was going on at that time, all of which is relevant to the ultimate foundation of the Skipton Fund.

4.10 In his witness statement, Alan Milburn stated that the DoH had been considering a possible compensation scheme for those infected with HCV from contaminated blood from April 2001.[2869] Given the clear line which had been taken to the issue before that point, it would be reasonable to infer that this was a result of the increasing political pressure caused by development in Scotland. The matter was being investigated there and considerable impetus for such a move north of the border was being generated from the HCCC. However, it was clear that from the outset the political pressure which had been created in Scotland caused a difficulty for the UK government. There was no evidence of any engagement with or assessment of the needs of the community having taken place at this stage or indeed at any other. This culminated in a key conversation about the matter took place between Malcolm Chisholm and then UK health Secretary, Alan Milburn. Again, this conversation was unminuted. It was reported that the steps being contemplated by Malcolm Chisholm were described by Mr Milburn as "a grave mistake".[2870] The extremity of his choice of adjective is noteworthy. One might even say that what evidence would have been available, had an assessment of need been undertaken would have meant that it would reasonably have been concluded that not to provide financial support would have had grave consequences, given the state of health of many of the infected by this time. It is clear from the materials available to the Inquiry that the key objective from the outset within the UK government was to seek to limit and control the way that the Scottish Executive was handling the matter and that the final bill, as opposed to the merits of the case, were the key driver of the approach and decision-making. Mr Milburn apparently urged Mr Chisholm to "tough it out" despite the context being that he had feared he would lose a parliamentary debate on the issue when the Ross Committee was announced. It is submitted that this was undemocratic – health was a devolved matter and the issue had been investigated by an independent committee investigation chaired by Lord Ross and was subject to the proper, ongoing scrutiny of the affected electorate and the HCCC in Scotland. The

[2869] Alan Milburn witness statement (WITN6942001) @ para 1.7
[2870] DHSC0042275_129 (email note of 4 November 2002)

Ross Committee report appears not to have featured at all in the consideration of the matter at UK-level. The approach of the UK government was clearly to seek to force Mr Chisholm's hand. Despite the fact that there had never been any doubt since the launch of the investigation into the disaster in 1999 (and indeed at the time of the petitions before it) that the issues involved related to health and hence involved devolved matters, the efforts on the part of the UK DoH at this time to seek to cause delay and confusion over the legitimacy of the plans were a clear attempts to interfere in the inevitable course which would now need to follow on from the Ross report. The lengths to which the DoH were prepared to go to achieve this obstruction were quite remarkable. The motivation was obviously financial, as they had known all along that such a scheme would need to be replicated UK wide. It would also involve an embarrassing U-turn from the policy which had been adopted by Frank Dobson from 1997. However, subsequent events would show that some financial settlement was not impossible and the policy change could have been explained away as a legitimate departure from a relic of the past which pre-dated the labour era, justifiable in light of the Ross recommendations and a more compassionate approach. The strength of feeling which the Scottish position represented hints at a more deep-seated desire not to have the matter looked at in any detail. The reasonable inference from this response was that the DoH knew that the proposals would not satisfy the demand for answers and proper compensation which had been called for in the petitions and the latter of which had been recommended by Lord Ross. It seems clear that there was a deep-seated desire on the part of the DoH to seek to supress any possibility of further investigation, which is consistent with the knowledge that a full inquiry into the matter would reveal a long history of failure on the part of the department and the NHS more generally, such is now apparent to this Inquiry. The vehemence of the response was consistent with the extremity of the need for the truth to be covered up and confined firmly to the past. Devolution had opened the door to this locked away matter to be looked at again. The attitude was that any more detailed examination of it must be resisted at all costs.

4.11 The solution of the DoH was to invent an issue around the competence of the Scottish parliament to take the steps it was proposing and to seek to delay matters

to seek to impose its own political will.[2871] It raised doubts about the legislative competence of the Scottish Parliament to deal with the issue of payments to HCV infected individuals, which had never been raised before. It delayed the instruction of a legal opinion on the issue. It did so in order to impede what had been portrayed to them as the democratic will of the Scottish parliament – expressed to them in Malcom Chisholm's apprehension that he would lose a parliamentary vote on the issue. A note to Mr Milburn on 6 August 2002 on "Hep C + Scotland" indicated that he would "need this in front of you when you speak to SofS. This is a devolved issue - but it will be v difficult for us to have different positions".[2872] It was clear at that time that DoH considered this to be a devolved matter. The reason which lay behind the DoH request for legal advice was "thereby [to] prevent them going ahead with any kind of announcement on Wednesday" ([ie to prevent further action on the matter being taken on what was admittedly a devolved matter].[2873] The request for the legal opinion was contrived to prevent action being taken in Scotland. The controversy, however, led to the need for a certain degree of obfuscation on the part of Mr Chisholm while it was sported out. In his statement, Alan Milburn pointed to the following being said at that time: "There is a Scottish government press release dated 6 Nov 2002 (WITN6942018), welcoming the report and stating that they would "like to find a way" of "doing something" to help those infected. However, the statement was described as a "fudge" which pleased no one in an email by Mr Lister to Hazel's office, copied to Sammy Sinclair of my Private Office".[2874] The illegitimate DoH intervention had for the time being halted progress in Scotland and had led to the position being "fudged" as far as the infected and the HCCC were concerned. Alan Milburn went as far as raising the devolution issue to First Minister Jack McConnell in November 2002, as opposed to simply dealing with Mr Chisholm on the issue, such as the need to try to exert political pressure to impede progress.[2875] By this point Mr

---

[2871] Alan Milburn witness statement (WITN6942001) @ para 13.9
[2872] DHSC0042275_131
[2873] Alan Milburn witness statement (WITN6942001) @ para 13.9
[2874] DHSC0042275_142
[2875] Hazel Blears first witness statement (WITN6658001) @ para 2.67(8)

Chisholm was formulating a plan to take a different course. Though he had no real concern about the devolution issue[2876], he does seem still to have felt the need to come up with a political spin on what the payments would be so as not to offend the more general principle about compensation.[2877] He made it clear that the preference was for "ongoing payments to surviving patients - triggered by progression to a stage of disease that could be easily linked to the concepts of need and suffering." He considered that these would be less likely to be regarded as a new departure from the principle that the NHS "does not pay compensation when there is no legal liability." Thus, from the outset, these payments were not intended to be compensation. This is consistent with the position of the current Scottish government at this Inquiry, insofar as their evidence is that no compensation has ever been paid to the infected or affected communities (see below).

4.12 On 30 January 2003 he announced that he was prepared to establish an ex-gratia payment scheme for people in Scotland who had been infected with HCV as a result of treatment with NHS blood/blood products.[2878]. The January 2003 announcement designed to break the political deadlock, assert the Executive's constitutional right to make its own decisions and force Alan Milburn's hand. It was clear at that time that the solution which was being proposed was a Scottish one, not a national one. The Scottish government planned to make payments of £20,000 and £25,000 (on development of cirrhosis) to the infected. There had been no assessment made of the appropriateness of those sums. They must simply have been based on a calculation of what could be afforded. Malcolm Chisholm confirmed that a line was fed at that time by an Executive civil servant to the DoH about the position over which he had had no control.[2879] The Ross report published in March 2003.[2880]

[2876] WITN6942015- correspondence from Malcolm Chisholm to Andrew Smith on 5 November 2002
[2877] WITN6942020 - correspondence from Malcolm Chisholm to Andrew Smith on 18 December 2002
[2878] DHSC6701261
[2879] Malcolm Chisholm witness statement (WITN0794001) @ para 32
[2880] HSOC0020367

4.13 By the time John Reid took over as Secretary of State for health in June 2003, the die had been cast politically due to the January 2003 announcement. It would have been impossible for a UK labour government to fail to replicate the proposals which had been committed to by Malcolm Chisholm in Scotland in January 2003. Despite his unilateral announcement in January 2003, Mr Chisholm was keen to discuss the matter with Mr Reid on his appointment. The First Minister remained involved in the dialogue at that time.[2881] The DoH clearly considered that the Scottish Executive had breached the agreed UK wide policy on this issue.[2882] It is submitted that it was with some considerable regret that the DoH's hand was forced and that the policy needed to be changed. The change of minister allowed this to be done with a degree of stage management. The DoH approach in essence remained as it had been before, namely that there was a basis to distinguish between those infected with HIV and those infected with HCV by blood or blood products.[2883] A final position of the matter could be delayed due to the delay in the instruction and receipt of the DoH advice on the competency issue. It had been instructed on 30 January and received on 20 June 2003.[2884] It is notable that the advice of the Attorney General had been to the effect that there **had been negligence on the part of NHS Scotland** in connection with the blood contamination disaster.[2885] This, of course, was contrary to the findings of the earlier Executive report. This merited the whole issue and conclusions of that report being revisited. They were not.

4.14 It is important to remember, however, that there was an ongoing dialogue in Scotland about the January 2003 announcement throughout the first half of that year and indeed beyond. The campaigning community was still keen to try to push its case and at least obtain answers for why the January 2003 proposals did not at least match the far more ambitious Ross committee recommendations, which included compensation and fatal damages for certain relatives. Malcolm Chisholm

---

[2881] DHSC5541406 - 9 June 2003
[2882] Mr Sinclair seemed to think it had been in his email, DHSC5541406 of 9 June 2003
[2883] DHSC5320518 - the Gutowski briefing, 17 June 2003
[2884] per para 8.4 of John Reid's statement
[2885] DHSC5320621 (20 June 2003)

was still being held to account by the HCCC at which he was likely to be asked questions, not least the disparity between the proposals and the Ross recommendations. He faced such questions at his appearance before the committee in September 2003, at which time the Committee at least was under the impression that the matters (by that time accepted to be within the devolved competence of the Scottish Parliament) was still up for debate. Despite the earlier announcement by John Reid, the Skipton Fund had not yet been finalised. The political reality which John Reid was faced was the possibility that the ongoing dialogue in Scotland would result in a more generous financial solution being acceded to by the Scottish government. The solution which was devised was that the January 2003 proposals would be matched UK-wide but that the new scheme would now be taken over by the UK government. The objective within the DoH was that Scotland needed to be kept "as minimalist as possible".[2886]

4.15 This issue was discussed by John Reid and Malcom Chisholm in yet another unminuted telephone conversation. The reasonable inference from the evidence heard on that telephone call was that the DoH took over control of the scheme, to make sure that it was restricted to what had already been announced. The effect of that was to take control and local accountability away from the Scottish government and ultimately from the HCCC and the campaigners. A cross-departmental meeting on 25 June was attended by the Scottish Office as opposed to the Scottish Executive. [2887] This was by that point being treated as a UK-level issue. Decision-making which would affect Scotland was now openly being conducted without them being present and a plan was being devised to force the solution onto the Scottish Government. It was considered essential at Westminster that hep C not be mentioned when the meeting between Malcolm Chisholm and John Reid was being set up, so it could be raised at the meeting.[2888] A discussion about funding the Scottish scheme and how that would "have let them off the hook" also took place, involving the Treasury, which was keen to

[2886] DHSC0042275_008 - E-mail from Sammy Sinclair dated 23 June 2003
[2887] DHSC0042275_005
[2888] WITN0793003 (25 June 2003)

make sure that the proposals were kept under tight control.[2889] Lord Reid gave evidence to the effect that he was keen that there should be a UK scheme.[2890] It is submitted that this was so that the Treasury could maintain control over Scotland. By July 2003, a decision had been taken at Westminster to introduce a UK scheme.[2891] As had been the case so often before (for example in relation to the decision-making around testing in the 1980s or the settlement of the HIV litigation) efforts made to progress the resolution of the disaster in Scotland in a democratic and compassionate way had been thwarted by Westminster influence or intervention.

4.16 The DoH position was announced in August 2003. Despite this, Malcolm Chisholm had agreed to tell the Health Committee (as he did) that Scotland was now free (due the resolution of the competence issue) to pursue its own scheme unilaterally.[2892] It is far from clear what the relevance of this was by that point as a decision appears to have been made to pursue the matter on a UK basis. It is submitted that this was a fudge to prevent any further questions being asked at the Committee appearance on 9 September 2023 about what the UK scheme was going to look like. This was because (as Peter Stevens set out in his evidence to the Inquiry) the DoH was completely unprepared ahead of John Reid's announcement of the scheme in August 2003.[2893] The announcement had been made to wrestle back political control as a matter of urgency, not as a result of any planning or consideration of the merits of the matter. It had previously been the expressed intention of the DoH to try to manage Mr Chisholm's appearance before the Committee on that date.[2894]

[2889] John Reid witness statement WITN0793001 @ para 8.14 and WITN0793003_0002
[2890] IBI transcript for 21 July 2022; page 41, line 24
[2891] DHSC5322954 – email from Sammy Sinclair 8 July 2003 regarding developments with the development of a scheme/ the Scottish position
[2892] Para 7 of the Note at DHSC0004421_ 127
[2893] Paras 30 - 32 of Peter Stevens' statement @ WITN3070003
[2894] DHSC5322954 – email from Sammy Sinclair 8 July 2003 regarding developments with the development of a scheme/ the Scottish position which mention the 9 September 2003 HCCC appearance in the context of the UK scheme plans

4.17 The briefing given to Mr Chisholm for the 9 September appearance was not committal on the idea of a UK scheme.[2895] One of the questions in the speaking notes is "are we looking at the possibility of a UK scheme?". Answer "I wouldn't rule that out as a possibility. It may have some attractions – but it could equally turn out that separate, similar schemes might be the best way forward". Plans for the UK scheme were already well underway. By July 2003 this stage it seems that the scheme being produced by Scotland and England together was mentioned.[2896] At meeting of Scottish Executive and DoH officials that month, it the position that a UK-wide scheme was favoured. The note stated that "The scheme will be progressed on this basis subject to ministerial approval".[2897]

4.18 The briefing note also covered the possibility of a question being asked about a public inquiry. The proposed answer was that he should say that he was not convinced that there are any lessons to be learnt that haven't already been learnt, including media allegations of a cover up, referring to a newspaper article. This was merely trotting out the familiar line advanced by the civil servants. There is no evidence that any independent thought was given to the possibility of a public inquiry at this stage, despite the evidence that the Attorney General had expressed the view that there had been negligence in the handling of the disaster by NHS Scotland (see above) and the fact that petition PE 45 remained unresolved.

4.19 Ultimately, the mechanics of the scheme were devised in secret at plenary meetings by individuals who were appointed by government and not accountable to anyone. It is clear that that process was overseen a number of civil servants, key amongst them Bob Stock and Dr Keel, who had shown themselves to be advocates of the pre-devolution policy which showed no willingness to engage compassionately with the needs of the community or to recognise or even contemplate any moral duty for their support, given the fact that there was clearly perceived to have been no negligence in the way that the infections had occurred. Dr Keel had, of course, shown in her involvement in the Executive investigation

---

[2895] DHSC5324617– speaking notes and background notes from Bob Stock for Malcolm Chisholm dated 8 September 2003
[2896] DHSC5110388 (15 July 2003), para 2
[2897] DHSC0004421_141 (30 July 2003)

that she was keen to accept the colleagues in the haemophilia treating community had to say about what had happened. In her, the government had appointed someone from that community to decide the fate of those who had become infected. Indeed, she was not the only haemophilia treater involved in that process – Professor Pasi attended the meeting in October 2003.[2898] Those who had inflicted the harm or at least those who were close to them had been given a key role in deciding how the State would respond to it. Though the petition committee processes of the new Scottish Parliament had started as with democratic engagement, the process had finished in accountability being ceded to the faceless committee charged with devising a scheme within the pre-existing financial limits and constraints imposed by the UK health minister, who of course had no authority of matters pertaining to health for Scotland post-devolution. The very fact that these medical experts were only consulted AFTER the financial awards which would be paid under the scheme had been fixed shows that the amounts were not fixed by reference to any medical criteria. In fact, the amounts had been fixed and the consultations took place as a way to limit the numbers who would qualify and the numbers who would qualify for the higher level payment.

4.20 In addition, there was an unnecessary delay between the scheme being announced on 29 August 2003 and the Skipton Fund finally being announced on 3 June 2004. At that time, the possibility of a waiver of litigation rights had clearly been mooted by the Scottish Executive. This showed a clear intention to use the Skipton scheme to try to limit the rights of the infected and affected community, as had been done at the time of the HIV litigation settlement. On 1 April 2004, Shona Robison asked the then First Minister whether people with Hepatitis C through contaminated blood products will have to waive their right to legal action to receive an extra gratia payment. She has told this Inquiry that she asked this question due to a newspaper article suggesting this may be the case.[2899] The First Minister said no such requirement would be required and that new guidance would make this clear. Evidence shows that this possibility was indeed

---

[2898] SCGV0000265_004

2899 Shona Robison witness statement (WITN6648001) @ para 19; RLIT0000660

contemplated at the time.[2900] Though this ultimately did not happen, the inclination of the authorities at that time is instructive of their true motivation being to bring the matter to an end and not one arising from compassion.

4.21 Throughout this period, there was a lack of engagement with the financial realities of the infected and affected community. The State ignored the outcomes of the Ross process in which the community was engaged, whose conclusions had been based on sound science and fair reflection of the needs and the unique circumstances of the community. Instead, the clear outcome was a Fund which was set up without any of those considerations being taken into account. No assessment of the needs of those communities was even contemplated over this period. It was suggested by Lord Reid in is evidence to the Inquiry that he had hoped that the formation of the Skipton Fund would be the first step in greater financial support being provided to the community in later years, though he made clear that the basis that the financial assessment of the possible costs of Skipton at that time as rough and ready - 200 million for the scheme as it was eventually (which he thought he could get), 400 million to include dependents and 600 million for the full Ross recommendations.[2901] There is no evidence to support his contention about the future. In fact, all that this statement should be taken to reveal is that he knew and knew at the time that the sums being allocated to the scheme would be woefully inadequate. No mechanism was put in place to assess the needs or losses of the community. No mechanism was out in place for discretionary payments based on need until the Caxton Foundation was set up in 2011. No mechanism was put in place to review the payments at any stage in the future. No assessment was made of the even the state of health of the infected (or the affected for that matter), far less any assessment of the likely prognosis for them or their consequent needs. All of the evidence pointed to this being a financial solution which had begrudgingly been entered into by the UK

[2900] DHSC0004421_095 – progress report for ministers on setting up of new scheme after discussion with Scottish Executive, which includes provision for a litigation waiver at page 4; see also the evidence of Mr anonymised witness Mr L, who seemed to think that he had signed a waiver in return for his £20,000 stage 1 Skipton payment (page 35 of IBI transcript for 7 June 2019)

[2901] IBI transcript for 21/07/22; 40 (1 to 11) (Lord Reid)

government based on a very rough assessment of what could be afforded, with no assessment of moral or other duty and certainly no assessment of the needs or losses of the community. The claim that the near total exclusion of the affected was based on a desire to prioritise the ill is merely another way of saying that the governments of the UK were unprepared to contemplate the breadth of the harm as they were not prepared to contemplate the possibility to having to pay for it. The Skipton Fund was the ultimate sticking plaster for a gaping wound, inflicted by the State.

4.22 Other failings in the way in which the Skipton Fund was constituted included the lack of access to it for those who had been infected by transfusion but had no medical record of their transfusion, on the basis of the evidence heard by the Inquiry. Despite the fact that the matter was considered at the time as important[2902], there was no evidence of continued monitoring was done by the Executive of the way in which the "balance of probabilities" criterion (which was part of section 28 of the 2005 Act) was applied in practice. The Inquiry heard evidence from anonymous withs Mr X, who had been part of the Ross Committee. He gave evidence to the effect that the way that this worked in practice had never been the intention of that Committee. Thus, it was the departure from the recommendations of Ross which led. The ultimate irony in that regard is, of course, that the individual who was part of the Ross committee and who gave evidence to the Inquiry about it was one of the people who ultimately did not get an award from the Skipton Fund due to there being no written record of his transfusion. Further, there was no reasoned justification for the 29 August 2003 date as cut off.[2903] This unjustifiably excluded not only widows claiming in their own right but also estates of those who had died before that point. This was clearly done on financial grounds and beyond the control and influence by that pint of the Scottish Executive.

4.23 The funds allocated to the Skipton scheme were wholly inadequate. As is stated elsewhere, the sums arrived at were not calculated as a result of any assessment

---

[2902] Malcolm Chisholm witness statement (WITN0794001) @ para 46
[2903] SCGV0000266_043 – 2005 bill.

at all of what was needed or morally justified. Though the sums had been proposed by the Scottish Executive in January 2003, the ultimate scheme was set up without their further control. In Shona Robison's statement to this Inquiry, she stated that: "In an exchange at FMQs on 2 October 2003, I asked the then First Minister, Jack McConnell, to reconsider the level of support to be given to those infected with HCV through contaminated blood and blood products in the light of the comments made by Lord Ross expressing concern about the level of financial assistance being offered. The response of the First Minister was that such a level of support would have a negative financial impact on other parts of the NHS and that the financial assistance on offer struck the right balance". The reasoned, evidence-based approach advocated by Lord Ross and his committee was not adequate. When his position on the matter was raised, the response of the Scottish Executive was further to stigmatise the infected and affected community by claiming that their legitimate call for more help made on their behalf would endanger the care of other patients. It is worthy of note that at about this time (when the debate about the possible outcomes for the Scottish community was still subject to debate in the Scottish Parliament) it was clear that Scottish officials were heavily involved in the preparation of a national scheme. Documentation from October 2003, shows that a presentation was given by Scottish officials at the UK level on the Scottish "scheme", though there was no Scottish scheme in contemplation at that time.[2904] At this same meeting, the materials suggest that payments might not be made stage 1 payments for those who were successfully treated as that might operate as a disincentive to seeking treatment. It was being suggested that someone might not take treatment, lest it be successful. Medical experts were being consulted and passed comment on the justice of certain proposed payments.[2905] This was the kind of restrictive approach which at the very time of Ms Robison's question showed Scottish official involvement in seeking to make the eventual UK scheme as restrictive as possible. Proper debate had been replaced by secret meetings.

[2904] SCGV0000265_004 (14 October 2003), para 1
[2905] Ibid, paras 12, 13 and 17

4.24 The ultimate exclusion of natural clearers was a matter which seemed to involve Dr Aileen Keel to a considerable extent. As is stated above, they were to receive a payment under the Ross criteria but were not ultimately included. Dr Christine Lee, a haematologist who had been responsible for infections of patients appears to have been allowed to determine whether natural clearers should receive payments or not.[2906] This was reminiscent of Drs Lowe and Ludlam being consulted some years before about the circumstances of the SNBTS heat treatment processes as part of the Scottish Executive investigation (see above). In his evidence to the Inquiry, Richard Gutowski was asked about the medical input they had for the press release about the launch of the scheme. he said "my guess is that Bob Stock would have gone to his medical advisers, maybe Aileen Keel, who was the Deputy Chief Medical Officer at the time".[2907] One memo from this period states that "Bob Stock has discussed matters with Aileen and suggests wording".[2908] It would appear that Dr Keel was the source of the requirement that "unless robust medical evidence is cited" to prove chronic infection, an application would not be successful. The practical reality of what this meant for applicants is discussed below. In Scotland, Dr Keel also appears to have been responsible some years earlier for advising about the destruction of blood samples which may have provided evidence of assistance in providing evidence about the nature, timing and extent of infection.[2909]

4.25 The importance of charity engagement and campaigning on behalf of the community throughout this period cannot not be over-stated. Without it, none of these developments would have occurred. It is also important to recognise that it was only at the point where the community's involvement was discontinued, in the aftermath of the Ross committee report that the solution which could have assisted in supporting the infected and affected over the last two decades went awry. It is also important to remember that the ambitions of the Scottish

---

[2906] DHSC0004510_080 (2004 meeting note re natural clearers)
[2907] IBI transcript for 10/06/22; 94 (Richard Gutowski)
[2908] 19 October 2004 - DHSC0004520_057, page 3
[2909] SCGV0000112_070 – 2 June 1997 letter from Dr McClelland to Dr David Goldberg re destruction of blood samples held from April 1984 due to storage issues. Suggests Dr Keel being consulted about that.

campaigners in the petitions to the Scottish Parliament which had instigated these developments had also included calla for a public inquiry. The Skipton sticking plaster had also been used as a means of avoiding the need for that call also to be addressed, which it was not over this whole period and beyond by the UK government and the Scottish government alike.

The comparison with Ireland

4.26 Throughout the period in which compensation was sought, campaigners frequently drew attention to the fact that individuals had been infected in Eire as a result of exposure to blood or blood products in similar circumstances to those infected in Scotland and indeed in the UK more widely. In response a generally disingenuous line was adopted by the government throughout the UK, which shows the lengths the State was prepared to go to to avoid taking responsibility. The basis upon which the compensation scheme in Ireland had been set up, was consistently represented as being different from the Scottish or UK-wide position. It was consistently claimed that it had been set up on the basis that the state had admitted civil liability to pay compensation to victims, as opposed to the requirement for civil liability to be established merely having been waived by the State for political or moral considerations.[2910]

4.27 A briefing note provided by the Scottish government on the position Ireland shows the line which ministers were urged to take.[2911] This demonstrates that the real issue with the Irish scheme approach was the cost. It was, in fact, a misrepresentation to distinguish the Scottish situation from that in Ireland based on the Irish State having accepted civil liability.[2912] The mention of anti-D before that HCC Committee on 9 September 2003 by Malcom Chisholm was a red herring

---

[2910] See Malcolm Chisholm witness statement (WITN0794001) @ para 35

[2911] SCGV0000241_086; MACK0002418_002 – letter from Christine Grahame to Malcolm Chisholm dated 12 March 2004 regarding comments at Health Committee on 9 September 2003 about Ireland.

[2912] WITN1055106 and WITN1055107 – letter from Malcolmson Law and Anne McGrane to Carol Grayson conforming the position) (see R (ex parte March) v Secretary of State for Health) [2010] EWHC 765 (Admin)

as payments had been awarded to haemophiliacs independently of anti-D related considerations.[2913] The line was one which had been part of government briefings UK-wide.[2914]

The calls for a public inquiry over this period

4.28 Though the period during which Malcolm Chisholm was health minister was dominated by the issue of financial support and the lead up to the formation of the Skipton Fund, it should be borne in mind that throughout this important time, the part of petition PE 45 which called for a public inquiry remained unresolved. Certain analysis is made about the position adopted in that regard above. At the start of his tenure in 2001, it ought to have been immediately apparent that the Executive investigation had not when further pertinent questions were raised by the Health Committee and petition PE45 remained outstanding.[2915] In his witness statement, he accepted responsibility for this issue but indicated that the civil servants were only giving him the "prevailing view".[2916] In this answer, the Inquiry should deem him to have highlighted the very problem. In essence, what civil servants had given him and his predecessor was only the perspective of the leading members medical profession whose actions would have been subjected to scrutiny, had there been a public inquiry. On any view, this was limited and not independent. A proper assessment of the position of the infected and affected community would have revealed that there was genuine dispute and many questions to be asked and answered. The prevailing view was not a complete view. The fact that he did not recognise it as an incomplete view is his responsibility.

4.29 In any event, elements of the advice were simply wrong, as they had been in the advice provided to Ms Deacon (see above). By 2003, a civil servant asserted that there should be no public inquiry as the responsibility for the infections lay with

---

[2913] DHSC5335287
[2914] Andy Burnham witness statement (WITN7060001) @ para 14.7
[2915] 17 August 2001 HCCC report – MACK0001929_001
[2916] Malcom Chisholm witness statement (WITN0794001) @ para 47 –

the licensing authority and hence within the reserved competence of the Westminster parliament.[2917] This was an inaccurate briefing. As the ambit of this Inquiry and the investigations which it has undertaken has showed, even in the area of imported products (of limited relevance in Scotland) licensing formed only a small part of the many issues to be discussed. In any event, blood and domestically produced blood products (which caused the vast majority of infections in Scotland) were not licensed. Many issues arose which licensing could not have touched upon, such as consent, testing, impact etc. This briefing was an attempt to hide behind the devolution settlement. By this point the advice being given to ministers by the civil servants had certainly become a defence of their policy, not advice given in the interests of the public. By May 2003, the same civil servant (Mr Stock) wrote "However, the fact that his allegations may be inaccurate does not prevent the likes of the Petitions Committee (and subsequently the Health Committee) swallowing them in their entirety".[2918] The attitude was clearly informed by a contempt for campaigners and for the committee system, and hence for democracy. In the penultimate paragraph he remarkably seemed to claim that staffing of SNBTS and the resources which may require to be devoted to a public inquiry would be a reason not to order one. He expressed a concern about the possibility of prompting an English inquiry as a reason not to hold a public inquiry. This was clearly an illegitimate approach. Health was a devolved matter. He referred to the "Lord Owen" issue which he was keen should not be looked into. It is far from clear what he wished not to be looked at in that regard. It would be reasonable to assume that the issue was Lord Owen's well-known support for self-sufficiently to be achieved in blood products. That seems to have been the issue which Mr Stock did not want to have ventilated in a public inquiry. That was, of course, a very important matter and in any event had little to do with Scotland as Lord Owen's support for that goal was an English policy, health policy and the operation of the SNBTS/ PFC having been a matter under the ambit of the Scottish Office and Scotland's independent NHS from the time when Lord Owen

[2917] SCGV0000262_166 (2003), Bob Stock analysis of calls for public inquiry
[2918] DHSC5541781 (May 2003), para 3

was Secretary of State for Health in the mid 1970s. Given Mr Stock's clear, unjustified animus against the campaign for justice in the contaminated blood community, it is important to note a key role in advising the Scottish Executive and was then given a key role in the secret discussions about the foundation of the Skipton Fund. The victims had the right to expect that they would be believed and that those acting within government would act fairy and responsibly towards them. That appears not to have been the case.

4.30 By 2004, the advice to the minister continued to focus on the need to refuse a public inquiry based on the need to avoid one in the rest of the UK.[2919] By this time the campaigning community had been driven to frustration by the lack of meaningful response. He was rightly characterized by one campaigner in a letter his MSP as being is "unwilling or unable" to answer his questions.[2920] By this time, there was a clear and reasonable basis for interpreting the actions of the minister, acting on the baseless advice of his civil servant as a deliberate cover up. It was. In his evidence to the Inquiry, Mr Chisholm described the main difference between the pre and post devolution situations was that after devolution there was more room for transparency, accountability and discussion.[2921] The evidence analysed above shows this to be nothing more than an assertion on his part, at least as far as his government dealt with the disaster.

Post Skipton

4.31 Andy Kerr MSP took over from Malcolm Chisholm as the health and community care minister in Scotland in October 2004 and remained in that position until the SNP won the election in May 2007, at which time he was succeeded in that position by Nicola Sturgeon. Like Mr Chisholm, he was not someone who came to the issue of infected blood with no prior involvement. He had been the finance

[2919] SCGV0001080_040 – Briefing for Minister for Health and Community care about Possible Public Inquiry
[2920] MACK0001853 – Letter to Christine Grahame MSP from Robert Mackie dated 7 June 2004
[2921] IBI transcript for 28/07/22; 10 (8 to 17) (Malcolm Chisholm)

minister in the period when Mr Chisholm had been the health minister and so must have had involvement in the finding of the HCV payment issue. In his statement he confirms that he did and that in that role he had expressed concerns about the possibility that the Ross recommendations (and possibly also the Skipton proposals) would set a precedent.[2922] He was against financial support in principle from before his time as health minister. As is narrated above, the original impetus on these issues arose from petition PE45 to the Scottish Parliament from 1999 seeking a public inquiry and compensation for HCV.[2923] These matters had still not been resolved by time Mr Kerr took office. The Skipton Fund was a far from complete solution to the latter issue. It is clear from the statement of Mr Kerr that he felt that he could not consider any wider application of the Scottish scheme (resulting in him rejecting the proposed SNP amendment to the 2005 to include dependents more widely) as the matter was now being approached on a UK basis, with the concern that taking back control would mean losing UK government support for benefits offset.[2924] This in effect meant that the Scottish government had given up the right to control how any scheme should work, which had been John Reid's intention (as analysed above). This meant that the SNP proposal (which was consistent with the Ross principles) could not be considered as a matter of fairness or logic, far less moral duty, as the Scottish Government had renounced its political right to make any such assessments. It appears that Mr Kerr's concerns about the consequences for benefit offset of an extension to the Scottish scheme were at best speculative as he did not have any warning from the UK government that the consequence of extension would raise an issue in that regard.[2925] This shows that the reason given was not a genuine one but merely an excuse used to mask the reality that control had in fact been surrendered. Mr Kerr also made clear that he was opposed to the appeals panel, based at least in part on cost.[2926] Again, this undermined the Ross principles (set out above) which were to ensure that

---

[2922] Andy Kerr written statement (WITN5753003) @ para 18
[2923] WITN2287022 - 7 December 1999
[2924] Andy Kerr written statement (WITN5753003) @ para 23
[2925] Andy Kerr written statement (WITN5753003) @ paras 26 and 27
[2926] Andy Kerr written statement (WITN5753003) @ para 24

entry to the scheme was not overly restrictive and that proper medical assessment of stage was undertaken. The right to appeal was part of the Ross committee proposals. The lack of Scottish government involvement in recruitment for the appeal panel meant that that panel was bound to lack any information about local transfusion practice in Scotland which was pivotal to the determination of eligibility for certain applicants.[2927] Again, despite apparent protestations to the contrary, the Scottish Government ceded administrative control to this national scheme and thus had no influence over the system of not allowing oral appeals.[2928]

4.32 In advice provided to Mr Kerr in 2005, many of the outdated liens were still being given to him by civil servants.[2929] The difference between Eire and UK was set out and was based on the fact that the Irish scheme was set up after a judicial inquiry had established that the Irish BTS had been negligent/that there had been wrongful practices on their part (Finlay tribunal). The note refers to the Lindsay tribunal as well though haemophiliacs had been included in the scheme before Lindsay had reported. A misplaced concern from the DoH was expressed as the possibility of creating a precedent for having an inquiry about the actions of a UK government department without its co-operation was prayed in aid. A focus on the issues being predominantly to do with licensing continued to be advanced.

4.33 The ceding of control over the scheme to the UK government also involved a cessation of active consideration by the Scottish government of the possibility of a public inquiry. Though the matter had never been properly determined, control over the issues within the (including the possibility of a public inquiry) had effectively also been ceded to the UK government. Petition PE45 was still before the Scottish Parliament at this time.[2930] Though the basis upon which a public inquiry might have been ordered before the Inquiries Act 2005 may have been a little unclear (though it must have existed as such inquiries were ordered) the standard after that date was clear for Mr Kerr to consider. There is no evidence of

---

[2927] Andy Kerr written statement (WITN5753003) @ para 29
[2928] Andy Kerr written statement (WITN5753003) @ para 30
[2929] SCGV0000044_024 (28 January 2005) – ministerial briefing note premeeting with Infected Blood Forum, including (by Sandra Falconer):
[2930] DHSC6264733 – letter of John Reid to Andy Kerr in April 2005

the standard having directly been considered at all. This was another symptom of ministerial wilful blindness. It is submitted that all times after the enactment of the 2005 Act the blood contamination disaster in Scotland or UK-wide merited a public inquiry being orders under the standard set out in section 1. By December of 2005, Mr Kerr continued to reject the pleas based on inappropriate arguments.[2931] By this point it was being argued that given the passage of time, it was likely to be expensive and hard to get evidence. The delay was now being used as a reason not to have an inquiry. It was stated that an inquiry would be likely to involve agencies outwith Scotland. That was no reason not to order a Scottish Inquiry and made clear the fact that by now the Scottish Government (which could not order a UK Inquiry) had given up Scotland's position as it was publicly stating that the matter required to involve UK-wide agencies. The line that it was unlikely that lessons would be learned which have not already been learned. This put the cart before the horse.

4.34 Though this remained a matter which was being addressed to the Scottish government, Mr Kerr clearly thought it necessary to consult with his counterpart at Westminster (Mr Reid) on the issue. The view he expressed to Mr Kerr on the subject at the time was to the effect that the advice he had received from his official was that there was no evidence of culpability, negligence or cover-up. He accepted in his evidence that taking advice on these matters from a service which might have been guilty of these things was not a very good system.[2932] This approach (to rely blindly on the advice of officials, acting on the advice the doctors, all of whom had a vested interest in the outcome) had been and continued to be the one followed in Scotland and indeed at Westminster before devolution. As Andy Burnham out it in his witness statement, this was all part of the "official UK Government line that civil servants have given to every Minister since the scandal first broke" based on ""fear of potential financial exposure rather than compassion for victims". That said, we agree with the assessment of Lord Waldegrave in this

[2931] SCGV0000040_030 – 1 December 2005 letter from Andy Kerr rejecting pleas for public inquiry
[2932] IBI transcript for 21/07/22; 92 (11 to 22) (Lord Reid)

regard that this ministerial blindness cannot be excused. In his measured evidence he said:

"But I'm one of those who is very averse to the idea that civil servants just overrule ministers all the time, and when you hear a minister blaming the Civil Service, it's because the minister doesn't know either -- either doesn't know what he or she wants, or doesn't know -- doesn't clarify it enough."[2933]

4.35 The administration and Mr Kerr remained resolutely against any consideration of advancing the matter. The issue had firmly become one which was, once again, filed as "dealt with" by his department. This was despite the fact that he acknowledged in his statement that the patient community continued to have questions to which they wished to have answers over this period.[2934] The position remained contradictory as it had been before, namely that in theory Mr Kerr said that they were open to having a public inquiry, if evidence emerged that they should. The inquiry would have been the place to get the evidence about what happened. No fresh investigation was undertaken by which fresh evidence could have emerged. The position rested on the flawed Executive investigation undertaken by Ms Deacon.[2935]

4.36 In his statement, Mr Kerr states that "For example, if new evidence was presented which pointed to the fact that (a) the NHS could have taken action earlier, (b) that it could have known that the blood was contaminated and that (c) the blood could have been tested for and the virus screened out earlier.[2936] Evidence of all of these things was available for anyone willing to consist even the most cursory of examinations. As regards (a) it was known or could reasonably have been inferred

---

[2933] IBI transcript for 06/07/22; page 59 (lines 11 – 17) (Lord Waldegrave)
[2934] Andy Kerr written statement (WITN5753003) @ para 15
[2935] Andy Kerr written statement (WITN5753003) @ paras 38 and 39
[2936] Andy Kerr written statement (WITN5753003) @ para 47

that the NHS could have taken action on screening, heat treatment, donor selection, product prescription etc earlier. As regards (b) it was known that the products were contaminated. The Fletcher et al paper meant that it was highly likely that this was the case from at the latest the early 1980s in both commercial and domestic products. As regards (c) it was known or could reasonably have been inferred from the decision in A v NBA that the blood could have been tested for anti-HCV and surrogate marker for NANBH earlier. It seems in any event that Mr Kerr was or should have been aware of these matters as his officials were, given that a 2005 briefing stated that documents existed which suggested that testing may not have been introduced due to cost as opposed to considerations of patient safety.[2937]

4.37 The Committee system remained a means to achieving justice and having the goals of petition PE45 (and its sister petition related to transfusion) dealt with. In 2006 the Health Committee recommended a public inquiry. The intransigent attitude of the Scottish government remained resolute. Again, no assessment of the losses or needs of the community took place. No assessment of the moral case was undertaken. Little if any engagement with the campaigning community was permitted. The lump sum solution embodied by the Skipton Fund which involved no provision for future needs or losses was deemed to have been the end of the matter, despite the reality faced by many of the infected and affected in Scotland. By this period, 20 to 30 years after many of the infections took place, many of those who were infected were starting to become ill. The State was deaf to their plight. In her statement to the Inquiry, then HCCC member (later cabinet secretary for health) Shona Robison said that "It appeared that there was a reluctance to take action on an issue that was out of step with the decision making of the Department of Health / UK Government more generally".[2938] She also said that "I believe that the Scottish Executive at the time were very slow to address issues and to get on the front foot. It appeared to be reacting to information that emerged at the time rather than being proactive. I believe this left them looking less than transparent at times".[2939] In our submission, these are accurate

[2937] Briefing dated 22 August 2005 (SCGV0000263_020)
[2938] Shona Robison statement (WITN6648001) @ para 48
[2939] Shona Robison statement (WITN6648001) @ para 47

characterisations of the approach of the Scottish Executive in the period between 1999 and 2007. It was only where it was politically impossible to avoid it that action was taken. When it was it was inadequate and not evidence based.

4.38 The events of this period continued to cause irreparable harm to the infected and affected in Scotland. The failure to engage properly with the infected and affected community and see the failed investigations and the formation of the Skipton Fund as causing problems in themselves was reminiscent of the attitude shown by the UK government to the infected community in the aftermath of the HIV litigation settlements – the infected blood disaster was seen as a matter which had been dealt with, when it was anything but for the victims who continued to be ignored, lacked answers to their legitimate questions and, in many cases, lived with substantial illness and in poverty.

5. The Penrose Inquiry

5.1 As is set out above, the Scottish Executive/ Government failed to discharge its responsibilities towards the Scottish victims of the disaster, including any meaningful engagement with (a) an investigation into what had happened and (b) the full extent of the harms which had been caused. These failures clearly compounded the harms which had been suffered by the victims of the disaster and increased their sense of having been abandoned by the State, which had not only caused their infections but failed to recognise their burning need to understand how their infections had occurred, who was responsible and have the State face up to the consequences which it had created for the infected and affected. These legitimate requests could only be met by a public inquiry, which had been refused for so many years. It was necessary that a mechanism be used with the power to compel witnesses to produce evidence to get to the bottom of wat had happened. A full public inquiry was necessary for there to be a realisation of the scale of what had happened.

5.2 The failure on the part of government at Westminster or Holyrood to recognise the need for such an inquiry led to the need to resort to the courts. The failure to hold fatal accident inquires into how the deaths resulting from blood contamination in Scotland was demonstrative a system which was entirely broken and was ultimately found to have been in breach of the petitioners' human rights. Following a successful judicial review which quashed the decision of the Lord Advocate to deny a statutory inquiry into a number of deaths of individuals who had been infected by contaminated blood[2940], the Penrose Inquiry was set up by the Scottish Government in 2008. It should be noted that this was a process which required legal action.

5.3 This process is not an inquiry into an inquiry. However, there aspects of the Penrose Inquiry which we submit to fall into this Inquiry's terms of reference. The impact of the failures of the Penrose process on the infected and affected community are part of the Inquiry's responsibility to look at the impact of the disaster under term of reference 4. Further, we consider that insofar as the impact could be deemed to have been the responsibility of the State by the way it which it handled or participated in the Penrose process, we consider that the Inquiry is obliged to consider that under term of reference 5(a). The UK Government was hardly involved in this Penrose process, or at least not its public hearings. We do not know why. There was an indication on the part of the DoH that it would co-operate with the Penrose Inquiry.[2941] It appears that, in material respects, it did not. Though the inquiry was prevented by section 28(4) of the Inquiries Act 2005 from being able to compel the UK government from participating, it could have done so voluntarily, as it appears that it indicated that it would in exercise of its democratic duty to the people of Scotland. This was clearly to the detriment of the ability of the Inquiry to get to the bottom of the issues which it was charged with investigating, as the current Inquiry has shown. Many decisions taken over the material period were taken as a result of information available to the DoH or

---

[2940] Kennedy and Black v Lord Advocate [2008] CSOH 21, 2018 SLT 195

[2941] WITN7299011, DHSC0041157_042; Nicola Sturgeon MSP, second witness statement (WITN7299002) @ para 20.3(b)

following their lead as the Scottish Office and the DoH were part of the same government.

5.4 The opportunity was however lost then to hold a UK Inquiry. This would have been more cost effective, and would have avoided years of additional delay. As it is Penrose was a Scotland only inquiry and was concerned with primarily just medical issues relating to infections which occurred in Scotland by blood contaminated with hepatitis C virus (HCV) and HIV. The fact that (as is demonstrated above) so much of what happened in Scotland needed to be understood in the context of UK decision making due to the broken system of administrative devolution, meant that the inquiry stood little chance of getting to the bottom of what had happened based on the full context. The length of time between the events in question and the Inquiry also played a part.

5.5 There was little engagement with the infected and affected in the setting up the Penrose Inquiry about the issues which they thought would need to be resolved should be approached. Though there was a degree of engagement, there was no formal consultation with them on the terms of reference. The result of this was that there are many matters which are included within of the current Inquiry (as set out in our earlier submission on the Penrose Inquiry process) which were not examined by that process. That failure (along with the inevitable limitations of a Scottish Inquiry which appeared to have no active involvement from the UK government) meant that there were limitations on what the inquiry would be able to achieve from the start. There was no term of reference related to financial elements of the previously failed financial support trusts and schemes or the ongoing financial needs of the infected and affected and so there was little prospect of those needs being addressed and resolved within the ambit of the Inquiry. The risk of and response to the vCJD threat was also not part of the Inquiry's remit.[2942] Similarly, the government response to the disaster which had so compounded the harms felt by the infected and affected communities were not part of the examination. It seems hard to imagine why such important matters did not form part of the remit of the Inquiry. Its remit was only to look at Scottish

[2942] Written statement of Dan Farthing (WITN4081001) @ para 18.21

matters, as defined by the Inquiries Act 2005. The current Inquiry has looked at these matters relating to Scotland and has also extensively gathered evidence from the infected and affected community from Scotland, despite its remit being UK wide. Having fought so hard for the Inquiry, the patient community should have been more formally involved in the consultation process around the terms of reference. Given that many were ill (and many have died between the end of that Inquiry and this), the Inquiry ought to have had a more comprehensive remit. As a result, much important evidence on matters which could have been covered but were not may have been lost. At the time, it ought to have been viewed as the victims' only and only chance at finding the answers. The consequences of this failure to involve the patient community in the terms of reference process to a greater degree is set out in evidence available to the Inquiry from the Scottish Infected Blood Forum. They describe the inadequacy of the way in which the Forum was allowed to be engaged in the setting of the terms of reference and the effects of the failure to involve their forerunner organisation, the West of Scotland Haemophilia Forum in their statement to the Inquiry.[2943] In particular they refer to the advice that they received from the civil servants engaged in the setting up of the Inquiry that their specific list of key issues would not be incorporated into the terms of reference but that a broader remit be proposed. This advice on behalf of government led to a number of these key issues not being addressed adequately by the Inquiry. In addition, campaigners made various practical suggestions as to how the Inquiry could be organised so as to maximise the input of the patient community, which did not happen.[2944] A report of a consultation exercise about the patient expectations prepared by the Haemophilia Society after a patient community consultation appeared not to be welcomed.[2945]

5.6 Little account taken of the views or priorities of the infected and affected in the way that the Inquiry went about discharging its terms of reference from the outset, or at least this was how things appeared to that community.[2946] Only a

---

[2943] WITN7165001, from para 96

[2944] Third written statement of William Wright WITN2287019 @ pars 18.5; WITN2287019; and WITN2287063

[2945] Written statement of Dan Farthing (WITN4081001) @ para 18.21

[2946] Written statement of Dan Farthing (WITN4081001) @ para 18.20

limited number of those proposed for CP status were so appointed.[2947] Papers were provided by campaigners which were never returned.[2948] The set-up period of the Inquiry between 2008 and the oral hearings in 2011 involved extensive work being carried out without significant involvement of the patient community or their legal representatives in the process (a significant number of witness statements were taken from them by the Inquiry over that period). An extensive preliminary report was prepared (running to 622 pages). The report gave the appearance of a number of conclusions having been reached before the public scrutiny of the oral hearings commenced in 2011. The Inquiry's preliminary report indicated that its preparation had been assisted by input from medical personnel, incusing some who might be deemed to have been apologists for the way in which the State had handled the disaster.[2949] It was specifically stated that they had "provided guidance on the approach that has been adopted to the investigation", creating a legitimate concern that the Inquiry had been captured by the very thinking which it had been designed to investigate and challenge. By the time of the oral hearings, numerous prominent campaigners with extensive knowledge of factual matters were not called to give oral evidence. Witness statements were taken by the Inquiry staff as opposed to the infected or affected's own lawyers. The Inquiry undertook an extensive factual investigation but appeared to listen predominantly to the medical profession. Campaigners who had much to add and had devoted yeas of their lives to the campaign were not called to give oral evidence.[2950] Much of the oral evidence was highly technical on issues such as heat treatment of factor concentrates. Supposed independent witnesses (mostly practitioners from England) were not really independent, given that they themselves in many cases had caused infections and were open to criticism. In

---

[2947] Ibid, para 87

[2948] Third written statement of William Wright (WITN2287019) @ para 15.2

[2949] See page (v) of the preliminary report – "Professor Brian Gazzard, Chelsea and Westminster Hospital; Professor Edward Tuddenham, University College, London; Professor Andrew Lever, Addenbrooke's Hospital, Cambridge; Professor Howard Thomas, Imperial College, London; Professor Jean-Pierre Allain, Cambridge University, and Professor Brian Colvin, Queen Mary University of London, made invaluable contributions to our understanding of the diseases and related matters and in that way provided guidance on the approach that has been adopted to the investigation."

[2950] Third written statement of William Wright (WITN2287019) @ para 18.8

many cases the evidence about practice in Scotland from such witnesses was limited by the fact that English practitioners had been conditioned in their approach to the disaster by the limitations of the regime in which they had operated and their consequent reliance on imported concentrates. The evidence was dominated by the "party lines" and sense of defensiveness akin to the litigation minded approach of previous years, as opposed to openness, honesty or a spirit of trying to examine and improve the system which it had been hoped that the Inquiry would be able to encourage to come to the fore.

5.7 The evidence heard by this Inquiry confirmed that important witnesses were not called to participate in the public process, despite potentially having evidence to give which may have assisted with uncovering the truth. Some civil servants from the Scottish Office gave evidence. No UK health minister gave evidence. No UK civil servants gave evidence. For example, Dr Walford was a key medical advisor in the DoH at the time of the emerging AIDS crisis with a background in haematology. Her pivotal role in this area is analysed above. Her advice had an indirect effect on the position adopted at that time by the SHHD due to the practice of that department relying on the superior knowledge base and staffing in the DoH. Dr Walford expressed certain views about the need for a re-draft of the then current donor leaflet in a memorandum dated 14 February 1984 in which she said that '[i]n view of the published evidence of transmissibility of AIDS by blood transfusion, our current advice to donors could seem too lax'.[2951] A request was sent by the Penrose Inquiry for her to comment on this aspect of the written evidence in a statement on this and other related matters.[2952] The request contained material which had been contained in the Inquiry's preliminary report and other materials deemed relevant to the issue and hence to the terms of reference of the Inquiry. In her reply, she declined to provide a view on these matters, having been informed by the Inquiry that she was under no obligation to do so.[2953] In her written statement to this Inquiry, she expressed the view that she

[2951] PRSE0002006
[2952] PRSE0004167
[2953] PRSE0000656

would have wished to have had any earlier inquiry.[2954] She did not give evidence to the Inquiry. Dr Rejman was another key advisor to government who provided played a role on the ACVSB and whose position with regard to the Penrose Inquiry became apparent in his evidence to this Inquiry. Despite him performing that role and the fact that the evidence showed that decision making from 1989 (a) was heavily influenced by the advice of the ACBSB and (b) was undertaken in Scotland generally in deference to the position being adopted in London, other than a warning letter and subsequent correspondence he mentioned in his statement, he had no other engagement with the Penrose Inquiry.[2955] Despite his apparently important role in this important issue (in connection in particular with the Inquiry's topic C4) he was never asked to provide a witness statement to the Inquiry or give oral evidence. His desire to correspond with the Inquiry to clarify his role in response to the warning letter suggests that he (unlike Dr Walford) would have been prepared to do so.[2956]

5.8 Scottish Office minister in the late 1980s and early 1990s and Secretary of State for Scotland, now Lord Forsyth was, for example, not invited to be part of the process.[2957] Some SHHD evidence was limited due to the age of the witnesses and their limited recollection of events. Lord Forsyth's evidence may have been useful, in particular if his ministerial papers had been available at that time (which they were not for his evidence to this Inquiry). No UK minister gave evidence to the Inquiry, despite calls for this to happen and the apparent commitment of the DoH to co-operation. Calls by the patients for evidence from individuals like Lord Owen and clinicians like Dr Jones from nearby Newcastle did not result in their giving oral evidence. Thus, the business of the Inquiry was conducted without key witnesses being involved, some as they refused to become involved and others because they appear not to have been contacted for comment, despite the DoH's apparent commitment to participation.

[2954] Dr Walford written statement @ para C.5

[2955] Dr Rejman's third witness statement (WITN4486040) @ para 3.3

[2956] See WITN4486045 (letter to Penrose Inquiry after publication of final report) – he asserted that his response to the warning letter had not been taken into account in the drafting of the final report concerning his involvement on the ACVSB in early 1990

[2957] Witness statement (WITN7126001) @ para 5.1

5.9 Thus, the Inquiry did not constitute the opportunity for truth and reconciliation, for openness and closure which it had promised. This led to disappointment and a compounding of the sense of frustration and isolation which the infected and affected community had felt for so many years. It constituted a missed opportunity to make up for some of the failures with regard to the infected and affected community but also an opportunity for the system within Scotland to take a look at itself and make improvements against the backdrop of such a huge disaster. The Inquiry's single recommendation is redolent a process that had run out of enthusiasm for its task by the time it reported in 2015, some 7 years after it was set up.

Post Penrose developments

5.10 It was common to all the infected and affected that the experience of the Inquiry had been so limited. They all suffered as a result. However, the response of the Scottish Government to the end of the Inquiry was a positive one. The Short life working group, the financial and clinical reviews all engaged with and involved the patient community.[2958] The commitment to proper, regular financial support from the SIBSS was a matter which should and could have been achieved many years before. Justice delayed has been justice denied and in this case, justice has not included compensation, which is addressed in some detail below. The principle of self-assessment as a key cornerstone of the SIBSS is also assessed.

5.11 The Inquiry has clear evidence of the principles upon which the SIBSS (and hence the other the UK support schemes currently in operation) is based. The importance of those principles requires to be acknowledged and endorsed by the Inquiry, including the need for schemes to be locally politically accountable.[2959] These principles were based on wide consultation and consideration of how the previous

[2958] Third written statement of William Wright (WITN2287019) @ para 20.7 *et seq* for a narrative of the relevant events

[2959] Third written statement of William Wright (WITN2287019) @ para 20.13

trust and schemes operated and also how other international schemes of a similar nature functioned.[2960] Engagement of the community was essential to the scheme ending up as it did.[2961]

6. Ministerial and other government papers

6.1 The evidence heard by the Inquiry is that at this remove, government papers, including ministerial papers were not available which those concerned thought should be. Lord Owen gave clear evidence that his ministerial papers had disappeared and that he would not have expected that to be the case. In Scotland, former Scottish Office minister and Secretary of State for Scotland Lord Forsyth had similar problems and a similar reaction when he tried to access his ministerial papers to assist with his recollection and evidence and he thought that these should have been retained.[2962] Indeed he thought that it was part of the civil service code that written records of matters be kept and that it was important that this be tightened up on. [2963] He was largely not able to access briefings with his manuscript annotations which were the main means by which his thinking on matters was recorded. His evidence was thus limited as a result. Lord Glenarthur also described not being able to access certain key documents for the compilation of his statement, including important written briefings relating to the PQ on 14 July 1983, the debate in the Lords in March 1985 and the Haemophilia Society meeting on 8 September 1983.[2964] Lord Fowler described how he required to be supervised by a secretary when he wanted to study what yhe considered to be "his" ministerial papers years later.[2965] The lack of these papers and the lack of clear explanations as to why they are not available to assist elected representative

---

[2960] Third written statement of William Wright (WITN2287019) @ para 20.16
[2961] Third written statement of William Wright (WITN2287019) @ para 20.17
[2962] Witness statement (WITN7126001) @ para A; IBI transcript for 20/07/22; 5 (9 to 15) (Lord Forsyth)
[2963] IBI transcript for 20/07/22; 7 (5) to 8 (10) (Lord Forsyth)
[2964] Witness statement of Lord Glenarthur (WITN5282001) @ para 1.11
[2965] para 0.36 of Lord Fowler witness statement at WITN0771001

and other servants of the State in providing their democratically mandated answers to the victims of the disaster have contributed to accurate and comprehensive answers not being provided, or at least doubt about those answers. Practices which have led to the loss of comprehensive, available records undermine democracy and have compounded the harms of the victims at the hands of the State.

6.2 As is set out in our non-financial recommendations submissions below, we are of the view that the Inquiry should recommend that a more effective system be put in place for the retention of these papers so that these harms are not visited upon victims of other similar events or disasters in which government decision-making has played a part in future. It is an important part of a democratic system that there be honesty in the dealings of the government and the people. Honesty is promoted by accountability. Clear, comprehensive and honest record keeping is an important part of the way that the people hold those whom they have elected to govern them to account. The lack of availability of such records has hampered the fight for justice arising from the blood contamination disaster. The Inquiry must do what it can to avoid this happening again.

7. Other means of redress open to the infected and affected in Scotland

General

7.1 The failure of the State to investigate and explain its failings in the occurrence of the blood contamination disaster in Scotland and increasingly in its response to it set out above have led to certain infected or affected individuals seeking to avail themselves of other mechanisms of the State

Litigation

General

7.2 Concerted attempts were made on behalf of the infected and affected community, in Scotland more widely in the entire UK over many years to have the government acknowledge their suffering, the fact that the infections had been caused by treatment dispensed by the State and thus through no fault of the infected (or indeed affected) and provide for the needs of the infected and affected which had been created by the infections. The government response was wholly inadequate, as is analysed in detail above. Its inadequate response has significantly compounded the harms caused by the original infections. A significant body of evidence was made available to the Inquiry about actual or contemplated litigations throughout the UK. The attitude of the government to the need for the infected and affected to resort to litigation and in their conduct of them is of significance in understanding the inadequacy of the government's response to the disaster. In this section, we present our submissions in this regard, with particular focus on the Scottish litigations.

7.3 The following general submissions are made about the way in which the HIV litigation was concluded:

(a) There was little prospect of the HIV litigations being successful, given the fact that expert support from the pursuers'/ plaintiffs' positions was likely to be necessary. In this regard, the deck was clearly loaded in the defendants' favour from the start. The evidence available to the Inquiry demonstrates that (as opposed to focussing as one might have expected on the care of patients with bleeding disorders, many of whom were infected with at least one potentially fatal disease as a result of NHS treatment) the UKHDCO directors were keen to make sure that their position was arranged and their legal position secured in the aftermath of the English HIV litigation being commenced. The meetings round the position on the litigation are important. They play a significant part in

the "party lines" of the UKHCDO being created *ex post facto* and the associated medial and hence the government "cover up". These party lines were the answer to any queries about the disaster which helped convince civil servants and government there was nothing to look into for many years.

(b) One such meeting of the UKHCDO took place in June 1989.[2966] It was attended by MDU reps as well. The discussion centred on the strategy on how to deal with the litigations which had been raised regarding HIV. Dr Ludlam presented a paper on HIV history. The group was told that directors should act as expert witnesses as otherwise the solicitors will get experts from outwith the UK directors group. This was a start of the manipulation of the investigation, active discussion of having insiders act as independent witnesses to avoid truly independent witnesses being brought in. An analysis of the Scottish position given. Dr Ludlam said all cases were different, an ironic statement in light of the way that ultimately the government treated all cases the same. He specifically refers to patient being treated in 1986 with non-heat treated material. This was clearly a reference to the case of Mr Wright about which he clearly felt exposed. Dr Ludlam said that he had asked patients if they still wanted to be treated by him in front of a witness and made a note of the response in the file. He has started to act very defensively in the knowledge that the relationship of trust had broken down. As he acknowledged in his letter to Robin Cook MP, the patients had no real choice in the matter. In 1989 at least one of his patients did not know about his infection. Dr Ludlam was a member of the UKHCDO litigation committee[2967] He was also acting as an expert witness on behalf of the NHS. The "capture" of the situation by the UKHCDO had truly begun. The remit of this organisation was to organise haemophilia care in the interests of patients. It had become about defending themselves and each other. Instead of being able to manage their clinical responsibility to them, the doctors were formulating a strategy as to how to reveal as little to them as possible to minimise their and

---

[2966] PRSE0002656 – UKHCDO meeting re litigations – 16 June 1989

[2967] PRSE0001175

the government's legal exposure. They had, in effect, become professional litigants.

(c) Mr Mcintosh wrote a letter to regional transfusion directors in Scotland telling them the lines to ta and encouraging them not to comment about infections with HIV in transfusion patients.[2968] Similarly, they were being encouraged to tow the party line in 1991.

(d) At a further meeting of the UKHCDO AIDS group on 27 April 1990, representatives from medical defence unions were in attendance and a discussion about the HIV litigation took place. This was a group which was meant to be discussing matters in support of and in the interests of patients. However, during discussion it was minuted that Dr Lowe (the director of the Glasgow centres at the time) used the opportunity to ask questions about the possibility of hepatitis infection becoming part of the litigation.[2969] Concerns were raised about the presence of directors who were representing the plaintiffs, both in the English and Scottish litigations. It is submitted that this meeting was being used to develop a consistent approach to the litigations, from which the experts needed to be excluded.[2970] Dr Lowe was seeking advice here on the possibility of centre directors stopping the collection of collection of data on hepatitis. It was decided that this data should not be sent to the Haemophilia Society.[2971] In this context, it appears that this agreement was reached to defeat the possibility of claims in respect of hepatitis being raised and pursued.

(e) It is submitted that these meetings were wholly inappropriate and that they were the start of the development on the part of the UKHCDO of "party lines" to take in response to the allegations being made against its members, the formulation of an agreed position of solidarity. Part of this exercise also clearly demonstrates the problem which would be faced by the plaintiffs/ pursuers in the actions – the experts engaged by them to provide advice to the pursuers/ plaintiffs were part of the very club which had provided the treatment which

---

[2968] PRSE0001649

[2969] HCDO0000271_014_0003

[2970] HCDO0000271_014_0001 - _0002

[2971] HCDO0000271_014_0004

had infected them. Professor Ludlam, one of the key protagonists of the blood contamination disaster in Scotland provided an expert report in support of the defendants in England. No expert available to the plaintiffs/ pursuers could ever have been said to have been independent from that club. In these circumstances, it is hardly surprising that despite the plethora of experts who were consulted by the plaintiffs' legal team in the HIV litigation "[r]egrettably, there has been a great reluctance by almost all haematologists to assist the plaintiffs in the litigation".[2972]

(f) In addition, the government was aware that the financial realities of litigation would make it practically impossible. Litigation funding from insurers similar to what might be available today did not exist at the time. The only means by which litigation of this nature might have been funded at the time was by way of legal aid support. The pursuers/ plaintiffs were all infected with a disease which was thought would be likely to kill them. They were turning to the government for financial support and could not have funded litigation themselves. Legal aid support would have required expert support, in order that probable cause could be demonstrated. This would have proven to be an impediment imposed by the State on the action progressing for the reasons stated above. Specific evidence available to the Inquiry about impediments to access to legal aid in Scotland in the context of the HCV litigation is set out below.

(g) The government consistently confused its obligation to provide financial and other support to those infected with HIV as a result of NHS treatment with its legal rights/ position in the litigation. It is in this context that the government's consistent mantra (in response to claims relating to HIV and later to HCV) that individuals who claimed that the government or the NHS had been negligent could also resort to litigation requires to be understood. Though this was, of course, an accurate statement this position hides behind the reality that these were individuals who had been infected by the State to whom litigation was a practically impossible option for the following reasons:

[2972] WITN4486030_0023 (13 December 1990, advice on settlement in the HIV litigation)

- It was unreasonable in that it failed to appreciate the reality of the process which was going on in the background whereby the alignment of the "experts" undermined any prospect of any litigation being successful;
- It failed to engage with the reality that the government ought to have been more focused on its moral obligation to look after those whom it had infected with potentially fatal diseases as a result of NHS treatment; and
- It failed to take account of the impact of having to engage in litigation on the sick and dying. In a parliamentary answer on 11 December 1990, in response to a question about the settlement of the HIV litigation, Secretary of State for Health Mr Waldegrave indicated that it was well known to the government that the litigations would have a "harrowing effect" on the plaintiffs, one of the reasons given for the attempts at settlement.[2973]

7.4 This approach had a significant effect on the infected and affected community. It seriously compounded the harms which the original infections had created in the first place. Those infections had been at the hands of the State to which the infected had turned for medical help when it was needed, either to treat an inherited bleeding disorder or a medical situation which merited at least consideration of a blood transfusion. Those individuals turned to the State for help when they needed it. They became infected with potentially fatal diseases. They turned to the State again when they needed help dealing with the consequences of the infections. They were told they would need to resort to litigation, a process which was loaded against them succeeding by the very system which had infected them in the first place. That system also thereby refused to acknowledge that it had any moral obligation to assist them beyond their legal duty, the enforcement of which was known to be practically impossible.

[2973] DHSC0002451_006 (11 December 1990)

HIV litigations

7.5 The evidence heard by the Inquiry was focussed on the HIV litigation which took place in the High Court of England and Wales. It is anticipated that submissions about the inadequacy of that litigation, the way in which it was conducted by and on behalf of the UK government by other core participants who had a more direct interest in it. It should also be borne in mind that there were Scottish litigations in which litigants sought damages in Scotland. It was clear from the evidence which was heard and is available to the Inquiry that these litigations (which were separate court actions, co-ordinated by one firm of solicitors based in Edinburgh) had not proceeded to the same procedural stage as the High Court litigation in London at the time when it was settled or heading towards settlement in December and, in any event, appear to have attracted little attention on the part of the Secretary of State for Scotland against whom the actions proceeded. The solicitor representing the Scottish group required to write to the Secretary of State for Scotland, having seen the advertisements in the press on 11 December 1990 that the English HIV litigation had settled or was heading towards settlement. He asked what the implications of this were for the Scottish pursuers.[2974] This letter makes it clear that the Scottish pursuers and their representatives were excluded and were, in fact, not even aware that the settlement was taking place. Thus, the Scottish litigations had not been considered at all in the government's assessment of the strengths and weakness of their position, not had how their position in them might impact on the reasonableness of the settlements, insofar as they might be offered to the Scottish pursuers. It is clear from the evidence heard by the Inquiry that no separate consideration was given to the rights and positions of the Scottish pursuers. As Mr Tyler stated in his letter to Mr Lang, separate issues arose in the Scottish litigations than those which had been considered in England. A settlement proposal was arrived at as a result of a negotiation undertaken between the UK

[2974] PRSE0003064 – letter from Mr AJ Tyler to Ian Lang (12 December 1990)

government and the legal representatives of the English plaintiffs. Legal advice was provided to each side on the basis of the English case as it stood at the time. The Scottish pursuers were thus deprived of the right to conduct a negotiation of the settlement of their own cases. Their rights and positions were never considered by government. They were at the very least deprived of the "day in court" which a proper consideration of their cases by way of negotiation would have entailed. They were, as so often throughput the disaster, an afterthought. The settlement proposal made to them was a *fait accompli*.

7.6 Despite this, the Secretary of State for Health (William Waldegrave) announced in response to a parliamentary question on 11 December 1990 that, if accepted, the "outcome" of the settlements would be applied by the government throughout the UK.[2975] By the time of Mr Tyler's letter, the Secretary of State for Scotland had been quoted in the Glasgow Herald on 12 December 1990 as having said that talks would be held with the Scottish pursuers and that he had hoped that the offers made would be acceptable to them. No such offers had even been made to the Scottish pursuers. They had not been involved or considered in the negotiations. The government's handling of the matter caused further unnecessary anxiety.[2976] It is clear from the response issued on behalf of the Secretary of State for Scotland on the same day that the Scottish Office had no instructions in connection with (and thus had had no involvement in) the English settlement, despite what the Secretary of State had said about the extension of the settlement offers UK-wide in the House of Commons the day before.[2977]

7.7 In fact, the evidence shows that the Scottish litigations were settled at a time when no proper advice could have been tendered to the Scottish pursuers. Their cases had simply not reached advanced enough a stage for the legal advisors to provide them with proper advice. They had little choice but to accept the offers which were being made to them without effective, properly considered legal advice being possible and without their opponents in the Scottish Office and the Scottish NHS

[2975] DHSC0002451_006 (11 December 1990)
[2976] PRSE0003064 – letter from Mr AJ Tyler to Ian Lang (12 December 1990)
[2977] WITN2189054 (12 December 1990)

having given any proper consideration to the strengths and weaknesses of their cases. By these actions, the government took advantage of sick and dying people, whose health conditions had been caused by the State. Indeed, as is considered in more detail below, the very fact that it was thought that the pursuers would die imminently was exploited as a means of pressuring them into accepting the settlements.

7.8 In his evidence to the Inquiry, Lord Forsyth said that communication could have been better from the DoH over the issue of the HIV litigations and their settlement.[2978] This was an understatement. In his evidence, Lord Waldegrave agreed with the position that the Scottish litigations had been an afterthought in the settlement of the HIV litigation in England.[2979] A memo dated 15 January 1991 from GW Tucker about Scottish Haemophilia/ HIV Litigation Group confirms they were not involved in negotiation process at all and were not involved in English Steering Committee's consultation procedure. It refers to the fact that Scottish solicitors had been unable to investigate claims due to lack of legal aid or other funding.[2980] As Lord Forsyth conformed in his evidence the Scottish Office should have been consulted before the settlement offer was made for the whole of the UK.[2981]

7.9 It is argued elsewhere in this submission that the State was more culpable in its infections with HIV of haemophiliacs who were infected in Scotland than elsewhere in the UK. Though it is course hard to generalise, the UK government was prepared to do so when it offered generalised settlements to the plaintiffs in the English HIV litigation. The evidence available to the Inquiry indicates that no consideration was given to the culpability of the State in the infection of the Scottish pursuers at the time of the settlement ultimatum was put to them. They were put over a barrel without any relevant material held by or on behalf of the Scottish NHS or Scottish Office having been made available to the Scottish litigants. The settlements were thrust upon them without them having been afforded the

---

[2978] Lord Forsyth witness statement (WITN7126001) @ para 69.1
[2979] In this regard see BNOR0000064 – dated 11 December 1990
[2980] SCGV0000231_019
[2981] IBI transcript for 20/07/22; 81 (Lord Forsyth)

opportunity by the Scottish NHS or Scottish Office to assess their legal rights or take properly informed advice.

The waiver of the right to pursuers litigation in respect of hepatitis infection

7.10 The eventual requirement that plaintiffs in the HIV litigation sign a waiver of the right to pursue any future claims against the government in respect of infections with hepatitis constituted an exploitation of the vulnerable and often sick and dying plaintiffs. The Inquiry addressed significant questioning towards Dr Rejman, amongst other witnesses, on the issue of how a requirement to sign a waiver of this nature had become part of the government's demands in the settlement. His position was that this stipulation had been part of the offer made by the plaintiffs' legal representatives and that hepatitis had formed part of the litigation, of which settlement was reached. This explanation bears neither logical nor factual scrutiny. The very fact that there required to be a separate waiver in respect of the right to pursue damages in respect of HCV infection is indicative of the fact that it was not part of the HIV litigation. Otherwise, settlement of that litigation *per se* would *ex lege* have been a discharge of the defendants' obligations to pay damages for having caused that infection. Hepatitis had formed part of the litigation but not as part of the loss which the plaintiffs were seeking damages for. The very fact that this was not a cause of action in the HIV litigation was what necessitated it being specifically covered in the settlement agreement. A judgement of the HIV litigation would not have been *res judicata* in a future litigation about damages for HCV infection. Hepatitis had been part of the argument of the plaintiffs on breach of duty and causation – they argued that the State ought to have prevented the importation of dangerous foreign factor concentrates, as a result of which these would not have been in use or in such prevalent use at the time of the AIDS crisis and HIV infections would thereby have been avoided. This was an argument which was addressed by Justin Fenwick QC in his statement as an argument limited in that way. At no point did he suggest that

it was caused of action being asserted by the plaintiffs that the State had breached its duties and thereby caused having caused hepatitis infections. The argument about hepatitis was said by him to have caused the plaintiffs some difficulty as regards remoteness, as covered in recent authorities such as *SAAMCO*.[2982] Indeed he made it clear that no such action for damages was included in the HIV litigation.[2983] Factually, Dr Rejman's assertion the offers made in settlement of the HIV litigation by the plaintiffs did not include a waiver in respect of other infections also appears to be inaccurate, on the documentary evidence available to the Inquiry.[2984] In the government's assessment of the those offers, they did talk about the importance of the finality of the litigations, in the sense of the possibility that the acceptance and the fact that the settlement proposals would not bring an end to litigations (if some did not accept or the court did not endorse settlements made on behalf of minors) with a medical negligence element.[2985] These remained points of contention on which the Secretary of State had been advised to seek assurances from the plaintiffs. The detailed response did not cover the possibility of waivers having been offered or indeed being sought at all. Further, the suggestion that the hepatitis waiver would have emanated from the plaintiffs would not bear logical scrutiny – why would they unilaterally offer to compromise something which they could never lose in the HIV litigation, namely the right to pursue the State for damages for having caused that infection? It is clear that the State was concerned to minimise its exposure to other legal liability in the way in which it sought to defend robustly arguments about breach of duty, in particular on the part of the CSM and the licensing authority so as not to set a precedent for other litigations.[2986] The government clearly had an eye to preserving or securing its position in other litigations. Mr Fenwick did not recall the role that he had played in reaching the final settlement[2987] but had been minded not to seek to make any further counter proposal in response to the plaintiffs' initial settlement

---

[2982] WITN7067001 _0014 (statement of Justin Fenwick QC), para 14.10
[2983] WITN7067001 _0050 (statement of Justin Fenwick QC), para 47.1
[2984] DHSC0046962_067 and DHSC0003654_117 (9 November 1990)
[2985] DHSC0046962_028_0003 (12 November 1990)
[2986] WITN7067001_0030 and _0034 (statement of Justin Fenwick QC), paras 28.3 and 30.10
[2987] WITN7067001 _0049 (statement of Justin Fenwick QC), para 45.1

offers, which had the benefit that they had emanated from the plaintiffs' legal advisors on their assessment of what would be acceptable.[2988]

7.11 Mr Fenwick expressed the view that it was necessary for there to be a waiver of the plaintiffs' rights to pursue other claims of damages which would have involved similar arguments to the argument raised in the HIV litigation as the purpose of the settlement was to avoid the costs and anxiety of the multiple complex issues in the litigation requiring to be litigated to a conclusion. That objective would not have been achieved, had there been an ongoing possibility of litigation seeking damages for hepatitis arising out of similar accusations of fault. That may very well have been the thinking within the government's mind but there appears to have been no mention that that was the agreed interpretation of the settlement announced in Parliament by the Secretary of State on 11 December 1990. The negotiation of the settlement agreement appears to have taken place over many months thereafter, starting around 12 December 1990.[2989]

7.12 In relation to the evolution of the wording included in the final settlement agreement, Mr Fenwick commented that "There was from the outset an acceptance by both sides that those who wished to take advantage of the settlement would have to waive claims arising out of the subject-matter of the action" and also that "I believe that the development of the wording was simply to define more accurately what claims would be waived and in relation to what period."[2990] These two statements appear at least to raise the possibility of inconsistency. A claim for damages for HCV would not arise out of the subject matter of the action as there had been no claim for damages for HCV in the HIV litigation. The development of the term to include actions which included similar allegations of fault as the HIV litigation is a subtle but significant change in definition and scope.

7.13 The hepatitis waiver appeared to get no attention whatsoever in the submission to Ognall J by Daniel Brennan QC which otherwise set out the terms of the

---

[2988] WITN7067001 _0034 (statement of Justin Fenwick QC), para 39.8

[2989] See DHSC0003654_032_0009, para 5 which contains no reference to an HCV waiver merely that the current proceedings would and and the plaintiffs would not bring "fresh proceedings"

[2990] WITN7067001 _0051 and _0052 (statement of Justin Fenwick QC), para 49.1

settlement for the court's approval at the hearing on 10 June 1991.[2991] It does not appear that this particular development was seen as one which could be deemed to justify a departure from what had been announced 7 months before as a settlement in the House of Commons. In the circumstances, one imagines that it would have been almost impossible to have contemplated explaining to the sick plaintiffs that the government had inserted a materially new clause into the settlement deal which meant that the limited lifeline of the payments on the table would be lost. The evolution in the position of the extent of claims being waived emanated from the government. In these circumstances the introduction of this as being part of the settlement deal was a material change in the settlement which had been announced in parliament. The government must have known that there was no realistic means by which the plaintiffs could have pulled out of the deal in 1991, in the circumstances and as such took advantage of the plaintiffs to protect its future legal liability. The reason why this was not considered to be a material change is hinted at in Mr Fenwick's statement at paragraph 46.1 where he says that:

"From my recollection, which is not particularly good on this point, what was principally in mind was infection with Hepatitis A and Hepatitis B which were considered comparatively mild by way of comparison with the benefits of Factor 8. I do not recollect much discussion of what was then described as Non-A, Non-B hepatitis or Hepatitis C."

7.14 This would tend to suggest that waiver of rights to claim for damages for hepatitis infection would have been thought to be a minor matter as the condition would case little loss.[2992] Whether the potentially severe consequences of HCV had penetrated the consciousness of Mr Fenwick or not, the government was certainly aware of the potentially serious consequences of HCV infection, in particular

[2991] DHSC0003663_042
[2992] WITN7067001 _0049 (statement of Justin Fenwick QC), para 46.1

amongst those who also suffered the immune-suppression associated with HIV infection. That this was known to the Department of Health at the time of the settlement was later acknowledged, including that HCV could cause serious liver disease and even death amongst haemophiliacs.[2993] This had been known from the Sheffield studies. Amongst others – Preston et al published in 1978 and Hay et al published in 1985. Of course, at the time of the settlement the government was in the process of making significant investment in the development of anti-HCV testing, which it would not have been doing, had the disease cause by that virus not been a serious one. The risks of HCV infection were, therefore, at the forefront of the minds of the very government officials who were assisting in the negotiation of the settlement. Importantly, there is no good reason to suspect that patients were aware of the possible consequences of their HCV infections and hence the value of the rights which they were agreeing to give up. Generally, the evidence heard from patients was that they were unaware at that time of their HCV infections – no officially used test was available until September 1991 and generally patients who were tested were tested without the knowledge or consent. Most did not know of their diagnosis by the time, far less the potential consequences of that diagnosis. Thus, the government knew or ought to have been aware of what the patients were signing away. The patients generally did not.

7.15 It may also have been thought immaterial as the plaintiffs would mostly die of AIDS before HCV would start to affect them. In either case, the change proceeded on a material misunderstanding of the medical position in quite desperate circumstances for many of the plaintiffs. Many did not die and for them the consequences of their HCV co-infection did prove to be serious. In these circumstances, one option which might have been considered would have been to reach a settlement provisionally, reserving the right to seek damages for hepatitis should actionable loss arise. The fair and reasonable thing to have done would have been not to include the term, such as to preserve the plaintiffs' separate rights to claim for damages for hepatitis.

[2993] WITN1055022_0002 (12 March 1993 letter from John Horam to Jim Cousins MP for Carol Grayson)

7.16 It was later argued by officials within the devolved Scottish administration that the pursued in the Scottish litigation had not signed the HIV litigation waiver.[2994] The reference in the memo in 2003 by Bob Stock must refer to the HIV waiver as no other litigation had been settled by this stage. This was inaccurate, in light of other evidence heard by the Inquiry from those who actually signed the waiver. It was clear from the evidence of Lord Waldegrave at the Inquiry and at the time that no material change to the terms of the settlement, including to the litigation waiver allowed.

7.17 In due course, recipients of funds from the Macfarlane Trust were required to sign a Deed of Undertaking precluding future litigation against "the Department of Health, the Welsh Office, the Licensing Authority under the Medicines Act 1968, the Committee on Safety of Medicines, any district or regional health authority or any other Government body involving any allegations concerning the spread of the human immuno-deficiency virus or hepatitis viruses through Factor VIII or Factor IX (whether cryoprecipitate or concentrate) administered before 13th December 1990."[2995] That this waiver made no specific mention of the Scottish Office shows that its genesis was in the HIV litigation in the English High Court and that no particular consideration had been given to the position of Scottish litigants in the determination of the fairness or legitimacy of the waiver. Scottish applicants of course had to sign the same waiver to access the MFT payments. In any event, the settlement agreements drafts (including the hepatitis waiver) were copied to the civil servants in the Scottish Office for comment while they were being finalised in 1991.[2996] The context of the 2003 email by Bob Stock is discussed elsewhere in this submission. At that time, the unfairness of the waiver was part of a call for there to be a public inquiry into the blood contamination disaster. The civil servants arguing against such a call appear to have received erroneous information about the application of the waiver to Scotland. It is also interesting to note that the answer being proposed to the equally compelling question of how imported

---

[2994] SCGV0000262_166 (7 April 2003)
[2995] MACF0000086_225
[2996] SCGV0000233_038 (24 April 1991)

products had been allowed to be used in Scotland was, by this stage, being characterised as one which would have fallen within the remit of the licensing authority. This was used as an argument to support a position that any such action would have been part of the responsibility of a government department the activities of which were reserved in terms of the Scotland Act 1998. No doubt at the time, this being relied upon was being out forward as a means of resisting an inquiry which it would have been within the competence of the Scottish Parliament to permit, one involving devolved matters. The characterisation of the licensing authority as the likely actor with responsibility for allowing imported products to be used in Scotland has the following interesting features:

(a) The assessment of the likelihood of an inquiry ordered by the Scottish Government to get to the bottom of this element of the disaster was limited by restrictions on its competence arising from the devolution settlement. This rather technical argument was being deployed by the State against the campaigners who sought an inquiry from getting one which was likely to be able to reach an answer on all important matters;

(b) As is made clear in the statement to the Inquiry of Justin Fenwick QC, the possible legal liability of the CSM/ licensing authority was robustly defended by the State. That litigation had been settled on the express condition that it was the first defendants and not these licensing bodies which was making the payments. Liability on the part of the LA or the CSM was expressly discounted. The plan of the defendants had been to seek to strike out the arguments against them based on them not owing the plaintiffs a duty of care. If those bodies did indeed bear responsibility, the State had never to this point entertained any possibility of that possibility being investigated; and

(c) The very fact that officials at that stage appeared to wish to characterise the calls for the Inquiry as being about imported products (and hence beyond the competence of the Scottish Parliament to investigate) as an inaccurate characterisation. Though the importation of products was an issue, the majority of patients infected in Scotland had been infected by blood collected and blood

products produced in Scotland. The possible responsibility of the State for the caution o those infections was nothing to do with the transfusion and health services in Scotland which were devolved matters. The argument about resisting calls for an Inquiry based on competence issues was thus a red herring.

7.18 Even it were to be contended on behalf of the UK government that the HCV waiver was a fair part of the settlement of the litigation based on the prospects of the parties (which is not accepted, as this played no part in the deal was originally presented to Parliament and only appears to have emerged as part of the subsequent drafting of the settlement agreement which was designed to reflect that deal), no such consideration of the fairness of the waiver could have been assessed in the context of the Scottish litigations. Therefore, any such argument could not be said to have been considered in that context. Therefore, no consideration of the fitness of the waiver for the Scottish pursuers could have been undertaken. The waiver was therefore imposed on the Scottish pursuers without any consideration of the fairness of that step in the context of their claims.

HCV litigations

7.19 Litigations were commenced on behalf of individuals who had been infected with HCV by both blood and blood products in Scotland. As had been the case with the HIV litigations, these legal actions were all pursued separately and were co-ordinated by one solicitor on behalf of the whole group. There is a good deal of evidence available to the Inquiry which allows conclusion to be reached about the way in which these litigations were approached and conducted by the defenders, in particular the government was obstructive and sought to make the litigations as difficult as possible. We submit that the conclusion which can be drawn from this is that there was a material inconsistency in the way in which these issues

were approached by the government. When approaches were made by campaigners and others to the government about their financial needs as a result of infection which had been caused by the State, they were consistently told that the government was not prepared to meet their demand as its policy was that compensation would only be paid when there was a legal requirement for it to be paid as a result of breach of legal duty. They conflated the request for support (argued usually on the basis of a moral duty to provide it) with the legal duty to pay compensation, thereby deliberately evading the moral case. As the Inquiry has heard from numerous witnesses, including former secretaries of State for health Andy Burnham[2997] and Jeremy Hunt MP, this "line" was maintained in briefings given to them by civil servants who regularly failed to brief the ministers with the whole truth about what had happened. The reference to litigation was adopted as a convenient shorthand which allowed consideration of the moral case to be avoided and the infected and infected to continue to live in poverty. However, when it came to litigations, there was no realistic opportunity for the infected (far less the affected due to the limitations of the common law) to find any financial help. Many impediments stood in their way, all of which were known to the government or ought to have been known to them or indeed were caused by their own approach in defending such cases. Litigation funding provided few options. Speculative funding was generally not available. Legal aid funding would often require supportive evidence from medics or other experts, many of whom were part of the same establishment which the claimants sought to criticise. When actions did get off the ground, they were vehemently defended by the State (see examples below), which made access to a successful financial outcome near impossible and caused the claimants untold harm and re-living of the trauma of their infections and their consequences, having to undergo assessments and give all their limited energy to the litigation process.

[2997] IBI transcript for 15/07/2022; 60 (10 to 24), 68 (6 to 14), 77 (17) to 78 (7), 79 (6 to 15) (Andy Burnham); IBI transcript for 27/07/2022; 16 (3 to 6) – "there was a sense that we should not go public with any mistakes the NHS had made because that would be bad for the reputation of the institution and would shake public confidence in the NHS"; 141 (21) to 142 (18) (Jeremy Hunt)

7.20 The option of litigation so frequently offered by the government was thus well known to them to be an option which would almost invariably result in infected patients spending their time and effort in what would be a fruitless and exhausting process. This approach to matters by the State over many, many years as a response to genuine requests for the truth via a public inquiry or to much needed financial support seriously compounded the harms of the infected and the affected.

Early response by government to the litigations

7.21 The government exhibited a similar approach to the HCV litigations instigated in Scotland as had been the approach to the HIV litigation in England and by extensions to the HIV litigations in Scotland. The position of the government is exemplified in a letter from Gary Wildridge of the health department of the Scottish Office to the lead solicitor (Mr Donald) of the Scottish HCV litigation group, comprising at least some of those pursuing actions in the Scottish courts in respect of their HCV infections dated 24 July 1996.[2998] Though the lines taken by the Scottish Office in the letter can be found in other similar correspondence of the time, it is a useful snapshot of the position taken by the government at the time. In particular:

a) The context of this response is a letter written to the Secretary of State on behalf of those represented by the solicitor requesting an update on the likelihood of an ex-gratia payment scheme being established for patients infected with Hepatitis B or C as a result of NHS treatment with blood or blood products. The author had written on a number of occasions to the Department's Solicitors. The author indicated that he was aware of the Haemophilia Society's

[2998] BNOR0000130_036 (24 July 1996)

representations to the Department of Health in England and of their report completed earlier that year which graphically described the problems experienced by some sufferers who now find that they have to contend with the effects of the Hepatitis C infection on top of those of haemophilia. It is against this background that this composite response to those seeking an ex gratia payment scheme for Scotland need to be understood, including that that was the purpose the letter to which this one responds and also the nature and extent of the suffering of the infected which by 1996 was well known, the extreme effects of HCV and its treatment having already become apparent.

b) The government indicates in the letter that it great sympathy with those patients who have become infected with Hepatitis through blood transfusions or blood products. In light of the unsympathetic analysis to follow and against the background of the extent of suffering having been communicated by various means, this can be taken to be no more than a mere assertion unsupported by action of genuine expression.

c) Despite the letter being about an ex gratia scheme, the responses given by the government appear to conflate the defences advanced to litigations and its responsibility to its citizens whom it had infected, whose infections were known to the government to have caused great harm and need and for whom it had asserts great sympathy. In particular:

- The government indicates in the letter that these patients received the best treatment available in the light of medical knowledge at the time. This line conflates what might be a defence to an action in negligence with the purpose of the latter, a query about the plans for ex gratia payments. The letter is thus deliberately evasive about the possibility if the government in the circumstances owing a moral responsibility to those in need to provide for those needs on an *ex gratia* basis. The letter goes on to say that Government does not accept that there has been negligence and has no plans to make ex gratia payments to such patients. In this one sentence the government confuses the two separate issues.

- The letter goes on to say that "the first anti-Hepatitis C tests did not become available until late in 1989. These first tests had too large a number of false positive and false negative results and no satisfactory confirmation tests were available. Expert advice at that time was that these tests should not be introduced because of these deficiencies. The Department of Health in England funded several trials of the first and second generation anti-Hepatitis C test kits. Routine screening of all blood donations was introduced in late summer 1991 when satisfactory kits became available together with confirmatory tests. The screening tests now available are even more accurate than the second generation kits". It is not accepted this is an accurate summary of the position as regards the failures to introduce HCV testing in the period between 1989 and 1991, as is explored elsewhere in this submission and as was found to be the case in the context of the statutory duties incumbent upon the State under the Consumer Protection Act 1987 by Burton J in the case of A v National Blood Authority. In any event, the reference to testing was a mere diversionary tactic as it was not related to ex gratia payments (instead relating to a legal case alleging breach of statutory duty) and the arguments enumerated there could only have applied to a small proportion of those who were infected and who sought such *ex gratia* assistance as many were infected before that period.
- On the more general issue of compensation, the letter states that "the Government has never accepted the case for a no fault scheme of compensation for medical accidents and that it would be unfair to others and still requires proof of causation which is often difficult to establish". These considerations are of no relevance to the case made by an individual group of infected persons like those on whose behalf a response about the possibility of an *ex gratia* payment scheme had been sought.
- The letter states that if the NHS is shown to have been negligent, it accepts its liability to pay damages. This is self-evident and nothing do so with the question of an *ex gratia* payment scheme.

7.22 The letter goes on to state that it was "its view that the most effective use of resources is to be realised by seeking to improve the understanding, management and treatment of the condition. Only in this way can the impact of the disease on individual patients and their families be effectively minimised". Again, this evades the true question. Clearly the NHS has a freestanding duty to provide the best treatments to the infected to manage their health and minimise the effects of the infection. The request which prompted the letter was not about that but was about the need for financial payments as redress for the consequential need and harm which had already been caused and continued to be caused by the fact of infection.

7.23 It goes on to state that "the Department of Health in England is supporting an initiative by the Haemophilia Society to undertake a study into the best way to support its members who are affected by the virus and has made £91,000 available in 1995-96 with a commitment to further funding in 1996-97 and 1997-98". This statement is clearly of no relevance to the Scottish individuals upon whose behalf the request for an update had been made.

7.24 The letter states that "Special provision was made for haemophiliacs and others who tragically contracted HIV through treatment with blood or blood products because of their exceptional circumstances. Those affected were considered to have a very poor life expectancy. The decision to compensate also reflected the understanding that there might also be significant numbers of young children who had lost a parent or perhaps both of the disease had been transmitted to their partner. HIV sufferers were also subjected to significant social problems including varying degrees of ostracism."

7.25 This passage fails (it is submitted, deliberately) in a number of respects to grasp and address the realities of the situation. First, there appears little logic to the proposition that haemophiliacs who were infected should be treated differently than those infected by other means. Secondly, it suggests that the haemophiliacs had been "compensated" in the HIV litigation. They had not. They had received a settlement payment from the HIV litigations without admission of liability. Money

was paid into trusts which they may or may not have been able to access. The monies paid to them were the same as the payments no being sought in respect of HCV. Thirdly, it confirms that the rationale for the offers made in settlement of the HIV litigation did include consideration of the vulnerability of the plaintiff who were thought to have a very poor life expectancy. Fourthly, it fails to understand that many of the applicants on behalf the request about HCV payments had been made were haemophiliacs who were co-infected (and thus in even more "exceptional circumstances"). Importantly, the letter fails to make reference to the circumstances in which individuals who received those settlements (who may also have been recipients of ex gratia HCV payments with which this response was concerned) had come to sign waivers in respect of their HCV infections. In urging people to go to court to receive compensation for their HCV infections, the letter fails conveniently to mention that the government had already done what it could to preclude that route, which fact would logically make the case for *ex gratia* HCV payments stronger. Fifthly, that the decision to "compensate" also reflected the understanding that there might also be significant numbers of young children who had lost a parent or perhaps both of the disease had been transmitted to their partner is is no relevance to the question for consideration at that time. That is an issue to do with the class of applicants who should be able to apply for payments, not to do with whether the infected should be precluded from accessing payments. The claim that "HIV sufferers were also subjected to significant social problems including varying degrees of ostracism" shows a clear misunderstanding of the nature of HBV and HCV infection, both of which by this time had already started to involve such features as well, given their common infection routes with HIV infection. The letter relied on the assertion that "many people with Hepatitis C live perfectly normal lives for decades without any symptoms appearing". For many who had been infected in the 1970s, these symptoms were indeed starting to appear which was precisely why the treatments were being made available (and indeed causing further problems for many). The government claimed that they were not trying "to make light of the physical suffering of those who have been infected with Hepatitis C". In essence, this is exactly what this letters and others like it did.

7.26 Finally, it was stated that "In the absence of proven negligence on the part of the NHS, there is no case for using funds which would otherwise go towards the care and treatment of other NHS patients to make special payments to those affected". By this statement (an oft repeated mantra of the NHS in various different guises and forms) the government did little other than to exacerbate the feeling of stigma and ostracization felt by the HCV infected community. They were made to feel guilty and unworthy for asking for much needed help for the consequences of their State caused infections by being told that by doing so they were taking money away from the treatment of other NHS patients. This line was at that time and at all times, wholly unacceptable and inconsistent with the government's asserted position of sympathy elsewhere in this letter. In his statement to the Inquiry, Justin Fenwick had made clear that this was a conundrum in the HIV litigation year before.[2999] He and his colleagues had been instructed to give legal advice on the complex legal issues arising. The raising of the litigation had been the only option available to the infected and affected in light of the lack of government engagement with any moral case for proper financial assistance to be provided to them beyond the inadequate initial aum which had been put in the MFT. Beyond that, the government had urged that they would require to resort to litigation. The settlement of the HIV litigation was reached in the context of the government's attention having been grasped by having to deal with the litigation and the possibility of a lengthy litigation and the expense of public money in defending it. It was, however, settled in the context of the State's moral obligation to compensate the infected which had not previously been recognised or properly engaged with, a moral obligation which even Ognall J had felt compelled to intervene to point out. Had the government done so earlier, the litigation would not have been necessary. That moral obligation, by extension, also existed in respect of those who had been infected with HCV. The repetition of the same line – that the government would not make payments without proof of negligence – merely repeated the same mistake of the previous decade in respect of the HIV claims, namely a failure to recognise the State's moral obligation to provide

[2999] WITN7067001 (statement of Justin Fenwick QC),

financial support from those whom it had infected with a potentially fatal disease. The government was fully aware that the same moral arguments would arise in respect of hepatitis. The insertion of the hepatitis waiver into the settlement of the HIV litigation (addressed above) was an attempt to close of the gateway to a discussion about the moral obligation for the caution of hepatitis by closing the door to litigation, which would equally have led to the government needing to face its moral obligation in respect of hepatitis.

7.27 The lack of proper engagement by the government with its moral responsibility (as opposed to the complex issues arising in connection with its potential legal liability) and the confusion of the legal and moral realms was a consistent and characteristic theme in the government's response to the disaster. In response to calls for a public Inquiry in 2001, the government was challenged to compare and contrast its response to the vCJD crisis with its response to the infection of people by blood and blood products. On behalf of the government, it was said that the compensation scheme introduced for vCJD sufferers had been introduced as "the government decided that society as a whole should bear a moral responsibility. New variant CJD is a particularly distressing condition. Even though we were advised that we were unlikely to be legally liable, we considered it right to make payment to the victims and their families".[3000] This scheme had been introduced without knowledge of how many people would be able to apply to it, acceding to Justin Fenwick QC.[3001] In seeking to endorse the government's response to the vCJD allegedly caused by exposure to human growth hormone, the government demonstrated the fallacy of its position. It had accepted a moral but not a legal responsibility for the HIV infected haemophiliacs in 1990 and for the vCJD patients later. The government had, however, failed to recognise the extent of its moral responsibility to any of the victims of the blood contamination disaster and had also failed to recognise its logical moral responsibility for having by blood and blood products HIV and HCV were by 2001 well known to be potentially fatal conditions. The government's failure to do so was a culpable failure to live up to

---

[3000] DHSC0020742_093_0001 (15 October 2001)
[3001] WITN7067001 _0056 (statement of Justin Fenwick QC), para 56.1

its responsibilities. The failure significantly exacerbated and compounded the harms of infection, leaving many to whom it owed this responsibility in poverty.

CPA cases - HCV

7.28 The Inquiry heard evidence about the outcome of the decision in *A v National Blood Authority*, which related to cases raised in terms of the States' obligations relating to defective products under the Consumer Protection Act 1987, in force from 1 March 1988 which were raised by certain individuals who had been infected with HCV from blood transfusions. The Inquiry heard evidence that in light of the outcome of the case, a decision was taken to the effect that the Scottish government would seek to settle actions with claimants (pursuers) in Scottish actions raised on the same basis, given the likelihood that a similar decision would be reached against the government in the Scottish courts.

7.29 These were situations in which the government had clearly taken the decision as basis for instructing settlement on the basis that it was likely to be in breach of statutory duty for having produced defective products, in the form of blood transfused to patients which had not been subjected to surrogate testing or anti-HCV testing, rendering the blood as a defective product. One might have expected that in these circumstances, the government would require to face up to its responsibilities and pay what in some cases might be substantial damages for the considerable loss and hardship experienced by those exposed to this defective blood. The evidence available to the Inquiry is to the effect that actions which were settled were mostly settled for token sums. A hard fought FoI request by one claimant (referred to below) led to information being released about all claims settled in Scotland.[3002] 14 claims had been instigated against the SNBTS/ CSA which had been settled in respect of infection arising from blood transfusions. 26 HCV claims so raised had not been settled in 2006. There were 2 such unsettle claims not relating to HCV. Of the 14 settled claims, 11 had settle for £25,000 or less. The top settlement sum was £105,000. These may or may not have been CPA

[3002] WITN0363027

claims as the request was for all claims relating to HCV infection from blood transfusion against the SNBTS/ CPA. One might also have expected that (as had happened in at least some the A v NBA cases[3003]) actions might have been settled provisionally; leaving the right to pursuers to return for further damages as the possibility of their condition worsening to a substantial degree as well-known at that time. No cases appear to have been settled on that basis. Even in circumstances where it was accepted that a finding of breach of statutory duty was likely in a limited number of cases, the State failed to take the opportunity to pay anything like adequate compensation. One might also have expected that efforts might have been made, in light of this ruling to seek out others who for whatever reason had not raised legal actions but whose infections were caused due to blood infused after the 1 March CPA date. There was no effort to try to locate these people, either to inform them of their infections (as some may well have remained undetected) or that their infections had been in breach of the State's statutory duty.[3004] Efforts to evade not only moral but legal responsibility continued to dominate the thinking, it would appear. The HIV litigation in England had eventually settled as a result of there being some sense of moral duty to those infected, though legal duty was not accepted. Even against a backdrop of established legal duty for some cases, the State refused to take the same attitude to HCV infections. The clear inference that the Inquiry should draw from this was that as HCV infection was far more prevalent and so the bill for accepting such a moral (or even legal duty) would be far larger, the State remained unwilling to do so. This was in breach of its moral duty to support the infected and affected and in some cases in breach of its legal duty to pay fair compensation. The harms of the community were further compounded, unnecessarily.

7.30 The Inquiry has evidence of one action of this type in Scotland which remains unsettled to this day. The individual who had brought that case had, like those from the haemophilia community, resorted to litigation after having been "met with a wall of silence" from the medical profession about the circumstances of her

---

[3003] *A v National Blood Authority (No 2) [2002] Lloyd's Rep Med 487*

[3004] see DHSC0004601_021 where it sems to be recommended that that should happen in 2001 post A v NBA in England and Wales

infection from a blood transfusion. [3005] When her action as started in the mid 1990s, there was no speculative/ conditional fee arrangement available. Legal aid proved elusive over a period of years (even for CPA claims which were pursued amongst other HCV claims by a Scottish group, whose actions were separate but were organised via a single firm) and so the family had to make payments to fund the action.[3006] The action was sisted (stayed) as the family could not afford to continue to fund it, given the financial hardships caused by infection.[3007] Efforts mase by the claimant to find out publicly available information about other litigations was made difficulty by the CSA which had attempted to stifle the information which was potentially helpful to the claim being released.[3008]

Experiences of witnesses involved in litigation arising out of infections from haemophilia

7.31 The Inquiry has heard evidence about the experiences of a number of individuals involved in litigation, in responses to the government's manta that this is the way in which they should seek financial support. Above we make submissions about the genesis of the "cover up" relating to what had caused the disaster as having been in (a) the secrecy around the truth having been caused by a sort of "domino effect" resulting from the failure of medical professionals to inform their patients about the risks of their treatment and (b) the concerted and co-ordinated efforts of the medical profession (in particular the UKHCDO) to close ranks, develop consistent "party lines" to stifle the discovery of the truth and to frustrate it being discovered through litigation.

7.32 The same attitude was encountered by those who, despite these impediments, embarked upon litigation. They encountered obstacles to progress at every turn.

GRO-D

[3005] WITN0363026 @ para 4 (supplementary written statement of Gill Fyffe)
[3006] Ibid, paras 7, 10 and 13
[3007] Ibid, para 16
[3008] Ibid, paras 22 to 37

GRO-D

7.33 GRO-D

7.34 As is discussed below, attempts were made on behalf of haemophiliacs who had been infected in Scotland as a result of products manufactured in the US, of which evidence is also available to the Inquiry. GRO-D

GRO-D

3009 GRO-D

cou
3010

3011
3012 GRO-D
3013

GRO-D

GRO-D [3015] Another Yorkhill patient involved in the same process also received a token settlement sum and received no advice about it, simply being told he had no option but to accept, the US lawyers taking a third of that sum.[3016]

7.35 The Inquiry heard further evidence about litigation by a mild haemophiliac in Scotland in which damages were sought for his infection with HCV as a result of his first infusion with a factor concentrate in May 1986. His case is considered elsewhere in this submission, where it is asserted that he ought not to have been infected due to the timing of infection, the fact he had not been treated before and the availability of other less risky treatments at that time. In these circumstances, one might have expected that the possibility that he would have a legal case, given that he would not have been infected at that time elsewhere in the UK, would have been recognised. The way in which the case was approached by the ultimate defenders (Lothian Health Board and the CSA on behalf of the SNBTS) is illustrative of the State's approach to the disaster and litigation arising out of it. Like others, he gave evidence to the effect that his clinicians, Dr Ludlam, had tried to dissuade him from embarking upon the litigation.[3017] In his statement to the Inquiry on the subject he describes (a) the difficulties he had getting funding for the action to proceed[3018] (b) the fact that the extent of his liver disease was attributed to his own behaviour as opposed to infection[3019] (c) the fact that a limitation pleas was taken against him[3020] and (d) the traumatic need for his psychiatric state and life expectancy to be assessed during the course of the litigation.[3021] In addition, during the course of the Penrose Inquiry, the fact that he had an ongoing litigation was used by the NHS as a means of opposing details of

---

[3014] GRO-D

[3015] (GRO-D)

[3016] WITN2172002 @ paras 8, 9 and 14 (second written statement of WITN2172)

[3017] WITN2287019 @ paras 17.23 (third written statement of William Wright)

[3018] WITN2287019 @ paras 17.2 and 17.3 (third written statement of William Wright)

[3019] WITN2287019 @ paras 17.20 (third written statement of William Wright)

[3020] WITN2287019 @ paras 17.8(a) and 17.18(a)(third written statement of William Wright)

[3021] WITN2287019 @ section 17.18(f) (third written statement of William Wright)

his case relevant to the Inquiry's investigation of systematic issues relating to patient care at that crucial time being investigated.[3022] He had issues with important details of his case being missing from his medical records[3023] and getting expert medical advice to support his claim.[3024] Mr Wright made the point that he had been able to derive a certain benefit from information becoming available to him which showed various matters relevant to his case due to public inquiries. He (correctly) expressed the view that this would not have been able to others and so they would have been hindered in advancing similar cases.[3025] The traumatic nature of the assessment which Mr Wright had to undergo and the extent of the challenges taken to his claim are, in our view, an important matter to be taken into account in the Inquiry's recommendations relating to how a compensation tribunal should work. It is important that there be a factual presumption that the facts presented are true and that any assessment is kept to an absolute minimum, as we submit below.

7.36 A response to a campaigner (Mrs Carol Grayson) in 2003 from Dr Charles Hay also indicated another important practical restriction on individuals taking legal action. Mrs Grayson was at that time seeking information about batch numbers for products which her husband (and others) had received, in particular the details of "suspect" batches which she had discovered were being investigated in a study by Dr John Craske in the late 1970s and early 1980s. In his dismissive response, Dr Hay indicated that the records would have been destroyed after 7 years as a result of the "statute of limitations" pertaining to them.[3026] As Professor Ludlam recognised in his evidence, the records of patients with a chronic, lifelong, hereditary bleeding disorder ought never to have been destroyed by the State, even after their death, given the importance which they may have in providing care to future generations of relatives with the same disorder. In any event, it appears that the official position was that the State should not be blamed for their

---

[3022] WITN2287019 @ paras 17.15 and 17.24 (third written statement of William Wright); WITN2287060
[3023] WITN2287019 @ paras 17.24 (third written statement of William Wright)
[3024] WITN2287019 @ paras 17.26 (third written statement of William Wright)
[3025] WITN2287019 @ paras 17.27 (third written statement of William Wright)
[3026] WITN1055011 (November 2003, in repose to Mrs Grayson's letter of September 2003 - WITN1055010)

destruction. That decision was indeed something for which the State should be blamed – it was clear that haemophiliacs may be infected with a disease with a long latency period and that future investigation and access to records from the time of infection at the time of symptoms would inevitably have been necessary. In any event, retention was necessary for their continued care and that of their future relatives. All of this must have been known to the clinicians of the day. Their destruction was thus either intentional (to avoid any such investigation) or culpably reckless, in that endangered the patients' and their relatives' future care. That Dr Hay (a prominent centre director and future UKHCDO Chair) saw fit to defend that decision to destroy these records in 2003 seems to imply that centre directors like him accepted it and were therefore complicit in it and its consequences. In any event, these actions deprived individuals like Mrs Grayson and her late husband access to justice. The evidence available to the Inquiry shows that this happened frequently in Scotland as well. In addition to the lack of legal aid funding for largely impoverished potential litigants, the destruction of records created an important and unjustified State-made impediment to litigation, the very solution which the State consistently urged the victims to take. In addition, the thrust of Dr Hay's response is worthy of consideration. Mrs Grayson was looking for batch numbers in order to help her husband's US litigation. These were needed to be able to identify the origins of particular batches of imported concentrates and link them to particular pharmaceutical defendants. The response by Dr Hay was that this did not matter – all of the products were infective on first infusion, irrespective of origin. It is hard to see how this assists his position – an admission that all products (even domestic) were infective seems to heighten, not diminish at least the moral imperative of the State to accept responsibility for the infections, as is argued elsewhere in this submission. The batch numbers were not relevant (at least to the causation of HCV) as they were all equally infective.

Evidence of the government's approach to HCV litigations in Scotland

7.37 The context in which the approach to HCV litigations came to be considered in Scotland is considered above. The aftermath of the outcome of the A v NBA case in England occurred at an important time in Scotland, namely the emerging political will for a public inquiry and/ or compensation for the victims in Scotland, in particular those who had been infected with HCV and had never before received any money from the government in the early years of the Scottish Parliament. It is submitted above that the investigation was in fact a "PR exercise" as it was later described. The existence of the litigations is important in understanding why. The government mantra from the start of its response to the disaster in the late 1980s had been conditioned by the need to minimise its exposure in the HIV litigation. It is submitted that the same approach conditions the Scottish Executive's position in its investigation into the HCV infections.

7.38 Issues with legal aid for HCV litigations appears to have been well known within the Executive, including the implications of financial support for such access.[3027] Such issues are addressed in the analysis of the evidence available to the Inquiry from potential claimants (discussed above). Email correspondence available to the Inquiry refers to a meeting taking place on 2 July 2001 to go through the list of court actions prepared by CLO/SNBTS to endorse the proposed categorization into those where the CLO will enter into discussions with the legal representatives of claimants and those where they will not.[3028] It is clear from the list of those who were to attend this meeting that the analysis was being conducted by a number of those who had been involved in formulating the government response to the Executive investigation, including government advisors Bob Stock, Aileen Keel, Lynda Towers and also SNBTS representative Brian McClelland. It seems that the defence of the government/ NHS position as conducted in the litigation by many of the same people who carried out the internal investigation. It is also clear that the scrutiny had been instigated by the minister - "Hopefully this will be a straightforward matter but the Minister is anxious that the list is thoroughly scrutinized (particularly by SE solicitors) before any letters are sent out". There

[3027] SCGV0000180_127 – 21 September 2000
[3028] SBTS0000357_059 – email dated 29 June 2001

was apparently a need for matters to be dealt with particular care and attention. It is submitted that the unusually details approach was because the need to settle cases in a way which did not expose the government or the NHS to further action. In an email from Dr Keel memo regarding settlement of HCV litigation, she estimates of numbers that will progress to serious liver disease were too low. This is of interest in light of the sums for which cases settled, as analysed above. It was clearly known to government at that time that serious disease was part of the futures of a number of the infected. Despite this, it appears that the settlements were reached at levels which did not reflect this possibility.[3029]

7.39 As far as the Scottish approach to the CPA cases such like the A v NBA litigations is concerned, it appears that the Scottish position was initially to repudiate liability on the basis of no test and no way of making the blood any safer.[3030] This was despite the fact that in May 2000, the executive was aware that the DHSS had received advice in England that they will be liable for the post September 1991 infections and possibly for the year before that.[3031] Despite this letter and an indication at that time that the DHSS wished to achieve consistency of approach, Counsel's opinion regarding settlement of the HCV litigations was not procured until 13 May 2001.[3032] By August 2001, Scotland indicated an intention to settle competent cases where facts can be proved which are analogous to A v NBA.[3033] As indicated above, these were settled mostly for token sums and at times not at all.[3034]

Conclusions

[3029] SCGV0000240_054
[3030] SCGV0000191_037 – 15 February 2001 letter from Sandra Falconer to solicitor re infection in 1988
[3031] SCGV0000240_085 – 15 May 2000 DHSS letter
[3032] SBTS0000357_022
[3033] SCGV0000244_112 and HSOC0011961
[3034] WITN0363027

7.40 The Inquiry is invited to draw the following conclusions from the evidence which it has heard pertaining to the State's position in response to litigation arising out of the blood contamination disaster:

a) The constant mantra of the state that patients should resort to litigation to ventilate any grievances they had in respect of their infections consistently and deliberately ignored the clear moral obligation (as opposed to the legal obligation) of the state to look after those who had been infected by it;

b) This response deliberately ignored the practical limitations created by the State on taking legal action;

c) Despite the mantra, the State (including the medical profession and the government) did what it could to stand in the way of litigations progressing to a settled conclusion in Scotland, making the process as hard as it could possibly be. It would be unlikely that litigations would be defended with such vigour or that the medical profession would become involved in such a concerted effort to prevent litigations taking pace or progressing if they were isolated in character. It is submitted that the approach to litigation on the part of the State was part of a concerted effort to prevent even worthy claimants from being properly compensated. The clear reason why this happened was due to the scaler of the disaster. Litigation needed to be prevented to discourage others with similar claims from taking action. This is a unique feature of the blood contamination disaster – its scale meant that individuals were treated differently than they would have been, had their situations not been similar in character to so many others. As this unique detriment has been suffered by so many (not just in connection with litigation but more widely in their treatment by the medical profession and by government) a unique set of harms has been created. As is argued elsewhere in this submission, a unique solution in the form of compensation for these harms is justified; and

d) Even those who embarked upon litigations faced insuperable impediments. It must be remembered that few even got a litigation close to or actually off the

ground. The vast majority were prevented even from contemplating such an action, irrespective of what the legal merits of such a course might have been.

e) When litigations we handled in Scotland they were generally handled in a way which was designed to minimise information being given to individuals which might assist in the other litigations being taken forward. Consistent with the "no compensation, no public inquiry" mantra of government, the approach to litigations and even their settlement might be characterised as being "minimum compensation, minimum information". This was consistent with the general position adopted by the government over this period to seek to do all that it could to minimise information being made available to the infected and affected about what had happened.[3035]

GMC

7.41 The Inquiry has heard evidence about individuals from the infected and affected community in Scotland having sought to have the GMC look into allegations of unethical conduct arising out of the disaster. Patients used the processes of the GMC to try to find the answers which they had not been given in connection their care and the resultant infections and to achieve a sense of justice or at least being listened to by an official body, charged by the State with such matters. The evidence heard by the Inquiry is that investigations were carried out in an unsatisfactory way to those individuals, leading to a compounding of their sense of injustice and an increased impression that the State and the medical profession wished to defend its own to the exclusion of the patient interest.

7.42 One main theme of the evidence which was heard in this regard relate to the fact that the GMC apparently excluded the complaining patients from having access to the material which was considered in support of a decision not to proceed with a

[3035] See SCGV0000194_028 (12 May 2000). Paper about whether minister should agree to SNBTS participating in the Irish tribunal. Recommended that SNBTS should not become involved by the Solicitors' Office. "Possible that they might get involved in areas we would not want them to".

complaint/ allegation of unethical conduct. Two witnesses have complained to the Inquiry about the lack of transparency in the process at the GMC. GRO-D

GRO-D

GRO-D The GMC guide to "Good medical practice" includes requirements on doctors to establish and maintain partnerships with patients which includes obligations to treat patients as individuals and respect their dignity and privacy, to work in partnership with patients, sharing with them the information they will need to make decisions about their care to support patients in caring for themselves to empower them to improve and maintain their health.[3037] The body clearly has a role to play in investigating complaints made against doctors, part of the purpose of which is to restore confidence public confidence and the confidence of those making the complaint in particular in the medical profession. One would expect this body to maintain these standards itself. This is all the more important in situations where the complaining patient has an ongoing professional relationship with the doctor and relies on his or care, such as in the case of individuals with bleeding disorders. The rebuilding of trust in such situations is of paramount importance. It is hard to see how this aim can be achieved where there is no transparency about the body's decision making.

7.43 In the recommendations below, we seek to argue that there requires to be more engagement with and involvement of patients in the GMC's processes. Transparency is the key to rebuilding trust where it has been lost, even of the decision not to proceed with an allegation has been reached.

The police

[3036] GRO-D

[3037] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-3--communication-partnership-and-teamwork#paragraph-46; Paras 46 et seq

7.44 The Inquiry has heard evidence about individuals from the infected and affected community in Scotland having sought to have the police look into allegations of criminality arising out of the disaster. Not only have these not led to any prosecutions but also they have not added to the community's understanding of events. In 2003 a police investigation involved members of the infected and affected community being interviewed. The report which was compiled at the time has not been disclosed to those involved. Therefore, the process had provided no information and no explanation as to why no charges resulted. Again, the theme of the State producing no answers to the community has emerged.[3038]

Fatal accident inquiries

7.45 In Scotland suspicious deaths can be subjected to a discretionary fatal accident inquiry ("FAI") if the Lord Advocate within the Crown Office considers that it is in the public interest for one to be held. The failure of the Crown Office to hold fatal accident inquiries into the deaths of certain individuals who had died of HCV in Scotland led to litigation which ultimately resulted in the Penrose Inquiry (as is discussed above). In that case, the State was held to have been in breach of its obligations under the ECHR. The evidence available to the inquiry makes it clear that there were other opportunities for such fatal accident inquiries to be held. One example was in the case of a member of the Edinburgh cohort, the circumstances of whose infections have formed a large part of this submission and the circumstances of which (it is submitted) clearly merited an investigation in the public interest. It is hard to imagine how it could be maintained that the infection and subsequent deaths of multiple patients in a unit in a prominent Edinburgh teaching hospital, including in case evidence of considerable issues with his treatment did not merit such public scrutiny. The individual concerned died in 1988. Despite efforts on behalf of his widow to have the matter reviewed by

[3038] Third written statement of William Wright (WITN2287019) @ para 16.1

an FAI, these efforts were summarily dismissed.[3039] The evidence connected to the application and its dismissal are indicative of an unwillingness to open up the issues involved. Actions like this on the part of the State and the need in other cases for court action to be taken to force its investigative hand have reasonably led to accusations of a State-level cover-up related to what happened. It is hard in these circumstances to resist such an argument. The context of which this witness' pleas for an FAI is also important. She narrates in her statement that she had tried after her husband's death for have Dr Ludlam explain what had happened. She received no explanation. The fact that he also had hepatitis was not mentioned, a common theme in the narrative of widows whose husband's died.[3040] She was not informed of the full extent to which the State had harmed her band. She was kept in the dark at every turn and was failed by the state which had infected her husband and caused his death.

8. Conclusions about the response of government to the blood contamination disaster

8.1 The harms which have been suffered by the infected and affected community in Scotland have been significantly compounded by the State in its response to the disaster. The various opportunities which the State has had to provide answers and/ or support to the infected and affected have not been taken. Investigations have generally been undertaken with a complete lack of compassion and a lack of responsibility. The infected and affected community have generally not been believed, involved or informed about the progress or outcome of these investigations. They have been treated in the same way as they were by the medical profession, adding stigma to stigma. The importance of the patient not being a passive recipient of medical care but an active and equal participant in it

[3039] WITN2665001, para 24 (first statement of Linda Grigor); WITN2665002 and WITN2665003

[3040] WITN2665001, paras 26 and 28 (first statement of Linda Grigor)

has become clear from the evidence heard by the Inquiry about what happens if that model is not fundamental part of the treatment model. In addition, the "nothing about me, without me" approach to the patient's right to access information about his or her care has clearly been demonstrated to be of fundamental importance. [3041]

8.2 The State has failed to realise that the harms caused by the infections could have been lessened by an appropriate, compassionate response, which was urged upon them on various occasions, not only by the infected and affected community but also by bodies such as the Ross Committee and the HCCC. Instead of recognising a moral responsibility, the State has from the time of the HIV litigation adopted an approach of complete secrecy. A fear that the full extent of State culpability may be revealed, leading toa. Legal or moral duty to compensate and/ or support the victims has clearly been the driving force behind government decision making. There has been a complete and undemocratic lack of accountability. The State has consistently failed to take the opportunity properly to investigate the circumstances of the disaster as a result of the overriding commitment to this need to protect itself. There has undoubtedly been a cover-up of the truth.

M. THE FINANCIAL TRUSTS AND SCHEMES

1. General

1.1 Elements of the financial supports schemes (the "trusts and schemes") which have been set up by government are discussed in connection with the response of government above. The financial awards made under those schemes are part of the inadequacy of the government response to the contaminated blood disaster in Scotland

[3041] Written statement of Dan Farthing (WITN4081001) @ paras 5.4 and 5.5

1.2 There was confusion as to what they were meant to be, providing services or financial support, discretionary or money to which applicants were entitled. The origins of the schemes were the MFT. There was confusion when had been set up (or the limited company had) to administer compensation agreed as part of the HIV litigation settlement. This have rise to a sense that this money was the money of the community to which it was entitled but additional controls seemed unnecessary and certainly unfair.

1.3 Underfunding was the main issue. The fact that they were set up "at arms length" allowed the government to evade direct responsibility/ accountability for looking after the community while reviewing fiscal control.

1.4 Interpretation of the charitable objects of the trusts was a problem. That test was satisfied on qualification for entitlement and ought not to have been re-analysed at every turn. This led to sense of "begging bowl" for something to which the community was legally and morally entitled.

1.5 The schemes caused massive additional harm to the infected and affected community caused by the way in which the trust and schemes were administered and individual were treated by them. That so many had to live in poverty meant that they trusts had failed in themselves. The sense of frustration that there had never been any State assessment of the needs and losses of the community meant that the schemed were inadequate. The fact that this was not understood lead to frustration, psychological harm.

1.6 Many were humiliated by being called benefits cheats when there was a lack of understanding of the nature of the payments and exemption on the part of the State. This was compounded by an absence of social work provision to assist with this problem. This led to considerable reliance on charitable support of the infected and affected community.

1.7 Their involvement in administering and this controlling access to services like psychological support was is a problem. There was a need for separation of (a) care provided to those who need it as part of the NHS and (b) financial support for the infected and affected to be able to live their lives.

1.8 There was a lack of effective representation of the infected and affected communities via user trustees/ patient engagement groups etc.

1.9 There was a lack of Scottish representation/ engagement with the particular needs of the Scottish communities whose circumstances and for whom the impact of the disaster was

not the same as elsewhere. This led to a loss of local engagement which has been achieved by the advent of the Scottish Parliament/ the engagement of the SP Health Committee which led to the Ross Committee.

1.10 There was a gradual realisation that the needs could not be simply the needs attributable to the infections as the needs and the harms which had caused them were so complex, mutually inter-linked. There was always a need to provide holistic support for the infected and affected due to holistic nature of the harms caused.

2. The Macfarlane Trust ("MFT")

2.1 The initial MacFarlane Trust was set up in March 1988 (having been announced in November 1987) with an initial funding allocation of £10m, and within less than a year was beset with complaints and concerns regarding the ability of beneficiaries to access the funds. In October 1988, the Sunday Times published an article noting that, of the £10m initial endowment, only £132,000 had been dispersed to beneficiaries. Subsequently, the Macfarlane Special Payment Trusts 1 and 2 were set up in 1990.

2.2 The set up of the MSPT 1 appears to have been without recourse to the trustees of the MFT, and, as Peter Stevens said in evidence to this Inquiry, appears to have been *"an attempt to buy people off"*[3042]. Indeed, the Minister of Health appears to have accepted as much in her evidence to this Inquiry. [3043] The initial proposal of the government was that they would pay £19m towards the costs of financing the lump sum awards, with the MFT paying the balance of approximately £5m, with a view to being reimbursed by the government in due course. It seems that the DoH/ Treasury considered the MFT to be sufficiently under their control/ management

[3042] IBI transcript for 23/02/21, 23 (Peter Stevens)

[3043] WITN5289001, para 4.7 (Virginia Bottomley)

that such a striking request of a supposedly independent Trust could be countenanced; the Charities Commission advised that Trust monies could not be so used. The MSPT1 was subsequently required to be created to permit the payments of £20,000 on a no-discretionary basis. The attempt to 'buy off' the HIV litigation having failed, the MSPT2 was set up in 1991 as a mechanism for settling the claims in that litigation.

2.3 The trust deed for the MFT provided that the "*objects for which the Trust is established are to relieve those persons suffering from haemophilia who, as a result of receiving infected blood products in the UK, are suffering from AIDS or are infected with human immunodeficiency virus and who are in need of assistance, or the needy spouses, parents, children and other dependents of such persons and the needy spouses, parents, children or other dependents of such persons who have died*"[3044]. The deed gave the trustees permission to provide or assist in the provision of financial and other aid such as holidays, clothing, and accommodation, to promote education of young persons in need, and to collect and receive funds and donations for the promotion of the object of the trust.

2.4 When the MFT was established, there were no trustees from Scotland, and no offices outside London. In November 1988, visits were made to the Haemophilia Centres in Glasgow and Edinburgh with the apparent intention of explaining what the Trust was doing. We say it is notable that these visits were a year after the MFT had been announced; the notes of the visits recall anger directed from the beneficiaries or their relatives regarding a variety of matters, including the manner in which payments from the trust were made, the inadequacy of the total fund, and the failure to distribute copies of the trust deed to the beneficiaries.[3045]

2.5 Although the MFT arranged holidays/ away weekends for beneficiaries, it does not appear much consideration, if any, was given to the ability of those infected with HIV to travel long distances. The geographical reality means that such an issue almost certainly disproportionately affected those in Scotland more than those in

---

[3044] MACF0000003_064, page 5, para 4

[3045] MACF0000002_011 page 6

England and Wales. Furthermore, the number of infections in Scotland was significantly smaller than in England. This meant that the community was smaller, and had different needs to those in England and elsewhere; those differences ought to have been considered when assessing the needs of the community more generally. They were not, leaving applicants to the MFT at significantly greater risk of isolation, and their needs and vulnerabilities being overlooked.

2.6 Within the first c7 months of its operation, the MFT received 350 applications for assistance, making payments to 297 applicants. The highest payment was c£3,000, and the average was £440. It was suggested, in a memorandum responding to Mr Mellor's request for information, that "*some applicants clearly thought they were entitled to 'compensation' and unless they could demonstrate need have not been given a grant*".[3046] It was further noted that the MFT was planning to make regular payments to those applicants with low incomes, with one-off sums being made for specific items outwith that primary approach. It was accepted in the memo that the payments made in the 6 months or so of the Trust being in funds and functioning reflected a cautious approach.

2.7 The administration of the Trust was subject to a Trust Deed, and was not directly accountable to the Department of Health, although the evidence suggests that there were high-level communications between the MFT and the DoH on a regular basis. Indeed, the MFT sought advice from the DoH in respect of whether payments of spouses were within the class of beneficiaries where there was no dependency on the infected individual themselves[3047] Following the adverse media coverage of the pace of beneficiary payments in 1988, David Mellor, the then minister for health in Westminster apparently sought to intervene, requesting bimonthly reports. Mr Mellor, in his evidence to this Inquiry, said that he told the Trust that it should not be concerned about ongoing funding, and encouraged it to make payments where it was deemed appropriate to do so[3048].

[3046] DHSC0003303_005

[3047] MACF0000002_015

[3048] IBI transcript for 19/05/22: 41 to 44 (David Mellor)

Mr Mellor also gave evidence that he considered the initial sum transferred by the government to the Trust of £10m was insufficient. Yet, the following year, the government sought, in the first instance, approximately £5m from the Trust to assist in the payment of lump sums to all beneficiaries. Although this was ultimately rejected (and was a concept considered "ludicrous" by one of the trustees to the MTF in his evidence to this Inquiry), that the government considered the MFT to be a source of some support in the way of funding for a proposal that was intended to 'buy off' the HIV litigation at an early stage demonstrates their views on the scheme, and perhaps explains at least in part why the trustees felt that their approach to applications for grant had to be so strict.

2.8 It is submitted that there were a number of significant flaws in the MFT that gave rise to concern amongst the infected and affected community, and compounded the harms impacting on an already vulnerable group:

a. Firstly, there was a degree of confusion as to the purpose of the Trust. Little explanation was provided regarding the purpose or processes of the Trust, such that many potential beneficiaries quite understandably and reasonably felt that the fund should be paid out in more generous lump sums to all those infected with HIV as a result of treatment for their bleeding disorder, rather than on individual, and piece-meal basis;

b. Secondly, there was a degree of concern on the part of the Trustees to ensure that they had sufficient funding in place in the absence of a guaranteed or agreed income stream such that the payment of beneficiaries was overly restricted;

c. Thirdly, there was insufficient recognition of the needs of those who could apply for payments from it, resulting in a very cautious approach to payments out. The need to demonstrate, in effect, extreme hardship, resulted in feelings amongst the infected community of having to 'go with their begging bowl' to the Trust. That would not have happened had clearer processes and approaches been set out from day one, and if the trustees had been given greater assurances about the MFT's funding model. It should not have happened. It compounded the harms experienced by the community.

d. Fourthly, the MFT required applicants for grants to demonstrate that they had sought assistance elsewhere such as their local authorities, before applications would be considered. Despite the MFT being established with the stated aim of helping a specific group of beneficiaries as a result of their infection with a disease which had broad and deep impacts on every aspect of their lives, the Trust considered itself to be a *"fall-back [...] the sources of finance of last resort"*[3049]

e. Fifthly, there were concerns amongst the potential beneficiaries that the MFT (and the subsequent special payment trusts) were not truly independent, given their reliance on funding from the government. Business cases had to be made to government.

2.9 Peter Stevens told the Inquiry that many of those issues were a result of the MFT having been set up as a charity with insufficient funds, such that the Trust never had enough money and they *"had to ask beneficiaries to try elsewhere, even when we were aware that this was imposing considerable burdens on them"*[3050]. Given the very purpose for which the MFT was set up, the imposition of considerable burdens on the community should not have been allowed to happen. It was entirely contrary to the interests of the beneficiaries for those burdens to have been imposed, and for the feeling of the 'begging bowl' to have been reiterated. Underfunding, and concerns about future funding, appeared to have a significant impact on how the scheme operated. The evidence of Mr Stevens was that he believed the government had set up the Trust on the assumption that the beneficiaries would, for the most part, die within a fairly short period of time.[3051] As is set out elsewhere in our submission, a theme arising from the evidence surrounding the state's response to the disaster was that the government applied sticking plasters to gaping wounds, in the thought that such a response would be sufficient to consider the matter closed, without – at any time – taking any steps

---

[3049] IBI transcript for 23/02/21: 61 (Peter Stevens)

[3050] Ibid

[3051] IBI transcript for 23/2/21: 77 (Peter Stevens)

to consider whether the needs of the community were adequately assessed and addressed. This short-term thinking, with the veneer of finality imposed on decisions, caused repeated and deepening harms to the infected and affected community over the course of decades. The government were given forewarning of this fact, and the issues they caused, on regular occasions over a protracted period and still refused to act.

.

Conclusions

4.3 The

3. The Skipton Fund (SF")

3.1 The initial problems with the way in which the Fund was set up, in a process shrouded secrecy and lacking any accountability are addressed ion the government response section of this submission above. In addition, the migration of the scheme from its Scottish roots to a UK scheme with no local accountability as opposed to the anticipated implementation of the Ross Committee's recommendations is also discussed. Some of the operational failings of the Fund are also analysed in that section, insofar as they highlight discrepancies in the way that the fund was supposed to operate as per the Ross recommendations or could have operated in the best interests of patients and their families. In this section, we predominantly address he operational deficiencies of the Skipton Fund.

3.2 Before doing so, it is important to realise the context in which payments were being made. Lump sum payments were available which had been fixed without engagement with the infected and affected community. There was no

compensatory element, contrary to the Ross committee's recommendations, for either the infected or widows. As Pater Stevens pointed out in his statement to the Inquiry, the government took the apparently "crucial" decision that the HCV scheme should not be charitable.[3052] Thus, the scheme had no ability to meet charitable need in particular cases. The government could, of course, have devised a scheme which could have catered for such need at that time. It did not. Wider relatives were excluded completely. No assessment of the needs or losses of the community had underpinned the fixing of the lump sums. The context in which the Fund operated was therefore already a miserly, inadequate sticking plaster for a State-caused tragedy. That the scheme was then run in a way which was restrictive and often unfair needs to be understood in this context. The operation of the scheme was not defective in isolation – it was piling harm upon harm. The fact that (as discussed above) consideration had been given by the State to the requirement for the low payment(s) for a waiver of future rights to be signed was indicative of the State's ongoing willingness to try to take advantage of the infected and affected community/ undermine its legitimate claim to support and/ or compensation. It showed that the State under-appreciated the level of suffering in the infected and affected community. The fact that (unlike payments in respect of HIV which were and continued to be funded for the devolved nations by the UK government) payments for HCV infections under the Skipton Fund were drawn from the local government health budgets meant that the payments were a drain on the health budgets of the devolved nations. This created a new stigma for those who made a claim based on the assertion that payments were taking money from frontline care. This arrangement lacked any logic. Though the MFT had been set up pre-devolution and the Skipton Fund had post-dated the devolution settlement, the payments were for current need. There was no reason why the payments could not have come from ring-fenced finds, like for HIV. The effect of the arrangement was, however, to crate this new stigma and also to engender an inevitably restrictive approach. As Lord Penrose said of the was in which his Inquiry was funded every penny spent on the Skipton Fund was a penny which could not

[3052] Witness statement of Peter Stevens, para 50

be used for patient care. This funding arrangement has unnecessarily consequences of the way in which the fund operated. The machinations of John Reid in 2003 (explored above) had resulted in the control over the find being taken away from Scotland. Despite that, Scotland had retained responsibility for the bill.

3.3 In his oral evidence to the Inquiry, Peter Stevens made clear that, despite his involvement in the original planning for the SF would work, there was absolutely no room for compensation (or the "C word" as he described it) being part of the system.[3053] As such, there could not have been any role for the Ross report or its recommendations for compensation being part of the discussions at all. By the time he was involved, the fund had become all about limiting the final bill and nothing about the needs or losses of the infected, far less the affected community.

Eligibility

3.4 The intentions that the SF should have relatively simple eligibility requirements for transfusion patients to prove infection by that route which worked on the basis of the balance of probabilities is set out above under reference to the evidence of Mr X. Despite this, Peter Stevens gave evidence to the effect that there was a "volume of detail" in the SF eligibility requirements.[3054] This was contrary to what the scheme should have been – a means by which the infected should have been able to receive the financial support they needed and deserved without the need to have to prove themselves. The Inquiry has heard much evidence about how this left deserving applicants being unbelieved. The internal guidance documents for stage 1 payment defined evidence as information to be provided on a form, seeking answers to basic questions from the applicant.[3055] There was no provision for personal statement of the applicant or parent about transfusion. If the asserted route of infection was not a concentrate, in cases where there was evidence of a

[3053] IBI transcript for 24/02/21; 78 (18 to 23) (Peter Stevens)
[3054] Witness statement of Peter Stevens, para 191
[3055] SKIP0000030_045

source of infection, the application was rejected.[3056] Thus, the claim was not assessed on balance as to which was the likeliest cause. In essence, this meant that claimants were expected to prove that a transfusion was a more likely cause of infection than other routes, without any real support or access to possible sources of expert evidence to be allowed to do so. This, once again, had a compounding effect on the loss which they had suffered at the hands of the State. A clearer definition of what the SF was meant to achieve from the outset and a greater commitment to helping those in need would have assisted in avoiding this outcome.

3.5 The way in which the eligibility question was resolved was plagued by significant practical overwhelmed in the operation of the SF. The evidence heard by the Inquiry shows that the lack of a written record of a transfusion proved to be insuperable hurdle to applicants being accepted as having been infected by that route. As the evidence heard by the Inquiry has amply demonstrated, medical records were often inaccurate (in that they contained no detailed record of medical interventions at hospital at all, which in many cases meant that there was no record of transfusion. This was not the fault of the patient. It was a failing by the State which left what would have been otherwise welcome and necessary. The evidence showed that where personal testimony was given in support of the application, in some cases supplemented by similar testimony from parents or other relatives, this was disregarded. In effect, the patient's testimony was automatically disbelieved due to the absence of a record over which the patient had no control. This amounted, effectively, to a presumption against such patients qualifying, which was unjust in the extreme. It was particularly so, given evidence which might have been considered about the nature of and approach to medical records in the period over which the infections in question were occurring, ie in the period before September 1991 due to the eligibility criteria for the Fund. Medical records before the Access to Health Records Act 1990 were not considered to be material which was kept for the benefit of the patient. They were not records to which patients routinely had access. The legal classification of

[3056] Ibid

medical records is shown in cases like *Gibson Petitioner*.[3057] In that case, the statutory title of the health board to the records was not doubted. A patient's ability to seek to limit the extent to which they could be sued in a litigation was deemed to be limited. Therefore, it is unlikely (a) that the possibility of the patient using them to have to prove to have been in the contemplation of the doctor making a medical note and (b) that a patient would have had any involvement in or control over their content.

3.6 In fact, the evidence heard by the Inquiry (discussed in more detail elsewhere in this submission) was that there was historically little control over blood transfusion which had the result of transfusion occurring more often than might otherwise have been deemed necessary. This was why a report into transfusion practice was undertaken under the stewardship of Dr Keel and Dr McClelland years later. This evidence suggests that, if anything, a presumption in favour of a transfusion having occurred would, in fact, have been more appropriate. This was compounded by the lack of engagement with oral testimony at any stage in the process. Patients with genuine claims were not heard. Further, one of the consequences of the loss of local control over the scheme which had resulted from the secret transformation of it into a national scheme was the lack of access to evidence of local transfusion practice. Questions about whether it was likely that a medical intervention had involved a transfusion were not determined according to local evidence. It seems that it was assumed that a transfusion could not have taken place in Inverness because it might not have done in London. This was not a fair approach to answering questions in individual cases fairly. In addition, medical evidence received from a treating clinician was not determinative of the questions of eligibility and entitlement to stage 2 payments.[3058] This removed a useful source of local information. Supportive evidence from clinicians would in most cases have been a reliable guide to what is likely to have been the cause of the infection. In his evidence, scheme administrator Nick Fish confirmed that the view of the treating clinicians could quite easily have been given more weight, if the DoH had

[3057] 1984 SLT (Notes) 61
[3058] Witness statement of Peter Stevens, para 203

ordered that this approach be taken.[3059] The evidence showed that a high number of appeals were successful but despite that the DoH did not change the way that the scheme operated. [3060] Little or any support was provided to applicants. The scheme which was already considerably more restrictive than had been envisaged by Lord Ross had been set up to be as procedurally restrictive as possible. All of this process was, of course, compounded by the amount of time which had taken to set up the Fund in the first place. The distance on time between the rendered all of the evidence less reliable. It made it more likely that medical records would not have existed in accordance with storage policies then in place.

3.7 The exclusion of natural clearers from the scheme was an arbitrary decision made without consultations with the patient community or any assessment of the effects of exposure to HCV on the part of such patients. This exclusion is a matter which is addressed as part of the financial recommendations proposal made below. Given that it was only those who had cleared the virus at the acute stage were excluded, assessment needed to be undertaken of whether clearance had happened at the chronic stage. For transfusion patients, this was in reality an impossible task. Proof of chronic clearance would require two positive tests more than 6 months apart for an applicant to be able to prove that clearance happened at the chronic stage. Transfusion patients would be, in many cases, unlikely to have had blood samples taken than 6 months apart, unlike bleeding disorder patients, who (in many cases) would have stored samples. This would enable historic analysis of the nature of the clearance and hence possibly qualification for a Skipton payment. In transfusion cases, it therefore seems that the system was rendered impossible for them to prove that they met the chronic clearance criterion.

Stage 2 eligibility

[3059] IBI transcript for 23/03/21; 50 (17) to 51 (3) (Nick Fish)
[3060] IBI transcript for 23/03/21; 57 (12) to 57 (24) (Nick Fish)

3.8 The stages which gave rise to an entitlement were the other main matter (as well as eligibility) which required to be proved and have rose to problems for applicants to the SF. The stages probably had their origin on the Ross recommendations. They were a crude measure, a way of providing some means of differentiating between those who should be entitled to certain payments. As is set out above, the stage 2 applicant and their relatives were thought by Lord Ross to have been deserving of payments equivalent to full common law/ 1976 Act damages. The government adopted the broad stage 1/ stage 2 system but did not attach to it the level of payments which Lord Ross had recommended. In any event as a cruse measure, the government ought to have include from the start a more sophisticated measure of loss than pure liver damage or at least a mechanism whereby the stages could be reviewed as knowledge about the disease grew. It was at least foreseeable that this could happen as it was a disease whose full effects would only emerge in this community over time. Payments had been so delayed that such an assessment of loss could have been undertaken at that time. It was not. The fact that the payments were "ex gratia" (a phrase Lord Reid was keen to emphasise, with a peculiar pronunciation which made it repetition memorable) in effect meant that the payments had no defined purpose. If they had no defined purpose, there could be no complaint that that purpose was no longer being fulfilled by changing circumstances. Hence no mechanism to monitor changes in circumstances was necessary. The lack of defined purpose was thus the flaw.

4. The Caxton Foundation ("the CF")

4.1 Like the other trusts and schemes which preceded it, the CF was insufficiently funded and its purpose was poorly defined. The lack of any clear definition of its purpose, as had been the case in the other trusts and schemes made it hard for there to be challenge that the purpose was not being fulfilled.

4.2 As was the case with the MFT, the way in which the CF operated compounded the harms of the infected and affected. The attitude towards the infected and affected

was disrespectful and harmful. The requirement that claimants produce receipts and quotes made them feel like they were not being believed or that they needed to come to the state with a begging bowl, as it if were being suggested that they would make fraudulent claims without such steps having been taken. There is no reason why these requirements could not have been avoided by the CF having procured costs for itself and allowing amounts to be paid without them. Instead, the trustees did not support the publication of the Office Guidelines because they were "a reference manual for staff".[3061] This was despite the fact that they also claimed to wish to give beneficiaries all the information needed for a successful application.[3062] They instead entertained a misplaced concern that the publication of the guidelines would serve as "shopping list", despite the fact that it could not have done as the CF still had the power to refuse an application based on a lack of charitable need in an individual case. This policy was or at least appeared to be based on an unjustified lack of trust in the applicant community. By definition, those who were making a successful claim had been harmed and often disbelieved by the State. Most were ill. They must have established a charitable need. The lack of compassion shown to the applicant community appeared completely to disregard the fact that the Fund was dealing with vulnerable people or the nature and cause of their vulnerability. This has resulted in further damage to the community and a consequent need for the principle of community "buy-in" inherent in the Francis compensation scheme, which we address in detail below, to avoid a re-occurrence of such consequences.

4.3 As with the MFT, the evidence was that there was a lack of Scottish involvement with initiatives, which were geographically distant from the infected sand affected north of the border. As HCV was such a major issue in Scotland, this caused particular issues.

4.4 In his statement to the Inquiry, Peter Stevens pointed out that there were no user trustees of the SF, CF and ET.[3063] The MFT had user trustees, though their role did not function well. As the Caxton Foundation was also a discretionary trust, it was

[3061] Witness statement of Charles Lister, para 180
[3062] Witness statement of Charles Lister, para 356
[3063] Witness statement of Peter Stevens, para 78

particularly important that there be user trustees so that the complex needs of the beneficiary community could be properly understood and their needs serviced in accordance with the trust purposes. That there were not was a clear failure of the Fund. By not appointing such trustees, the DH was able to avoid the realities that such trustees would have raised – that the find was insufficiently funded and had no clear direction or purpose. The problem was compounded by the fact that the Health Minister required to approve Caxton Foundation Board members.[3064] Thus, there was at least a reasonable perception that the trust, which had ostensibly been set up to provide discretionary support to the infected and affected was, like the MFT, one which paid little heed to the beneficiary communities and was, in fact, under the control of the DoH, whose interest in limiting what was paid out. This feeling was compounded actions such as the appointment of a former senior advisor to the DoH blood policy unit (Charles Lister) as a trustee in 2011 and by the appointment by the CF of external advisors (Pennysmart) to provide advice to claimant about the management of their finances.[3065] This created the reasonable impression that the priority of the trust was to portray them as people who were unable to manage their money, as opposed to worthy claimants in need of money due to the actions of the State.

4.5 Despite the fact that the beneficiary population of the Caxton Foundation was defined by entitlement to payment from the SF, evidence heard by the Inquiry shows that by 2013 the CF was still "finding out about its beneficiary population".[3066] This led to a delay of payments being made to worthy beneficiaries. This was a manifestation of the lack of clarity about the aims of the trust from the start. When Ann Lloyd became the Chair of CF in 2013, she said that she was "not aware of the principles underpinning [the CF's] establishment in 2011".[3067] It seems that those principles were still not clear at that time.

[3064] WITN3108003 (Jan Barlow statement) @ para 16
[3065] Jan Barlow witness statement at paragraph 35 (WITN3108003)
[3066] Witness statement of Peter Stevens, para 146
[3067] Witness statement of Ann Lloyd, para 10

Conclusions about the Alliance House Organisations

4.6 The AHOs which were in place before the SIBSS was formed in 2017 were an inadequate attempt on the part of government to provide financial support to the infected and affected. That they were was not surprising in that they were all formed as a sticking plaster in circumstances where the State had carried out no assessment at all of the needs or losses of the community whom they were ostensibly designed to support. Thus, the money provided for them (whether discretionary or not) was always inadequate both in amount and in the category of individuals who were able to claim – the affected being almost entirely excluded, the harm to them never having been addressed or assessed either. The purpose and objectives of the schemes was poorly defined. For these to have been clearly stated would have required a clear engagement of why the monies were being paid, engagement with the issue of the moral duty of the State to make the payments and its basis and extent and an assessment of the losses and needs of the infected and affected. That there was no clear definition is a clear indication that there was no clear purpose.

4.7 At page 60 of his statement to the Inquiry, Dr David Bevan said that:

> "However, I consider the charitable 'Ex Gratia' and 'discretionary' nature of the funds, together with the limited money at their disposal, a grave disservice to the patients infected with HIV and HCV. My view is that these funds were designed by HM Government as devices to evade proper restitution to individuals infected by HIV and HCV by their NHS treatment"

In our submission, this stands as an honest, informed and accurate assessment of the purpose, operation and effect of the trusts and schemes.

5. The Scottish Infected Blood Support Scheme ("SIBSS")

5.1 The founding principles and basis are important, including, engagement with the community, political accountability and self-assessment. Its main limitation is that its focus on need, not loss, leaving a justified sense of injustice for past life stolen. The principle of self-classification is based on a recognition that the losses are complex and material contribution to the whole. These principles are discussed in detail in the financial recommendations section below.

5.2 There remains lack of parity in discretionary payments. Exclusion of others in need, like the affected, remains an issue. Again, this elaborated upon below.

N. RECOMMENDATIONS

A. NON FINANCIAL RECOMMENDATIONS

1. General

1.1 This Inquiry has inevitably concerned itself with investigating events of the past as fully as possible, despite obvious limitations imposed on it by the passage of time. In certain areas it has been able to investigate in detail certain matters relating to current practice and service provision (including but not limited to services available for the care and support of the infected and affected, medical treatments available to patients with HIV, HCV etc). In other areas, where the evidence has shown there to have been shortcomings in the systems relating to the care of the infected or affected, these appear to be of more general aetiology and impact, such that the investigation of them may have been considered to have been disproportionate to the legitimate aims of this Inquiry. In our submission, that does not make the discovery of shortcomings of more general application, as seen through the eyes of this Inquiry, any less valuable. However, we recognise that in such areas, the ability of this Inquiry to make specific recommendations at this time may be inevitably limited. It is

important, though, that what this Inquiry has discovered be acted upon and the opportunity be taken for improvements to be implemented to the system which may be necessary in light of the analysis of past events which the Inquiry has undertaken. Therefore, where we submit below that the evidence has demonstrated systemic shortcomings which appear to us to merit action, we have proposed that the Inquiry make recommendations to the effect that further investigation be undertaken as to the specific ways in which the shortcomings might be further analysed and addressed.

1.2 The Inquiry asked core participants to provide initial written submissions outlining recommendations not related to compensation that they might want to invite the Chair to consider to allow the Inquiry to call for additional evidence where appropriate prior to the conclusion of the oral hearings. Submissions were duly presented in June 2022. The submissions below are represented in light of the evidence heard by the Inquiry in November 2022 regarding the non-financial recommendations.

2. ENFORCEMENT

Task force

2.1 As per the recommendations of the Cumberlege review, this Inquiry ought to recommend that a task force be set up to implement this Inquiry's recommendations.[3068] Its first task should be to set out a timeline for their implementation. It should include a Scottish sub-committee to report to the main task force in order to deal with the implementation of the measures which are specific to Scotland, whilst drawing on the progress of the main task force (on the assumption that many of the Scottish specific recommendations proposed in this paper may well be recommended for separate implementation elsewhere in the UK).

[3068] Cumberlege report, final report, page 188, recommendation 9

2.2 It is submitted that it is imperative that the task force include representation from the infected and affected communities, so that their voice continues to be heard in the implementation of the recommendations of the Inquiry. In Scotland, this could be provided by the charitable organisations Haemophilia Scotland and the Scottish Infected Blood Forum, whose activities in support of the infected and affected communities are considered in more detail below. The task force should also be subject to political scrutiny via the Health and Sport Committee of the Scottish Parliament to ensure that it is fulfilling its function and ensuring that the Inquiry's recommendations are implemented within a reasonable time frame. In turn, this will allow the Committee to hold the Scottish Government and NHS Scotland to account, as necessary.

3. APOLOGY AND MEMORIALS

A full and clear apology

3.1 The evidence heard by the Inquiry has demonstrated that the NHS in the United Kingdom, the UK government and the Scottish government failed the infected and affected community. Previous apologies issued by the governments of the United Kingdom have been general, inspecific, incomplete and insincere. The importance of those infected and affected receiving a full and specific apology from those who have caused the infections (or take responsibility for their occurrence) with which the Inquiry is concerned was clearly recognised by the Inquiry's psychosocial group, whose testimony was detailed, incisive and unchallenged in that regard. The beginning of any true recovery from the blood contamination disaster is such an apology. Therefore, the Inquiry should recommend that the UK and Scottish governments, on behalf of its departments, former ministers, civils servants and advisors should issue an unreserved apology for their past failings which caused the blood contamination disaster and for their failure to respond appropriately to

the needs and losses which were caused to the infected and affected as a result. In particular, it should be recognised publicly that:

(a) The UK government acknowledges its moral responsibility for occurrence of the blood contamination disaster and apologises for having failed the infected and affected community;
(b) The UK government recognises, clearly and unreservedly that significant harm, including death on an unprecedented scale has been caused to those infected and their loved ones as a result of NHS treatment and that such harm has been significantly compounded by the government's response to the occurrence of the infections;
(c) The Scottish government accepts responsibility and apologises for its part in compounding the harms by failing to recognise its moral responsibility for the infected and affected over many years, and the impact of its response to the occurrence of the infections; and
(d) The UK government accepts its legal and moral responsibility for the support and wellbeing of all those who have suffered as a result of the disaster, with the Scottish government specifically accepting responsibility for all the infected and affected who reside in Scotland.

3.2 The need for a fulsome government apology was recommended by the Cumberlege review.[3069] It is submitted that the Inquiry should recommend that the apology should be made at the commencement of parliamentary debates in the Westminster and Scottish Parliaments on the issue of the contaminated blood disaster, the findings of the Inquiry and the plans for the implementation of its recommendations. Further, the recommendation should include provision that the apology should be made in writing to each of the infected and affected on behalf of the governments who are making it. A clear statement of what the UK and Scottish governments intend to do as

[3069] Cumberlege report, final report, page 187, recommendation 1

a result and in implementation of the Inquiry's recommendations should be appended to these apologies.

Memorials

3.3 The Inquiry should recommend that permanent memorials should be erected to those who were infected and have passed away as a result of the contaminated blood scandal and those who have passed away from the affected community. There should be one in a prominent part of the capital cities of all four of the home nations. These should be State funded and maintained. Appropriate ceremonies should be organised for their unveiling.

3.4 Representatives of the infected and affected communities should be involved in the design of the memorials. The Scottish campaign for a memorial has already raised a substantial sum for an appropriate Scottish memorial. It will therefore not require to be fully funded by the Government. It is suggested that the inquiry should recommend that the Scottish or UK Government should add to the funds available for the memorial, the planning for which should remain the right of the Scottish infected and affected community.

NON-COMPENSATORY SUPPORT FOR THE INFECTED AND AFFECTED

4. Access to financial products such as life and travel insurance, mortgage protection and mortgages

4.1 The Inquiry has heard significant evidence about the extent to which the infected and affected have experienced issues with accessing financial products based on the fact of their infections. These products have included life and travel insurance, mortgage protection insurance and mortgages. The lack of access to these products has caused significant difficulty for those who have fallen into this

category. Important life experiences have been closed off to the infected and affected as a result. The significance of those restrictions should not be underestimated. The Inquiry should recommend that the government should work with providers to create bespoke insurance products for the infected and affected, underwritten by the government. A model for this has already been put in place in the Republic of Ireland for the infected and affected in that country. The significant work put into the creation of these products in that country should prove to be of significant assistance in the establishment of such a scheme in the UK.

4.2 In addition, there is a need for there to be a formal system to enable the infected and affected to be able to access mortgages. At present, some of the infected and affected have been able to procure a letter from the SIBSS which has proved sufficient for a mortgage to be obtained from a single provider. The letter explains the nature of the payments made from the SIBSS and that single provider has been willing to accept that as sufficient proof of future income to make a mortgage offer. In order to increase the range of options available and competition, a formal system should be instituted within SIBSS along with a range of providers to provide government backed assurances that the individual will continue to receive an income for mortgage purposes from the SIBSS.

4.3 The Inquiry heard evidence from Brian O'Mahony, the CEO of the Irish Haemophilia Society regarding the Republic of Ireland's state-backed insurance products. In 2006 in the Republic of Ireland, the Hepatitis Insurance Scheme was set up. It provides for travel, mortgage protection, and life insurance products to be underwritten by the state for those who were infected with blood or blood products. In essence, the premium that a 'comparator' applicant who is healthy would be quoted for insurance products is compared with the premium that an individual who has contracted an infection via blood or blood products and the difference between the two premium quotes is paid for by the government. Where an individual is deemed uninsurable on the open market, the government

effectively insures that individual.[3070] Mr O'Mahony gave evidence that beneficiaries of the scheme in Ireland considered the insurance provision scheme to be an important part of the state demonstrating that it recognised the effects of the blood contamination disaster in a tangible manner.[3071]

4.4 Samantha Baker of the Scottish Government, in a written statement to the Inquiry noted that, whilst she could not comment in detail regarding difficulties that registrants to SIBSS have had when seeking to obtain mortgages noted that, although she understood that some lenders accepted SIBSS letters as proof of ongoing payments for beneficiaries of the scheme, she had written letters on 2 occasions on behalf of beneficiaries to provide further information for lenders. In her evidence she says that she assumes she was asked to do so because the lenders were unwilling to provide mortgages on the basis of letters from SIBSS alone.

4.5 Ms Baker suggested that a possible solution to such issues would be further engagement between the 4 UK governments with UK Finance to provide more up to date information on the UK support schemes with a view to providing greater reassurance to lenders, and indeed applicants, of the long-term commitment to financial support for those affected by the disaster.[3072] We endorse that recommendation.

5. Benefit and healthcare passporting

5.1 The Inquiry has heard significant evidence about the traumatic experiences of infected and affected individuals who have been subjected to shocking accusations or at least considerable hardship and inconvenience within the benefit system. The Inquiry should recommend that DWP guidance should be reviewed to ensure that those working within the benefits system are aware that payments

---

[3070] IBI transcript for 08/11/22: 69 to 74 (Brian O'Mahony)

[3071] Ibid, 76

[3072] WITN0719018

made under the SIBSS or under any compensation tribunal mechanism are not to be taken into account for the assessment of benefits.

5.2 In addition, infected individuals who qualify for payments under the SIBSS should be issued with a passport which can be used as proof of status (for benefits and any other relevant purposes), in order to ensure that victims of the contaminated blood scandal do not have to endure the indignity of continually providing evidence of their incapacities and detriments which have been inflicted by the State. The requirement to do this has significantly compounded the harm suffered by the infected. Many have been stigmatised by the NHS based on assumptions as to the route of their infections. Such stigma must stop. There is a need within the NHS and the benefits system to have a user friendly, confidential, recognised way of proving that an individual's infection was caused by the State. Further, the card could indicate the level at which payments are made to the infected person under the SIBSS and/ or benefit entitlement, from which certain deductions could be made about level of disability. This issuing of such a card will, in turn, allow the infected to access associated entitlements to which they are already entitled as a result of their disabilities such as dental care and ophthalmic services more easily.

5.3 Although evidence has been obtained from the DWP (James Wolfe) regarding passporting, it appears he misunderstood the concept insofar as those on whose behalf this submission is made would seek a recommendation. He objects to a recommendation that receipt of an ex gratia payment and/ or compensation would automatically grant eligibility or ESA or PIP on the basis that such payments would not provide suitable validation for an award of benefits at the correct level to help the individual to meet their daily living costs. We submit that the issue of passporting is broader than recognised; firstly, passporting should be enacted to ensure that those impacted by the contaminated blood scandal are not subjected to accusations of ineligibility for benefits, or required to undergo financial assessments, in light of any support payments or compensation received. In our submissions regarding financial recommendations, we review the issues surrounding the interplay between benefits, support schemes, and compensation; this Inquiry should recommend that clear guidance is given to the DWP regarding the implementation of the scheme and the interplay between that and benefits in

due course. We remain of the view that a passporting scheme to avoid the need for applicants to rehearse the fact of their state-caused infection is a reasonable step to take in all the circumstances.

5.4 Equally, we consider a passport to demonstrate to medical professionals that the state has accepted that their infection was caused by the receipt of contaminated blood or blood products would benefit the community.

5.5 We also maintain that passporting could and should be used as a means of a means of identifying to the DWP that the individual has previously proved disability such as to entitle the individual to benefits and thus the associated entitlements of care and support which flow from that.

Psychosocial Support Services

5.6 There should be a national psychosocial support service in Scotland so that everyone who has been infected and/or affected by past treatments with contaminated blood or blood products in Scotland or those affected by it (including any relatives, carers or close friends of an infected person) get the professional psychosocial support they need. The Inquiry should recommend that the existing services in this regard should be safeguarded for the future by guaranteed ring-fenced funding.

5.7 The Inquiry has evidence available to it as regards the current functioning of the Psychological Support Service (PSS) which was jointly commissioned by the SIBSS and National Services Division of NHS Scotland (NSD – which commissions certain specialist services on behalf of all of the territorial health boards in Scotland) in 2018, in the form of a witness statement from Belinda Hacking, director of psychology services for Lothian.[3073] In her statement she talks about the history of the service which is currently provided to those with bleeding disorders, Scotland-wide and their families. The service is currently funded by the Scottish government

[3073] WITN4063001 (26 January 2020)

via the NSD.[3074] It operates as part of the Scottish Inherited Bleeding Disorders Network ("SIBDN"). It is a nationally managed clinical network commissioned by NSD on behalf of NHS Scotland. The SIBDN is a reference group of patients and families which was established when the Scottish Government announced a review of financial support schemes in 2015. Its purpose is to oversee the delivery of Scottish Haemophilia Services and help coordinate all parties involved to achieve the best possible service for bleeding disorder patients in Scotland.

5.8 The Inquiry should recommend that the existing PSS service should include bespoke social work advice alongside the psychological and psychiatric service. Despite increased monies being available to the infected and certain affected individuals, there remains an entitlement to benefits, in connection with which advice may be required from social workers. The Inquiry has heard evidence that many infected individuals have issues with the euphemistically entitled "brain fog" (resulting from psychological impact and/ or organic brain damage resulting from infection) and fatigue. Assistance with accessing services is required from the State, in conjunction with the charitable assistance detailed elsewhere in this submission. There is a need to have advice provided to assist with the accessing and funding of treatment and other services (such as transport, therapies, care etc) for those who are sick or otherwise affected by State infections.

5.9 The Inquiry should recommend that the funding of the PSS should be ring-fenced and guaranteed by the Scottish government. The project was initially launched as a 2 year pilot project within NHS Lothian in 2015/ 16. Though the service has been rolled out nationally, it remains a pilot project with no guaranteed future funding. The service (and the separate service mentioned below) should continue to have the ability to liaise with the two Scottish charities mentioned in this submission as a means of accepting patients who wish to access the service via the charities as opposed to via the haemophilia centre or other medical services.

5.10 The Inquiry has available to it evidence that the infected and affected in the transfusion community were required to rely on accessing psychological services

---

[3074] WITN0713010_0002 (written statement of Sam Baker)

through normal NHS channels or via application for a support and assistance grant, available from the SIBSS. There had been few such applications.[3075] It is understood that the system for the provision of such services to those infected via that community has changed. The Inquiry should obtain additional evidence from NHS Scotland about how these changes have been implemented and the extent to which they have been accessed throughout Scotland.

5.11 A newer system is available to the infected and affected from both the transfusion and bleeding disorder communities. It runs from the Astley Ainslie Hospital in Edinburgh and is called the Scottish Infected Blood Psychology Service (SIBPS), offering specialist psychological therapies to the infected and their families.[3076] The service is run by two clinical psychologists with an understanding of the history of contaminated blood within the NHS, the ongoing national Inquiry and the specific needs of this population. Patients are mostly seen remotely (secure video calling or telephone) but face-to-face appointments can be arranged if there is a clinical need.

5.12 Some in the bleeding disorder community prefer to use the SIBPS as it operates outwith the SIBDN and hence independently from the haemophilia centres. In addition, the Inquiry ought to recommend that this separate service continue to be made available nationally to the infected and affected from the transfusion community (and to those in the bleeding disorders community who prefer to use it) with appropriate secured funding and resources. If it continues to be thought that this service would be better offered to that community via local territorial health boards based on local need, the Inquiry should seek evidence on how such a system would best be operated in practice in the future to ensure that it is both accessible and its existence adequately advertised within primary care.[3077] In any event, the Inquiry should recommend that ring-fenced funding be provided by the Scottish government for the service in the future as the long as the needs of that

---

[3075] WITN0713010_0005 (written statement of Sam Baker)

[3076] See https://apps.nhslothian.scot/refhelp/mental-health-(psychology-other-services)/scottish-infected-blood-psychology-service; and https://www.sibps.scot.nhs.uk/

[3077] As is suggested might be the case at WITN0713010_0004 (written statement of Sam Baker)

community to receive such support persists. Access to a social care service, similar to that suggested above for the PSS should also be made available Scotland-wide, in connection with this new service. It had originally been the intention of the psychological service pilot as rolled out through NHS Lothian that it would also offer a social work support service, but the pilot for this service did not progress as the psychological pilot did.[3078]

5.13 Further, the Inquiry should recommend that these services should provide and advertise support for those who are involved in applications to or the process of SIBSS or any compensation tribunal. The need for support in such circumstances is shown by the good work done by the Red Cross who have provided support to the infected and affected during the course of the Inquiry when the infected and affected have experienced difficulties in reliving past experiences. The application processes involve similar such issues and support is needed for them as well.

5.14 The inquiry heard evidence from Professor John Collinge about the risks to those who have received blood or blood products in the UK of contracting vCJD. In his evidence, he indicated that the specialist service of which he is a part would be able and willing to provide advice/ counselling to those who either have been informed that they have been exposed to a possibly implicated vCJD batch or those who are otherwise worried about the possibility that they may have been exposed to vCJD.[3079] The paucity of evidence about the risks of transmission of vCJD and the evolving nature of knowledge in that regard make it important that those who have potentially been exposed to blood or blood products have access to the most up to date expert advice from Professor Collinge and his team about the risks and possible consequences for that group. The Inquiry should recommend that there being liaison between the two psychosocial support services in Scotland and Professor Collinge in order that a method be devised as to how best the most up to date and best-informed advice be provided sensitively to those within the

---

[3078] See pages 1 and 5 of interim report of the service (2017) - https://www.sibdn.scot.nhs.uk/wp-content/uploads/2017/05/Interim-Psychological-Support-Services-.pdf

[3079] IBI transcript for 13/05/2022, page 127 (Professor John Collinge)

infected and affected community who are reasonably concerned about the possible implications for them of vCJD exposure.

5.15 In November 2022, the Inquiry heard from Dr Hacking and Dr O'Brien regarding the positive reception that the services have had, and the importance of ongoing support for the communities both in respect of PSS and SIBPS. In particular, Dr Hacking spoke of the need for continuity of the service provision for those infected and affected by contaminated blood because of the need to build and maintain trust in the services provided such that the community can fully access the schemes, trust the professionals involved, and trust that the services will be available in the long term.[3080]

The provision of a national physiotherapy service for those with bleeding disorders in Scotland

5.16 The Inquiry should recommend that a physiotherapy service be provided for those with bleeding disorders in Scotland via the national haemophilia service, the SIBDN. The Inquiry is primarily concerned with the impact of infection. The infected bleeding disorder community comes from what is now the older generation of bleeding disorder patients. They are the most likely to be infected but they are also the most likely to have a pressing need for physiotherapy, due to the relatively limited benefit they have derived from modern treatments over their lives. The infected are therefore the most likely to benefit from such a service.

5.17 At present, physiotherapy (unlike the PSS referred to above) is not provided via the SIBDN. This means that those with bleeding disorders who need to access essential physiotherapy services need to rely on the provision they can obtain via their local health boards.

5.18 The Inquiry should make this recommendation for the following combined reasons:

[3080] IBI transcript for 11/11/22: 120 (Dr Hacking) and 141 (Dr O'Brien)

(a) The importance of physiotherapy to the infected bleeding disorder community, who are most likely to require such a service, given their history of treatment;

(b) The well documented benefits of physiotherapy to the health of bleeding disorder patients, which include the better management of joints;

(c) In this submission, many initiatives are proposed which will cost the government money. It is expected that the running of a more efficient physiotherapy service via the national haemophilia Network will save money and thus make these other initiatives more financially viable to be offered within NHS Scotland. This is because better, more accessible physiotherapy will decrease bleeds and thus decrease the need for haemophilia treatments to be purchased by the NHS;

(d) As has been the case with the PSS, a single, national physiotherapy service for patients with bleeding disorders will be easier to access and more efficient. This will be of great benefit to those with HCV infection, in particular, for whom navigating the local Health Board systems in order to access such service is difficult in light of the common mental consequences of HCV infection. The legitimacy of making the physiotherapy service part of the national service will be added to by the addition to the national service of a social work service, as is suggested elsewhere in this submission, as the national service will be larger as a result anyway;

(e) The Inquiry has heard a good deal of evidence that the infected community lost faith with the physicians who were responsible for their infections. As a result, some at least neglected their haemophilia treatment due to the reasonable concern that it would be harmful to them. The result for these patients is that their joints are likely to be worse and their need for physiotherapy greater. In this regard, their infections have made a material contribution towards their need for physiotherapy; and

(f) The expansion of the national Clinical Network allows a far more direct and effective means by which budgets can be allocated to the care of patients with bleeding disorders in the future. An expansion of this service/ delivery

mechanism for their care will be conducive to the better funding of care for this important service (*inter alios* for the infected) in future.

6. Access to and funding of treatments, therapies and other interventions

6.1 The Inquiry should recommend that the SIBSS and any compensation tribunal for infected and affected persons should operate and be funded completely separately from the system for the provision of treatments and interventions. This is necessary so that there is no risk that the funds which are designed for the support of victims or their compensation are diminished or diluted by the need for money for their treatment. The obligation of the NHS to provide these treatments and interventions exists independently of the State's moral obligation to support and compensate the victims for their financial needs and losses respectively.

7. Funding patient support/ advocacy

7.1 In Scotland, the infected and affected are represented by Haemophilia Scotland ("HS") and the Scottish Infected Blood Forum ("SIBF"). The Inquiry has heard significant evidence about the reliance placed on these patient advocacy charities in this sector as well as the considerable reliance which has been placed on these organisations by the Scottish Government in informing and shaping exercises like the Penrose short life working party, the Financial and Clinical reviews groups which led to the formation of the SIBSS and ultimately to the other UK support schemes, amongst others. These charities have played an invaluable role for the sizeable and vulnerable cohort of infected and affected individuals within Scotland. They continue and will continue to play such a role after the Inquiry comes to an end. Further, it is imperative that future generations of UK citizens who require blood and blood products (and their parents or carers) benefit from expert independent support, advice, guidance and education. There will be a requirement for patient representative groups to be part of the Task Force

recommended above. In Scotland, HS and SIBF are best placed to serve those functions.

7.2 The value of the charitable organisations which have at various times been involved in care of those who are infected or affected as a result of the blood contamination disaster in Scotland cannot be over-estimated. The campaigning activities of these organisations is described elsewhere in this submission and has been indispensable in securing inquiries (both parliamentary and public inquiries and leading litigation to achieve those aims) and securing financial support for the infected and affected communities. The toll which these activities have taken on the campaigners and the compounding of the harms which they have suffered as a result is unparalleled – these also are analysed elsewhere in this submission. Their sacrifice, dignity and determination in the face of relentless adversity should be recognised by this Inquiry. However, amongst the plethora of evidence available to the inquiry about the value of the charities to the infected and affected is the following:

a. Providing information to patients about the nature of HCV infection in the absence of clear information being provided by the NHS[3081];

b. GRO-D

c. Making patients aware of risks of alcohol and poor diet on the progression of HCV resulting from infection in the absence of any clear advice on this from medics[3083];

d. Pursuing benefits claims and appeals on behalf of infected individuals who could find no other support within the system, many of them prolonged and complex[3084];

[3081] WITN2118001 @ para 9 (first statement of WITN2118)

[3082] GRO-D (first written statement of William Barry); WITN2186001, para 35 (first statement of Margaret Campbell)

[3083] WITN2272001 @ para 26 (first written statement of Gordon Strang)

[3084] WITN2219001, para 66 (first statement of WITN2219); WITN2245001, para 30 (first statement of WITN2245)

7.3 In the aftermath of the Penrose Inquiry in 2015, the Scottish Government announced three years minimum continued core funding for key organisations supporting the infected and affected community. Such funding has diminished over the years since that time, despite the ongoing need for these charitable bodies to provide these key services to that community.

7.4 The Inquiry should recommend that a secure funding stream should be established for these charities. This should provide funding to secure the long-term future of patient support without restriction on its use. SIBF currently receives no such funding. HS has required to source funding from the pharmaceutical industry. Secure, unrestricted government funding is thus essential.

7.5 The recommendation should also provide access for the charities to restricted funding to provide targeted, project-based information and support to those affected by the disaster through their wider advocacy work to ensure that no decisions about the treatment or care of people with inherited bleeding disorders or transfusion victims/survivors are taken in future without the active involvement of charities which can speak on behalf of that community.

8. Locating the infected

8.1 The Penrose Inquiry made a single recommendation to the following effect:

"That the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV"[3085]

[3085] Penrose Inquiry Final Report, page 1748

8.2 The evidence heard by the Inquiry has (a) indicated that patients who have been could have been identified as being infected with HCV earlier were not and (b) not been provided with satisfactory evidence that those infected by blood transfusion in Scotland have all been located. Given the probability that there are individuals infected with HCV by blood transfusions who have not been located and the need that they be so located to access current treatments, a more proactive approach is required. This is all the more important given the success which has been achieved in Scotland with new treatments for HCV and its commitment to eradicate the disease from the country.[3086] The Inquiry should recommend that:

a) A review be undertaken of the steps taken by the NHS in Scotland in light of the single recommendation made by the Penrose Inquiry; and
b) A renewed programme to locate patients infected in Scotland in this way be undertaken, to include more prominent public appeals to individuals who have had blood transfusions in the past to come forward for testing.

8.3 It is also understood that efforts made by Dr Campbell Tait as part of this work led to the identification of around 70 mild bleeding disorder patients who it was thought had contracted HCV.[3087] This built on work which had been done in around 2005. The short life working group enabled those who had been identified at that time to be identified by CHI. Certain efforts were made to locate these individuals.

8.4 In response to an FOI request an update is available on this element of the work.[3088] Based on information received from Health Protection Scotland (HPS) in 2018, of 69 patients whose status was investigated as a result of the Short Life Working Group's recommendations, 33 patients were traced by CHI linkage

---

[3086] IBI transcript for 26/02/20 (Professor Dillon); page 190 (8) to (17) on the Scottish HCV eradication target of 2024 and SVR rates from new treatments in Scotland

[3087] See page 6 of the SLWG report from 2016

[3088] https://www.whatdotheyknow.com/request/penrose_short_life_working_group

analysis, and 36 could not be traced. Of those traced, 20 were alive and 13 had died. Of the surviving 20 individuals, 9 letters were issued to patients' GPs. 8 patients were contacted, one was found to have moved outside of the UK. One of the additional patients identified as being in England was having testing arranged for them at the time that HPS provided information to the Scottish Government. In addition, 7 of those identified as living in Scotland had already, in the interim, been identified as being HCV negative and 4 of those identified as living in England had also already been tested for HCV. Of the 8 patients tested following letters to their GP, 1 tested positive for HCV. Dr Tait could provide details of how many of these were ultimately found and whether further efforts could reasonably made to locate them.

8.5 A letter from the Scottish CMO was issued to clinicians in September 2016 in line with the SLWG recommendations.[3089] It remains unclear what audit was done of the success of that exercise.

8.6 Although the Inquiry has heard evidence from Professor John Dillon that the NHS Scotland Hepatitis C elimination programme has "some confidence that the numbers of patients who could be missed will be relatively small" with regards to seeking to locate those infected via blood and blood products[3090], he also noted that there were challenges associated with identifying blood transfusion recipients as a result of the record keeping in previous decades. We submit that, having regard to the evidence heard by this Inquiry regarding record keeping, and missed opportunities to diagnose individuals with HCV, a concerted effort to find people infected via blood transfusions should be undertaken to ensure that as many people as possible are identified. The Inquiry has evidence of individuals only recently being identified and diagnosed.

9. Long-term follow-up of the infected and affected

[3089] https://www.sehd.scot.nhs.uk/cmo/CMO%282016%2917.pdf

[3090] IBI transcript for 17/11/2: 49 (Professor John Dillon)

9.1 Evidence which has been heard by the Inquiry highlights that monitoring of the effects of treatments is insufficient to identify all *sequelae* of those treatments. The Inquiry should recommend that a scheme (participation in which should require to be explained clearly to patients) be instituted for anyone infected by the disaster to monitor long-term impact of treatment with blood or blood products, in particular as the victims start to enter old age. An assessment of this will enable (a) greater knowledge to be obtained about the long-term dangers of using blood or blood products, including the possible effects of other pathogens, the full effects of which are not yet well understood and (b) greater planning for the needs of the victims, including palliative care in the future. This work should take a broad and holistic view of impact and include educational and employment opportunities as well as deaths from all causes. This work could be supported by the psychosocial support service detailed above which could conduct home visits to ensure even the most isolated and unwell can participate.

9.2 There is a clear need for there to be both facilities and a national commitment within the NHS in Scotland for hepatological follow-up of the infected, even after treatment has been deemed to have been successful. The Inquiry should recommend that the NHS in Scotland should commit to a minimum of annual follow up of all patients who have been infected by HBV, HCV or HIV as a result of having received contaminated blood or blood products by appropriate medical professionals (irrespective of treatment outcome) with appropriate medical facilities being provided in all health boards for this to be done, including fibroscan machines.

9.3 The Inquiry has heard evidence from those who have achieved sustained virological response that they remain fearful that that response may not be maintained indefinitely. This is an understandable and natural response in light of the circumstances of their infection. The psychosocial expert group noted that the concerns about re-occurrence of the infection *"resulted in ruminative thoughts and surveillance of body symptoms, both of which can have detrimental effects on*

emotional well-being"[3091] The Inquiry should recommend that viral load testing is available for those who have sustained virological response where necessary.

10. Palliative care

10.1 The Inquiry has heard powerful evidence about the difficulties experienced by individuals who have been required to care for loved ones who have died as a result of their infections and associated symptoms/ conditions from blood or blood products in Scotland. Those who have been infected by the State deserve the very best of care in planning and managing their end of life care. Literature confirms the paucity of palliative care available for the kinds of individuals who are facing death as a result of their infection from contaminated blood or blood products.

10.2 A 2015 Edinburgh study found that "Living, dying and caring in advanced liver disease is dominated by pervasive, enduring and universally shared uncertainty".[3092] It concluded that in the face of high levels of multidimensional patient distress, professionals must acknowledge this uncertainty in constructive ways that value its contribution to the person's coping approach and that planning 'just in case' is vital to ensure that patients receive timely and appropriate supportive and palliative care alongside effective management of this unpredictable illness.

10.3 In "The incompatibility of healthcare services and end-of-life needs in advanced liver disease: A qualitative interview study of patients and bereaved carers" it was found that there were escalating physical, psychological and social needs as liver disease progressed, including disabling symptoms, emotional distress and

---

[3091] EXPG0000003_004

[3092] "Managing uncertainty in advanced liver disease: a qualitative, multi-perspective, serial interview study" per Kimbell et al, BMJ Open 2015

uncertainty, addiction, financial hardship and social isolation by a Bristol based group. The study found that end-of-life needs were incompatible with the healthcare services available to address them; these were heavily centred in secondary care, focussed on disease modification at the expense of symptom control and provided limited support after curative options were exhausted. Attitudes towards palliative care were mixed, however, participants valued opportunities to express future care preferences (particularly relating to avoidance of hospital admission towards the end of life) and an increased focus on symptomatic and logistical aspects of care.

10.4 It was recommended that novel strategies, which recognised the life-limiting nature of liver disease explicitly and improved co-ordination with community services were required if end-of-life care is to improve.[3093]

10.5 In "Palliative care for people with advanced liver disease: A feasibility trial of a supportive care liver nurse specialist" an Edinburgh based group looked at the use of liver nurse specialists in the palliative care of such patients.[3094] The study involved a feasibility trial of a complex intervention delivered by a supportive care liver nurse specialist to improve care coordination, anticipatory care planning and quality of life for people with advanced liver disease and their carers. Patients received a 6-month intervention (alongside usual care) from a specially trained liver nurse specialist. 47 patients, 27 family carers and 13 case-linked professionals were recruited for feedback. The proposed nurse-led intervention proved acceptable and feasible. The authors refined the recruitment processes and outcome measures for a future randomised controlled trial.

10.6 The expert group on palliative care in advanced liver disease which has given written and oral evidence to the Inquiry identified that there are various factors which contribute to the poor or sub-optimal delivery of palliative care for these patients, which is therefore delivered inconsistently across the country.[3095] There

---

[3093] Hudson et al, Palliative Medicine 2018, Vol. 32(5) 908–918

[3094] Kimbell et al, Palliative Medicine 2018, Vol. 32(5) 919– 929

[3095] IBI transcript for 04/03/2022, pages 34 – 35 (Dr Fiona Finlay)

is therefore a need for reform of the system. The need for improvements in this area have been supported by the British Liver Trust.[3096] Consistent with the evidence heard by the Inquiry from its expert group, there is support in the literature for (a) better use of clinical tools to identify the point of irreversible deterioration in advanced liver disease and (b) joint working between liver services and palliative care to improve care for people with cirrhosis.[3097]

10.7 In light of this evidence, there is a need to overhaul the system of palliative care in Scotland, in particular for those who have advanced liver disease and associated conditions and those whose infections are complicated by HIV infection. The Inquiry should recommend that a new system of palliative care for these individuals should be implemented in Scotland (to be delivered through existing pathways in a more effective manner) comprising:

(a) Minimum standards of and commitments to the provision palliative care and support for these individuals which are clearly set out along with a clear strategy as to how and by which agencies these standards will be delivered in each Health Board area in Scotland. At present, there are considerable issues when the infected are nearing the end of life in understanding what services are available for palliative care for them locally in Scotland. By the time the services are identified and/ or accessed, it is often too late;

(b) Funding for the charities in Scotland (see above) which should include funding for a palliative care officer to assist those in need of palliative care and their families to access the services which are available to them and direct them to the appropriate agencies within the NHS and elsewhere. The need for such a service will only increase in the future as the infected get older and more palliative care will be required. A trusted representative within the charitable sector to assist with applications to access services will be invaluable;

[3096] https://britishlivertrust.org.uk/new-research-end-life-care-people-liver-disease/

[3097] "Advanced chronic liver disease in the last year of life: a mixed methods study to understand how care in a specialist liver unit could be improved" by Low J, et al. BMJ Open 2017;7:e016887

(c) Meaningful care plans, devised in accordance with the patients' wishes (see above); and

(d) The availability of a nation-wide service of expert palliative care nurses to be delivered in each health Board region, with a named nurse allocated to each patient and a lead nurse to co-ordinate care and treatment.

10.8 In order to facilitate discussion about further specific measures which might progress these important aims that the Scottish Government should convene a short life working group on this issue (with patient representation from the relevant charitable organisations mentioned elsewhere in this submission).

10.9 For the victims of the contaminated blood disaster, palliative care should include the right to die, with full palliative care, at home.

MEDICAL INVESTIGATIONS

11. Testing and research

11.1 The ability of blood and blood products to transmit viruses and other pathogens in addition to those with which the Inquiry has primarily concerned itself (namely HBV, HCV and HIV) has been clearly established by the evidence heard by the Inquiry. In light of the possibility that victims of the disaster have been exposed to other pathogens or infected by them, the Inquiry should recommend that testing should be offered to all bleeding disorder patients and those who have been found to have been exposed to pathogens through blood transfusion already (including natural clearers of hepatitis viruses). Such blood tests are necessary to ascertain the precise nature and extent of viral exposure and infection amongst that community. It is only then that a fuller understanding can be ascertained of the nature and extent of the disaster and plans made to support and compensate and care for the victims fully. Recent press reporting suggests that single tests for

multiple viruses may soon be available.[3098] However, absent such scientific advancement in the immediate future, it is submitted that the Inquiry should recommend that the following tests should be offered to this community:

- Human parvovirus including B19 parvovirus and the new parvoviruses, human parvovirus 4 (PARV4) and new genotypes of parvovirus B19
- Herpes viruses, including Epstein-Barr virus, Cytomegalovirus and other herpes viruses which may be transmitted by blood including human herpesviruses 6 and 8 (HHV-6 and 8)
- SV 40
- HTLV I and II
- West Nile virus
- Dengue fever and dengue haemorrhagic fever
- Japanese encephalitis virus (JEV)
- Enteroviruses
- Circoviruses, including torque-tenovirus (TTV) and torque-tenominivirus (TTMV)
- SEN virus
- Hepatitis D
- Hepatitis G
- Q fever

11.2 The Inquiry should also recommend that testing for the viruses with which an infected person is or was infected should be made available to those who have been carers for those infected individuals and their spouses.

11.3 In addition, the Inquiry should recommend that UK Government should establish a research fund to support work to address some key questions where there is simply not enough current evidence to enable it to reach reliable conclusions on

[3098] www.bbc.co.uk/news/science-environment-33008590

important matters which would otherwise have fallen within its terms of reference. For example:

a) The clinical implications of being repeatedly infected/ exposed to viruses in blood/ blood products, in particular (i) on the immune system (i) as a result of repeated inflammatory response and (iii) in the developing child.
b) The clinical implications of being repeatedly infected/ exposed with multiple genotypes of Hepatitis C.
c) The clinical implications of having been exposed to the Hepatitis B virus amongst patients who are otherwise infected as a result of blood or blood products, including the possible additional *sequelae* of such exposure and its implications for prognosis, likely future medial and care requirements. Professor Tedder gave evidence to the Inquiry from a position of considerable, longstanding expertise on the possibility that after clearance of positivity to HBsAg an individuals who has been exposed to HBV (as all bleeding disorder patients who were treated with concentrates would have been) could experience viral replication and consequent liver damage as a result years later.[3099]
d) The impact of multiple viral exposure on the likelihood of clearing naturally, immune response fatigue, the success rate of treatment or prognosis.
e) Whether natural clearing rates of viral hepatitis lower for people affected by bleeding disorders, and if so, why;
f) Whether the long-term sexual partners or children of people with an inherited bleeding disorder, who have been exposed to contaminated blood products, experience an elevated rate of any condition or disease;
g) Whether there are any unique characteristics or issues for people whose viral infection was caused by contaminated blood or blood products compared to the much larger groups of people otherwise so infected; and
h) The health implications for those who have been exposed to but who are deemed to have "naturally cleared" the hepatitis C, including the long term

[3099] WITN3436003 @ paragraphs 155 and 156

impact on their immune systems and the possible connections between such exposure and the development of other medical conditions.

THE SAFETY OF BLOOD AND BLOOD PRODUCTS

12. Permanent ban on the use of blood or organs from incarcerated people

12.1 The Inquiry has heard evidence to the effect that blood collected from prisons, borstals or young offenders' institutions carries a significantly higher risk of transmitting disease than blood collected from regular volunteer donors. This has been known by the blood transfusion services for many decades. Blood, tissues and organs should never again be collected in prisons, borstals or other such institutions. The collection of such blood represents an unacceptably high risk to blood safety when the next blood borne infection emerges.

13. Better donor engagement in the blood collection system

13.1 The principles underpinning the "gift relationship" between the donor of blood, the system of collection and the ultimate recipients have formed an important part of blood transfusion in the UK. The Inquiry should recommend measures which seek to improve donor engagement and investment in the system in which they play such an important part such as the motivation of donors by providing them with more information about what their donations are used for/ when they are used/ when they have been used to save a life (as in Sweden).[3100]

[3100] See https://www.everplans.com/articles/swedish-blood-donors-get-a-text-message-when-their-blood-saves-a-life

14. Early adoption of new donor tests

14.1 Evidence heard by the Inquiry has indicated that the threshold for using blood tests, including surrogate tests, to exclude risky donors has been too high and too much emphasis placed on false positives reducing the blood supply. The Inquiry should recommend that the policy and guidance of the transfusion service must incorporate a precautionary approach to the collection of blood in the interests of end users of blood and blood products and that tests should be introduced as soon as reasonably practicable for safety with any shortfall in blood supply addressed by recruiting more donors. These measures are an important means of ensuring that all reasonable steps are being taken to eliminate future pathogens which emerge from the blood supply.

15. Medical education

15.1 The Inquiry should recommend that the Royal Colleges should promote teaching of the circumstances of the contaminated blood disaster and the findings/ recommendations of this Inquiry to all medical and nursing students, in particular in connection with the dangers of blood and blood derived products, public health, the requirements of informed consent, the possibility for a bad reaction to a medical mistake or disaster to compound the harm caused, patients' rights to information about research, patients' rights to consent to and access to information about testing, the impact of medical mistakes or disasters on the families of the patients and other relevant areas.

15.2 Further, the Inquiry should promote through medical education (and otherwise) the removal from medical vocabulary of the use of the terms (a) "natural clearance" after exposure to HCV and (b) "cure" from viral infection with HIV or HCV after treatment as opposed to sustained virological response to treatment, in

connection with the response to treatment for HIV or HCV infection. Both of these terms are medically inaccurate, in the sense that they create the impression that the absence of progression to the chronic phase of infection or the presence a sustained virological reaction to treatment respectively result in the patient being left with no *sequelae* which are connected with exposure to or infection with the virus. The evidence heard by the Inquiry demonstrates that patients who are in these categories may well have ongoing physical, psychological or psychiatric consequences of such viral exposure. The continued use of these terms creates the inaccurate impression amongst medical professionals that clearance or successful treatment represents the end of problems for such a patient.

LITIGATION

16. Lift the time bar and prescription rules in relation to obligations to make reparation

16.1 In Scotland, court actions are required to be commenced within the limitation rules provided for by sections 17 and 18 of the Prescription and Limitation (Scotland) Act 1973. The Act also provides rules whereby obligations to make reparation prescribe as a matter of law under section 6 of the Act. In addition, the Act provides for limitation rules and prescription rules relating to actions arising out of the Consumer Protection Act 1987 under sections 22B and 22C and section 22A respectively.

16.2 Any infected or affected person who asserts a legal right to receive damages as a matter of law arising from the blood contamination disaster should have recourse to the courts to do so. The Inquiry should recommend that the existing rules on limitation and prescription in this regard should be removed by legislation. The unique circumstances and scale of the blood contamination disaster, along with the practical limitations on the ability of the civil court system to be accessed by the infected and affected community over the decades merit that such a recommendation be made.

16.3 In addition, the Inquiry should also recommend that the right of any defender (defendant) to rely on any waiver of the right to litigate should also be removed.

AVOIDING AND ADDRESSING ADVERSE TREATMENT OUTCOMES

17. Reform of the MHRA

17.1 The Medicines and Healthcare Products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. The MHRA is an executive agency, sponsored by the DHSS.

17.2 The Cumberlege review recommended that:

> *"The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work."* [3101]

17.3 This Inquiry should make similar recommendations in particular in relation to adverse event reporting and regulation in respect of blood products, blood and blood components.

New treatment fund

17.4 The Inquiry has heard evidence about the difficulties faced by governments in the UK in finding money necessary for the financial support of those infected or

---

[3101] Cumberlege report, final report, page 188, recommendation 6

affected by contaminated blood products. This financial burden has been required to be borne by the State in the UK. In many cases, infections were caused by contamination of blood products introduced into the market by pharmaceutical companies which have made fortunes out of the sale of those products. These companies have largely evaded financial responsibility for the consequences of their products causing infection and devastating lives, either through litigation or other means. The Inquiry should recommend that the UK licensing regime should require companies introducing new treatments/ products to the UK to pay into an appropriate financial vehicle ("the new treatment fund"), to be managed by the government, to provide financial support payments to any patients harmed by their products.

17.5 Such a scheme would share the financial burden between the State, whose moral responsibility it is to look after its citizens when harmed in such circumstances and private companies which have profited from access to the lucrative UK market. Such a scheme would also lessen the financial incentive for governments to cover-up the details of such disasters as the financial burden to be borne by them would be reduced by such a fund. This would also have the effect of increasing the chances that such disasters could be examined quickly and relevant lessons learnt early, so as to minimise the risk of their re-occurrence. It would achieve this by allowing payment to be made quickly to those who have been adversely affected, removing or minimising the incentive to postpone or deny inquiry into or examination of the circumstances of the harm have been caused.

PATIENTS' RIGHTS

18. Handling when things go wrong in medical care

18.1 The need for a clear system to be available to meet the needs of patients and parents/ guardians when their care is not delivered in accordance with their

wishes for their healthcare is an essential component of any modern healthcare system. Failures both in advertising the availability of a system for complaints and in the effectiveness of the complaints system itself have had a number of serious adverse consequences for the infected and affected community. The ineffectiveness of the complaints system has led to patients not being heard/ listened to, loss of confidence in the system and feeling disconnected from their own medical care. As a result, opportunities have been lost to the medical profession to learn from things going wrong in the way that medical care had been provided. In order to make improvements in this important area of healthcare for the future, the Inquiry ought to recommend that there be a review of the system for handling NHS complaints in Scotland, in particular involving:

(a) The extension of the duty of candour;
(b) An integrated and effective system for whistleblowing within the NHS;
(c) Reform the system of NHS complaints in Scotland with a particular role for the Patient Safety Commissioner for Scotland and patient advocacy groups, in connection with which separate recommendations are proposed elsewhere in this submission.

The current system

18.2 The current system dealing with complaints by patients within the NHS in Scotland is complex. The following are aspects of that system which seek, in principle, to promote and protect the rights of patients. The system is currently unwieldy and hard for patients to navigate.

(a) The Patient Rights (Scotland) Act 2011 ("the 2011 Act") aims to improve the patient's experience of using health services and to provide support for patients to become more involved in their healthcare. It enshrines in legislation that it is the right of every patient to receive health care which (a) is patient focused and

must take into account the patient's needs (b) has regard to the importance of providing the optimum benefit to the patient's health and wellbeing (c) allows and encourages the patient to participate as fully as possible in decisions relating to the patient's health and wellbeing and (d) has regard to the importance of providing such information and support as is necessary to enable the patient to participate in accordance with paragraph (c) and in relation to any related processes, taking all reasonable steps to ensure that the patient is supplied with information and support in a form that is appropriate to the patient's needs.[3102] It is the right of every patient to give feedback or comments, or raise concerns or complaints about health care received.[3103] NHS bodies are required to encourage patient feedback, comment or complaint which they must consider with a view to improving the performance of their functions.[3104] A patient advice and support service is required.[3105] Health care is required to be delivered in accordance with certain principles.[3106]

(b) The Act created a Charter of Patient Rights and Responsibilities. Amongst other things, it states that patients have the right to be given all the information they need about medicines, any possible side effects, and other options which may be available, in an understandable way. It states that patients have the right to be involved in decisions about their care and treatment, and be able to take an active part in discussions and decisions about their health and treatment.

(c) Individual Health Boards in Scotland operate their own complaints and feedback processes, in accordance with their obligations under the 2011 Act. The way in which they operate varies.

(d) An appeal against the way in which a Health Board handles a complaint can be made under the Scottish Public Services Ombudsman Act 2002 to the Scottish

---

[3102] 2011 Act, section 3(2)

[3103] 2011 Act, section 3(3)

[3104] 2011 Act, section 14

[3105] 2011 Act, section 14

[3106] 2011 Act, section 6 and schedule

Public Services Ombudsman ("SPSO"). The SPSO is an independent Scottish Parliamentary Supported Body.

(e) There is a Patient Advice and Support Service ("PASS") which seeks to (a) promote an awareness and understanding of patients' rights and responsibilities and in particular, promotes awareness of the Charter (b) advise and support people who want to give feedback or comments or raise concerns or complaints about healthcare (c) provides information and advice on matters it considers people using the health service would be interested in and (d) make people aware of and, if appropriate, direct them to: other sources of advice and support and those who can represent them.

(f) Bodies which have a role in professional regulation within the health sphere include the General Medical Council, the General Pharmaceutical Council, the Health and Care Professions Council and the Nursing and Midwifery Council, each with its on jurisdiction and procedures.

(g) The MHRA (addressed below) operates a yellow card system which is open to the public to access.

Reforming the duty of candour

18.3 Patients and the groups representing them must be advised as early as possible when any potential apparent risks or problems with past, current or future treatments or products are identified. At present, sections 21 and 23 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (and the associated Duty of Candour Procedure (Scotland) Regulations 2018) provide as follows:

21 Incident which activates duty of candour procedure

(1) A responsible person must follow the duty of candour procedure set out in section 22 as soon as reasonably practicable after becoming aware that subsection (2) applies to a person who has received—

(a) a health service from the responsible person,

(b) a care service from the responsible person, or

(c) a social work service from the responsible person.

(2) This subsection applies to a person if—

(a) an unintended or unexpected incident occurred in the provision of a health service, a care service or a social work service to the person, and

(b) in the reasonable opinion of a registered health professional—

(i) that incident appears to have resulted in or could result in an outcome mentioned in subsection (4), and

(ii) that outcome relates directly to the incident rather than to the natural course of the person's illness or underlying condition

23 Apologies

(1) For the purposes of this Part, an "apology" means a statement of sorrow or regret in respect of the unintended or unexpected incident.

(2) An apology or other step taken in accordance with the duty of candour procedure under section 22 does not of itself amount to an admission of negligence or a breach of a statutory duty.

Section 25 of the Act defines a "responsible person" as:

a) a Health Board constituted under section 2(1) of the 1978 Act,

b) a person (other than an individual) who has entered into a contract, agreement or arrangement with a Health Board to provide a health service,

c) the Common Services Agency for the Scottish Health Service constituted under section 10(1) of the 1978 Act,

d) *a person (other than an individual) providing an independent health care service mentioned in section 10F(1) of the 1978 Act,*

e) *a local authority,*

f) *a person (other than an individual) who provides a care service,*

g) *an individual who provides a care service and who employs, or has otherwise made arrangements with, other persons to assist with the provision of that service (unless the assistance in providing that service is merely incidental to the carrying out of other activities),*

h) *a person (other than an individual) who provides a social work service*

18.4 Both Healthcare professionals and patients should be encouraged to voice concerns without fear of prosecution, reduction in service provision, or impact damage to career prospects. The infected and affected community has serious concerns about the way in which the duty of candour obligations operate in practice. The Inquiry should recommend that NHS Scotland undertake a review of compliance with the duty of candour procedure in order the inform the implementation task force in taking further steps to ensure that the duty of candour is being complied with in Scotland. This review would ultimately be subject to the jurisdiction of the task force, as with the other proposed recommendations. One particular concern of the infected and affected community in Scotland relates to the way in which the duty of candour operates in circumstances where things have gone wrong. The fact that the obligations under the statute apply to organisations or service providers, as opposed to being incumbent upon individuals within the system is reasonably seen as being part of that problem. In reality, the need for analysis, reflection and candid apology for rebuilding of the relationship of trust in such circumstances requires the involvement of individual clinicians and the patient as opposed to an organisation, like the relevant Health Board. At present, such institutionally driven processes or apologies can be impersonal and thus ineffective. The Inquiry should recommend:

(a) That the duty of candour should be extended from organisations to individual healthcare professionals. This would allow patients to be involved as equal partners in the reflective practice of clinicians and facilitate the re-building of the essential relationship of trust and partnership between the patient and the clinician;

(b) In any event, that protocols used as guidance for employees of the NHS in Scotland should include clear guidance on the requirement to observe the organisation's duty of candour, as agents of it; and

(c) That a confidential, effective system of "whistleblowing" open to patients and medical practitioner alike be implemented into codes of practice and contracts of employment within the NHS to ensure that problematic practices come to light and are handled appropriately.

18.5 It seems difficult to understand why the duty of candour extends to the organisations to which it applies when it does not also extend to elected government. The Inquiry has heard considerable amounts of evidence to the effect that in the past and today, important decisions made which affect the operation of the healthcare system are made within government. Therefore, in order to support the protections which they duty of candour is there to protect for patients, it is submitted that the Inquiry ought also to recommend that the duty of candour should extend beyond healthcare into both local and national government.

Patient Safety Commissioner for Scotland

18.6 The measures detailed above set out how it is proposed that the Inquiry should promote and champion patient involvement in the provision of care and putting the rights of the patient/ parent/ guardian to access information to enable informed decisions to be made about treatment at the forefront. The obligations in this regard require to be accessible in practice to patients like those who have significant health or social needs, as is the case with many of the victims of the

blood contamination disaster. There is also a need (in respect of which it is also proposed that the Inquiry make recommendations) for the patient voice to be heard and prioritised on a macro/ governmental level, as well as within the context of individual cases. The Inquiry should lend its weight by way of a recommendation to the need for a Patient Safety Commissioner in Scotland, with appropriate case workers and other staff within its office, such as the model proposed in England by the Cumberlege report.[3107] This role should be independent of government and operate via the Health and Sport Committee of the Scottish Parliament, given that health is a devolved matter. As was the case in the Cumberlege report, this Inquiry has also learned that when patients and their families have identified and reported harms, these reports have not been acted on until forced into public attention by campaigns or media interest.[3108]

18.7 Scottish Ministers committed in 'Protecting Scotland, Renewing Scotland: The Government's Programme for Scotland 2020-2021, to creating the role of Patient Safety Commissioner. The Scottish Government has already undertaken a consultation process in connection with the possibility of having a Patient Safety Commissioner for Scotland (March 2021).[3109] It remains unclear what actual progress in light of the consultation is proposed by the Scottish Government.

18.8 Legislation establishing an equivalent Patient Safety Commissioner role in England was passed in April 2021. The Patient Safety Commissioner for Scotland (the existence of which should be underpinned by legislation) should have a role in:

(a) promoting the role of patient safety and patient priority in the NHS in Scotland at governmental level and in the Health and Sport Committee of the Scottish Parliament. At present, the system for complaints is too cumbersome and slow. This means that (even where the system works relatively well) by the time there

---

[3107] See the details of this proposal at Appendix 2 to the Cumberlege final report, page 187, recommendation 2 and from page 202

[3108] Para 2 of appendix 2 to the Cumberlege final report

[3109] See https://www.gov.scot/publications/consultation-patient-safety-commissioner-role-scotland/pages/2/

is an opportunity for lessons to be learned, things have moved on and little effective change can be implemented;

(b) assisting patients and patient advocacy organisations in the co-ordination and presentation of patient involvement/perspective in complaints and disciplinary proceedings involving medical professionals. The role of the Commissioner should allow a single point of entry for patients and their representatives into the complaints system which can have a labyrinthine structure, involving numerous agencies at times. This would, in turn, help improve consistency of patient involvement in these processes throughout Scotland. There should be clear and visible advertising of the complaints procedure in order that every patient is aware of his or her rights and the mechanism by which they can be enforced, available after every procedure/ treatment; and

(c) making recommendations to government from the patient perspective as to circumstances where it would be in the public interest to hold a public inquiry into aspects of the healthcare system in Scotland in accordance with section 1 of the Inquiries Act 2005 (in connection with which see submissions below).

18.9 Though the role should have a wide remit as a champion of patient safety and interest, the remit of the Patient Safety Commissioner for Scotland should certainly include blood and blood products, given the evidence heard by this Inquiry as to the dangers posed by them and should not be limited to medicines and medical devices.

18.10 Although the Inquiry heard evidence from the Public Health and Administration Group regarding the role of the Patient Safety Commissioner, that evidence was limited to the position in England and Wales. In Scotland, we understand that a different approach is being taken to the role of the PSC. The expert group appear to have been unaware of this. With regards to the Scottish PSC, this Inquiry should recommend that, in light of the evidence it has heard and the lessons that we say should be learned arising from that evidence as explored in this submission, that the role of the PSC should include blood and blood products.

Care plans

18.11 The Inquiry has heard copious evidence about treatment plans for NHS patients being introduced without adequate patient (or parent where appropriate) involvement. It should be recommended by the Inquiry that a system be introduced (by legislation if necessary) so that patients receiving ongoing NHS care in Scotland have the right to receive a written care plan. Such a plan should be required to be co-produced with the patient (or parent/ guardian where appropriate) and be regularly updated. The purpose of such a requirement would be to ensure patient involvement in decision making and clarity about what care was proposed and its objectives with respect for patient autonomy and wishes.

18.12 The right to have a written care plan should include the right to have involvement in the compilation of a written plan for palliative care, where appropriate (addressed elsewhere in this submission). Such care plans should include a clear statement of how and to what extent an attorney would become involved in decision making, in appropriate cases, where there is a prospect of the patient losing capacity.

Medical records

18.13 The Inquiry has heard copious evidence about problems have been experienced by patients/ parents/ patient representatives across the country in accessing medical records. This has had the effect of limiting the ability of patients or their relatives to gain a proper understanding of what happened to them or their loved ones. In many cases, missing or incomplete medical records have created a justifiable sense of injustice or, in many instances, suspicion about the fraudulent

removal, destruction or concealment of records. Inexplicably missing or inaccurate records have prevented access to government support schemes in certain cases. The maintenance and retention of accurate records appears to have been seen by the NHS in the UK as an unimportant or at best ancillary element of medical care. In fact, medical records provide a means by which care is provided in the best way for the patient, with maximum clarity and consistency. Where things go wrong, medical records play an important part of any chance a patient has to get to the truth and to achieve justice. The lack of importance attached to the establishment, maintenance and retention of accurate and complete medical records must stop. The system relating to medical records should be overhauled, in particular for those who receive blood or blood products, tissues or organs derived in any way from other human beings. The usual systems relating to the maintenance and retention of medical records have failed many patients and families in such cases, in particular where the pathogens transmitted by the treatment have taken many years to manifest themselves in illness.

18.14 With the appropriate safeguards to protect personally sensitive content, all patient records should be held electronically for all patients. There is an ongoing system within the NHS in Scotland whereby medical records are maintained in different departments and are thus (i) not all entered into electronic systems and (ii) not available to all who may wish to access them to ensure continuity of care. These electronic records should be accessible to patients/ patient representatives and, once placed in the records, it should not be possible for the NHS to remove or amend documents within them retrospectively without consulting the patient/ their representative.

18.15 The Inquiry should recommend an overhaul of the system of making and retaining medical records in Scotland. The key principles which should underpin the reformed system should be:

(a) Allowing patients greater involvement in the creation of medical records, which will improve the accuracy of medical records but will also improve the involvement of the patient in decision making about his or her care. Notes of

consultations with medical practitioners should be written with the patient's involvement and co-operation, insofar as reasonably practicable;

(b) The requirement that any substantive correspondence about a patient written to another part of the NHS (for example letters from a hospital consultant to a general practitioner) should be copied to the patient;

(c) The maintenance of a single electronically accessible set of official medical records for each patient. There are current systems (on which the Inquiry could and should take more evidence) of such systems being in existence in other part of the UK at present[3110]; and

(d) Provision of a clear system whereby patients can seek to have their medical records corrected where there re inaccuracies in them or omissions from them, which can be adjudicated upon via complaints procedures supported by the Patient Safety Commissioner for Scotland.

18.16 In addition, and in response to issues relating to medical records about which the Inquiry has heard clear evidence, it should be recommended that:

(a) Requests to access medical records by patients or patient representatives in Scotland for the purposes of the Inquiry have proven difficult. Records have often been found and produced long after an original mandate was signed, in particular for bleeding disorder patients. The NHS in Scotland should undertake an investigation (on request by any individual patient or patient representative) into what records, blood, tissues or other bodily substances are still held relating to those with bleeding disorders or who have received blood transfusions in Scotland (both in vivo and post mortem) and by which departments. The findings should be published to the individuals concerned or their representatives with reasons as to why these are retained. Patients (or their representatives) should

[3110] See for example the "My Medical Record" system instituted by the University of Southampton NHS Foundation Trust, which is a secure patient owned medical record system to which patient can make contributions themselves, details of which can be found at https://www.uhs.nhs.uk/for-patients/my-medical-record

be accorded the right to continue to agree to the retention of blood, tissues or other bodily substances or not;

(b) The NHS in Scotland introduce clear rules as part of the contract of employment of any health service providers in the NHS that the maintenance or storage of medical records relating to NHS patients outwith recognised NHS facilities for the storage of such records is prohibited. This is to prevent the possibility that medical records relating to patients can be held privately;

(c) The NHS in Scotland introduce clear rules as part of the contract of employment of any health service providers in the NHS that research records which contain any information which derives from NHS patients be held only within recognised NHS facilities for the storage of such records. This is to prevent the possibility that medical records relating to patients can be used for research privately;

(d) The NHS in Scotland introduce a system whereby patients/ patient representatives can seek and the NHS is obliged to provide a comprehensive list of all records held pertaining to the patient concerned (including records kept post mortem) and the details of all records relating to that patient which have been destroyed and the reasons for such destruction;

(e) The NHS in Scotland introduce a system whereby the medical records of all patients with bleeding disorders be held indefinitely, in order better to inform the treatment of these hereditary conditions for the relatives of the patients in future and to allow monitoring of the presence of any patients transmitted by treatment;

(f) Similarly, that the NHS in Scotland introduce a system whereby the medical records of all patients who have received blood transfusions in Scotland be held indefinitely; and

(g) The NHS in Scotland introduce a register of blood transfusions (including blood components) administered in Scotland given the dangers of blood. This should include a system whereby the entry onto the register is intimated to the patient/ patient representative concerned.

18.17 We have made submissions elsewhere regarding what we suggest this Inquiry should recommend in respect of compensation. One element of the issue, arising in part from Sir Robert Francis KC's study, is the concept of an award of damages which reflects the insult and affront to the autonomy of those involved in non-consensual treatment and/ or research.

18.18 The Inquiry has heard evidence to the effect that these breaches of individual autonomy have had substantial effects on the psychological condition of patients due to the fact that the relationship between doctor and patient (in particular in patients with chronic conditions like haemophilia) has been seriously undermined and the treatment of the underlying condition(s) rendered less effective as a result. Many patients remain in the dark as to precisely what was done to them without their consent and what research was undertaken involving them without their knowledge. In some cases, medical records are incomplete and may not provide an accurate or full picture. Patients continue reasonably to suspect that records of their involvement in non-consensual studies or research may exist or have existed which contain details of their involvement in such work beyond what is contained in their medical records. Any such financial mechanism would require to be supported by a new system whereby the NHS in Scotland requires to provide (on application by a patient) what information it can about (a) testing undertaken on an infected patient or (b) research or other similar studies in which a patient was or may have been involved. The requirement to respond to such requests fully should be recommended by the Inquiry.

18.19 It may prove difficult for the Inquiry to make detailed recommendations in the absence of evidence of the whole system pertaining to medical records, which obviously extends into all areas of medical practice. It may, therefore, be the case that more work will require to be recommended in order that the Inquiry be used as a springboard to reform of the system.

19. A research subjects' rights framework

19.1 The Inquiry should recommend a research subjects' rights framework, produced in consultation with patient advocacy groups. Research should be defined broadly to include clinical studies and similar patient observational studies. This should facilitate a set of obligations whereby those undertaking any such study are required to make it clear to any patient involved in research what their rights are, including the right to information about risks and expected benefits of the research, to withdraw from research, to see the results of any tests, to be made aware of any published materials relating to their case, and to be assured that no blood or tissue sample (including historic samples) should be used for any purpose for which the patient has not given full and informed consent (or their next of kin if the person is deceased). The contaminated blood and blood products disaster should be used as a case study in the teaching of the framework in medical schools.

ETHICS

20. GMC probe into possible ethical breaches relating to failure to take informed consent from patients/ parents on the part of living individuals, unethical research undertaken on patients with bleeding disorders in Scotland

20.1 The evidence heard by the Inquiry has raised serious questions about the ethics of certain practices, such as the lack of or inadequacy of informed consent to treatment, patients being the subject of medical research without their knowledge or consent or at least consent to such research being obtained inadequately, patients not being tested for diseases without their consent and patients not being informed about the fact of their infections as well as the practices of ethics committees in this regard. Where these matters have already been subject to complaint to the GMC, the processes which have been undertaken have been inadequate or at least without access to the full information to which this Inquiry has had access.

20.2 Further, the evidence heard by the Inquiry has largely been to the effect that the process of GMC complaints has often led to disengagement of the complainer. The Inquiry should recommend greater patient rights and patient involvement in the GMC process, including the right to access to evidence and to information about the progress of a complaint and the reasoning for decisions taken. The Inquiry should recommend that a review be undertaken of the processes and practices of the GMC in order to achieve these aims.

21. **Ensuring patient consent in medical care and treatment**

21.1 The Inquiry has heard copious and unequivocal evidence that patients, their guardians or representatives were not involved in decision making about their care. Proposals for the improved use of care plans within NHS in Scotland are described elsewhere in this submission. Part of the purpose of those proposals is to try to have the Inquiry recommend a mechanism whereby patient/ patient representative involvement is central to the decision-making process about treatment and care. The Inquiry ought to make recommendations about the need for further and better measures to be taken by the NHS in Scotland to achieve this fundamental objective.

21.2 In 2016, the Scottish Government planned a review of the consent process within the NHS in Scotland in light of the Supreme Court decision in *Montgomery v Lanarkshire Health Board 2015 SC (UKSC) 63*.[3111] In a March 2017 report entitled "Informed Consent – Learning from Complaints", the Scottish Public Services Ombudsman (SPSO) identified that inadequate medical consent was the most frequently recurring issue identified in its complaints investigations and recommendations to NHS Boards over the previous 5 years.[3112] A Scottish Government report entitled "Shared decision-making and consent: good practice" (19 December 2018) set out the findings of a review on the practice of consent

---

[3111] Scottish Government's Healthcare delivery plan (December 2016); http://www.gov.scot/Resource/0051/00511950.pdf

[3112] SPSO report, page 3

and shared decision-making within NHS Scotland. The report found effective shared decision-making between clinicians and patients was not yet by that time universally embedded. The then current challenge recognised by the Scottish Government was to devise effective ways for supporting cultural transformation, engaging the public and embedding best practice within mainstream clinical processes.[3113] The recommendations made at that time were:

1. ***"Bring the conversation back to the room***

Ensure mechanisms are in place to allow a rich and meaningful dialogue built on partnership to be placed at the heart of every interaction between those providing, and receiving, treatment and care. Suggested ways that this could be achieved include:

- *Provide more guidance on the effective ways of communication (including evidence-based methods and resources) to enable health professionals to clearly explain risks, benefits, outcomes and alternative treatments;*
- *Develop a national standardised repository of validated evidence-based information about treatments and procedures and the associated risks, in a range of formats;*
- *Provide clear guidance on the appropriate use of and better access to high-quality decision-making aids for both healthcare professionals and patients to guide shared decision-making;*
- *Provide staff with education and adequate skills to both communicate information clearly to the patient and to ensure the patient has understood the information (e.g. the 'teach-back' technique);*

[3113] See https://www.gov.scot/publications/good-practice-shared-decision-making-consent/

- *Provide staff with training on how to build a more supportive relationship with the patient to enhance person-centred consultations in which the patient feels more actively involved in their own treatment plans.*

2. Promote cultural transformation

Transformation is needed within the healthcare system in Scotland to promote and subsequently accept a more personalised and less hierarchical model. Patients must be recognised as equal partners in their care and treatment, feeling supported to express their own needs and priorities through a process of information-sharing, goal-setting and action-planning. This could be supported by the following actions:

- *Encourage NHS Boards to share examples of good practice in consent and shared decision-making across NHS Scotland;*
- *Increase training opportunities and embed shared decision-making into undergraduate education for all healthcare staff;*
- *Promote peer review of good consenting practice across NHS Scotland.*

3. Engage the public

In addition to transforming the role of the healthcare professional, it is important to recognise the changing role of the patient as a more active partner in their own healthcare where possible. Individuals need to be made aware of their responsibility in managing their health and wellbeing, and to feel more empowered to take an active

role in their own healthcare decisions. Suggested ways to do this include:

- *Create clear guidance for healthcare professionals on how to most effectively involve people in decisions about their health and care, with respect to individual needs and capabilities;*
- *Create patient/public campaigns to increase people's knowledge, understanding, skills and confidence to use health information and navigate health and social care systems;*
- *Make information and training on shared decision-making publicly available to encourage people to become actively involved in decisions about their health and care.*

4. Improve local systems and processes around consent and shared decision-making

To support implementation of the other recommendations, it is important to improve the local systems and processes around consent and shared decision-making to enable more meaningful conversations around healthcare with the patient and to necessitate more collaborative and supportive ways of working between health and social care practitioners. This could be achieved by the following suggested actions:

- *NHS Boards should encourage healthcare professionals to ask about (and record) any specific priorities and concerns raised by the patient;*

- *Consent discussions should encompass a range of options, including the option of no treatment;*
- *Create a system, across all NHS Boards, which enables a further conversation with the patient when there is a change in the planned treatment;*
- *Provide greater support from advocates to ensure patients with learning disabilities receive appropriate help and support. Provide support and guidance to help patients with low health literacy.*

5. Support effective ways of working

Supporting and promoting effective ways of working for health and social care staff is key in enabling better processes of consent and shared decision making with patients:

- *Improve the consent process by making better use of technology to record care-planning and shared decision-making conversations;*
- *Create a national set of principles of good consent practice;*
- *Consider an effective Scotland-wide approach to consent and standardised patient leaflets;*
- *Provide more electronic resources for healthcare staff on the benefits and risks of common treatments or procedures."*

21.3 The Inquiry should make specific recommendations about what further steps could and should be taken to improve practices designed to ensure informed consent in light of the enormous body of evidence it has heard in this regard.

GOVERNMENT PAPERS

22. Retention of parliamentary papers

22.1 The Inquiry has heard that important parliamentary papers relating to the contaminated blood scandal have not been retained for various reasons. Important ministerial papers (such as the papers of Lord Owen when he was Minister of State for Health) have been lost with no adequate explanation being provided as to why. The Inquiry should recommend that parliamentary and ministerial documents relating to contested areas of public policy be held independently from the department involved.

INVESTIGATION OF MEDICAL ACCIDENTS IN THE PUBLIC INTEREST

23. Investigation reform

23.1 The Inquiry has heard considerable evidence about the difficulties experienced by the infected and affected in having any government accept that the contaminated blood disaster ought to be investigated in a public inquiry. Term of reference 9 enables the Inquiry to consider the response of government to the disaster, including the appropriateness of its response to calls for an independent public inquiry. Under section 1 of the Inquiries Act 2005, the power to call a public inquiry is vested in a minister (as defined by section 1(2)) who may cause an inquiry to be held under the Act in relation to a case where it appears to him that (a) particular events have caused, or are capable of causing, public concern, or (b) there is public concern that particular events may have occurred.

23.2 The current system enables government to evade responsibility for its actions by allowing it to determine when medical public inquiries should take place. As far as medical accidents are concerned, there is a need for an independent body to be given the power to recommend that a public inquiry take place and by determining

independently from government whether the tests in section 1(1) appear to have been met. The Inquiry should recommend that this power be vested in the Patient Safety Commission for Scotland. The role outlined above for the Patient Safety Commissioner for Scotland requires that a power of this nature be accorded to the holder of this office in order that there be a practical consequence (in the form of an inquiry) to investigations which he or she may undertake and conclusions which he or she may reach in the exercise of the other functions of the role. It should be recommended that in reaching a view on whether or not to recommend to ministers that a public inquiry take place, it will be necessary for the Patient Safety Commission for Scotland to take account of the views of those affected by the medical accident in question, to the extent that he or she considers it reasonable. Legal representation at public expense should be available for this purpose.

B) RECOMMENDATIONS ON ALTERATIONS TO THE EXISTING FINANCIAL ARRANGEMENTS FOR SUPPORT AND COMPENSATION OF THE INFECTED AND AFFECTED

1.1 The Scottish Infected Blood Support Scheme ("SIBSS") is focused on addressing the need for support amongst the infected and affected resulting from infections caused in Scotland. The minister responsible for the administration of that scheme in Scotland at the time made it clear that the purpose of such a scheme was to provide support to meet the considerable needs of those who had been infected as a result of the blood contamination disaster and their widows. It was clear from her evidence that the SIBSS had not been set up to provide compensation to the infected and affected community, only support.[3114]

1.2 The principles upon which the SIBSS was founded are of significance to an understanding of the basis upon which the four national schemes were founded. The SIBSS was the first of the national support schemes. It was the model upon which the

[3114] IBI transcript for 18/05/2021; 36 (4 to 7) (Mairi Gougeon)

other schemes were created. It resulted from extensive thought and consultation, including with and from representatives of the NHS in Scotland who brought to bear considerable experience of the epidemiological spread of diseases caused by blood and blood products in Scotland from blood or blood products and the consequences of those infections. The consultation also took place with members of the infected and affected community. Those exercises resulted in a Financial Review group reporting in 2015[3115] and a further Clinical Review group reporting in May 2018.[3116]

C) COMPENSATION TRIBUNAL

General

1.1 The government has given a commitment to making substantial compensation in connection with the blood contamination disaster.[3117] The minister responsible for the SIBSS who gave evidence to the Inquiry on behalf of the Scottish Government accepted that it was inevitable that the government would need to pay substantial compensation to the infected and affected.[3118] The urgent need to take action on compensation was also accepted by her. She also accepted in her evidence that the payment of compensation as opposed to financial support was long overdue.[3119]

1.2 The Inquiry should recommend that the government set up a tribunal to pay compensation to the infected and affected victims of the blood contamination disaster in the UK. It should recommend that legislation should be proposed to

---

[3115] HSOC0014638
[3116] WITN4081029
[3117] See WITN5665005_0002 (letter from Penny Mordaunt MP, then Paymaster General to Rishi Sunak MP, then Chancellor of the Exchequer dated 13/07/20) - "I believe it to be inevitable that the Government will need to provide substantial compensation".
[3118] IBI transcript for 18/05/2021; 96 (2 to 7) (Mairi Gougeon)
[3119] EIBS0000705 (letter from Penny Mordaunt MP, then Paymaster General to Rishi Sunak MP, then Chancellor of the Exchequer dated 21/09/20); IBI transcript for 18/05/2021; 73 (15 to 23) (Mairi Gougeon)

Parliament which sets up the tribunal and which creates an obligation on the government to continue to fund and administer the schemes in accordance with the principles and objectives noted below.

General assessment Sir Robert Francis KC evidence to the Inquiry

1.3 Evidence was given to the Inquiry by Sir Robert Francis QC (as was, now KC) over two days, the purpose of which was to examine the basis upon which he had reached the conclusions and recommendations set out in his report. Though his report was not commissioned by the Inquiry, it was an unusually valuable source of thinking from a renowned expert in the field who had significant opportunity to examine a wide variety of material and present what we submit are evidence based, reasonable and equitable conclusions. The Inquiry should broadly endorse and accept the findings and conclusions of the report and its recommendations as to how the infected and affected should be compensated, subject to the observations below which seek (a) to add to the arguments in support of elements of the Francis model and (b) to add to areas where it is submitted that the Francis model does not go far enough. It should be emphasised that those on whose behalf this submission is presented are not of the view that any of the additions or alterations alter the central premises upon which the Francis tribunal is founded. We argue that in the interests of fairness and in the interests of the more efficient operation of the tribunal, these additions or changes are reasonable and justified.

The moral case

1.4 In his report and his evidence to the Inquiry, Sir Robert made reference to the fact that the time in which he had been asked to prepare the report was limited and that he deferred to the greater amount of evidence which was available to the

Inquiry about the circumstances of the blood contamination disaster. For what it was worth, he appeared also to accept that the basis upon he was approaching matters based on the not inconsiderable evidence which he had seen (including statements to the Inquiry about the nature and extent of the harms suffered by the infected and affected communities) led him to predicate his assessment of a compensation mechanism on the basis that he considered such a moral duty to exist. It is submitted that by making his first recommendation "irrespective of the findings of the inquiry" Sir Robert indicated that he had seen enough to justify that the government accept the strong moral case for publicly funded compensation scheme. We agree with that proposition, *a fortiori* based on the full evidence to which the Inquiry has access of culpability and consequent harm.

1.5 In his assessment (which it is submitted is not the only means by which the question of the State's moral duty to provide compensation to the infected and affected might be determined), Sir Robert expressed the view that a moral duty to pay compensation should be taken to exit where certain conditions were fulfilled, as follows:

(a) It is likely that in hindsight, the transmission of infection to these patients could have been avoided. It is submitted below that the infections and their consequences could and should have been avoided;

(b) The harm caused has been devastating and lifelong. It is submitted that Sir Robert acknowledged elsewhere in his report and his evidence that the precise individual harms suffered by the victims of the disaster had been variable. Thus, this requirement must be read as meaning that the scale of the disaster and its consequences ought to be looked at as a whole, rather than this criterion requiring to be fulfilled in every case. As a whole, the consequences have indeed been devastating and for many lifelong;

(c) Those who have been injured have lacked reliable information about the infection, treatment, or not given informed choices. This is almost invariably the case based on the evidence heard by the Inquiry;

(d) They have endured a rollercoaster of raised and then dashed expectations with regard to support and recognition of their plight. This criterion has been fulfilled by the evidence;

(e) Legal redress, even if obtainable, would be likely to be an inadequate response. The inadequacy of litigation as a source of redress for the infected and affected has been addressed elsewhere in this submission;

(f) The State has over a long period recognised that this group has been deserving of support not available generally, and has gradually recognised the inadequacy of what has been offered previously. This has indeed been accepted by the government;

(g) In a civilised and humane society, it is right for governments to recognise and offer a remedy for those who have suffered through no fault of their own from the actions of the State, or indeed natural disasters. This is correct and has been accepted by the government; and

(h) In the circumstances of the infected, and at least some of the affected, a special case has been made out for compensation over and above the support offered to date. The case is a special, indeed unique one, as it set out below.[3120]

1.6 It is submitted that should be seen as a list of factors which ought to be considered in the Inquiry's determination of whether a moral duty exists to provide compensation to the victims of the disaster. However, the Inquiry should indeed find that the State has a moral duty to compensate the victims of the blood contamination disaster in the UK. The case for the culpability of the State has been set out extensively in the rest of this submission. The circumstances of the blood contamination disaster (which should be taken to encompass not only the causation of the infections in the first place but also the way in which the infected and affected were treated by the State in the many years since the infections occurred) show that the State has been culpable in multiple ways. Harm has been caused to the community by many such wrongful acts, including the following:

[3120] RLIT0001129_0015 to _0016 @ para 2.5

(a) The exposure of patients to dangerous and potentially fatal pathogens in NHS treatment, in violation of the trust which all of the patients placed in the NHS at the time of illness or medical need. It is argued above that the importation of foreign concentrates known to be of higher risk of viral transmission was avoidable, as were infections from HIV from blood and blood products of domestic origin. In the case of HCV, the increased risk created by poor donor screening policies, the collection of blood from high risk donors and the lack of surrogate testing meant that the risk of transmission was materially increased – that was avoidable. In any event, it would be difficult if not impossible to say whether these measures could have avoided an infection in any individual case. For example, it would not be possible to say if an individual donor had an increased ALT level or was anti-HBc positive, or would have been excluded with more rigorous screening procedures. What can be said on the evidence is that the material increase in risk caused by failures in these areas was avoidable. That is as much as any individual would be likely to be able to establish about his or her infection. The increased viral load created by an unnecessary use of concentrates or transfusion of blood was avoidable. In cases of more mild or moderate haemophilia, cases were avoidable as treatment which was given could have been avoided in favour of less risky treatments or no treatment at all;

(b) It is submitted elsewhere that the occurrence of infection is, in fact, only a part of the series of wrongful acts which have been perpetrated in the infected and affected communities by the State. In fact, the harms which have been visited upon them have been exponentially increased and compounded by subsequent failures by the State. Thus, the overall, highly magnified harm suffered by the whole infected and affected community were avoidable;

(c) The fact that these treatments were carried out largely without the patients exposed to the harmful pathogens being made aware of the known risks of the treatment and hence being unable to provide their informed consent to it. This also applies in many cases to treatments for the infections as well as the treatment which caused them. The breach of autonomy was avoidable. Further, the lack of

trust and the "domino effect" created thereby were avoidable. That lack of trust led to lack of faith in the medical profession, untold psychological damage – these consequences were avoidable;

(d) The fact that many patients who had believed that their treatment had been safe were tested without their knowledge, subjected to research and/ or suffered delays in being told about their infections led to avoidable harm. These harms included those similar to the above but also lack of opportunity to make lifestyle choices to minimise the impact of infection (such as relating to alcohol or diet) and the very real terror that loved ones may have been exposed to danger unnecessarily;

(e) Many were told about their infections in ways which were unsatisfactory. Few if any received adequate psychological support or counselling at all or for many years. The consequences of the failure to give adequate explanation of the causation of the infections, to provide adequate support have caused harms which were avoidable. These include huge psychological damage;

(f) That all patients can be reasonably deemed to have been exposed to stigma at the hands of the State as a result of their infections, either directly from the NHS of other emanations of the State or at least that the State did not protect them from or treat them for the effects of that stigma caused further untold harm. Many spoke of this being one of the most difficult parts of the experience. Many were branded IV drug users, alcoholics or sex workers, within the NHS or beyond. Poor public information meant that many families were ruined. People lived secret and lonely lives as a result. This harm was avoidable;

(g) The failure on the part of the State to take financial responsibility for the consequences of the infections which it had caused has resulted in untold hardship. The inadequacy of the financial solutions offered via the trusts and schemes (either to provide adequate support or to treat applicants with dignity and respect, or to provide adequate assistance such as with regard to benefits applications), and the constant focus on the need to resort to litigation which was in most cases practically impossible created harm which was avoidable;

(h) The lack of recognition over many years by the State of the full extent of the consequences of infection, in particular the extra-hepatic manifestations of HCV

led many patients feeling ignored or disbelieved and in some cases a denial of proper treatment for these consequences. Similarly, the insistence in more recent years that patients are cured and the labelling of patients as "stage 1" without full appreciation of the depth and breadth of the effects of their infections were intolerably harmful. This was all avoidable;

(i) In the absence of the NHS having generally provided any adequate explanation for how the infections occurred, patients rightly sought answers. They were consistently disbelieved and told that their experiences did not merit public scrutiny. This was due to a false narrative being provided to ministers, as accepted in the evidence of former Secretaries of State for Health, Andy Burnham and Jeremy Hunt. In Scotland, patients were forced to litigate by way of judicial review to force a public inquiry. Campaigners were treated with disdain. The lengths they were forced to go to ought not to have been necessary. This was all avoidable; and

(j) The very real, extensive and long-lasting impacts on the affected were also avoidable. They too suffered due to all of the matters above. They too were inadequately supported by the State.

1.7 Sir Robert clearly expressed the view in his report that the infections were largely avoidable.[3121] These wrongful acts have included multiple breaches of ethical duties owed to the infected and affected community. These multiple ethical breaches are in violation of the duty that the State owed to its citizens in receipt of care from the NHS. These wrongful acts have led to multiple, complex harms. The inquiry should conclude that the combination of these multiple ethical breaches on the part of various emanations of the State and the extent and severity of the harms caused as a result have given rise to a unique moral responsibility on the part of the State to provide compensation to the victims. As a result, we submit that Sir Robert was correct to interpret the statement made by then Prime Minister David Cameron as an acceptance that in moral terms the

[3121] RLIT0001129_0058 @ para 4.66

infected had been wronged.[3122] We submit that Sir Robert was right to characterise the moral case advanced by the infected and affected to be an "overwhelming case which this group has for special treatment".[3123]

The principles upon which the Sir Robert Francis KC conclusions and recommendations are based

1.8 It is submitted that the evidence of Sir Robert Francis KC was predicated upon certain important principles (in addition to the moral case, addressed above) which merit further analysis and comment. These are principles which underpin the structure of the compensation mechanism upon which he was ultimately instructed to report.

1.9 First, it was a correct interpretation of the existing schemes for support that they provided support payments and not compensation.[3124] We agree with this assessment. This was an important principle and (as is stated above) has been accepted by government in the various evidence sessions on them. Important practical elements of the proposed scheme flowed from this including the fact that past payments should be disregarded for the purposes of the determination of past compensation. The rationale relating to their role in the calculation of future payments is addressed below. As to past payments, it is, in our submission, implicit in the Inquiry's interim report that it accepts the principle that past support payments should be discounted for the purposes of calculating past compensation payments.

1.10 Secondly, that for the compensation mechanism to serve its purpose the community which might stand to benefit from the infected and affected communities required to "buy in" to the scheme for it to serve its purpose, namely for the State to discharge its moral duty to them. It is submitted that this was an

---

[3122] RLIT0001129_0048 @ para 4.26
[3123] RLIT0001129_0058 @ para 4.65
[3124] RLIT0001129_0127 @ para 10.3

integral part of Sir Robert's approach. We agree with this principle. It was why the following concepts were indicated as part of the thinking of Sir Robert early in his report - Respect for dignity, Collaborative, Choice, Individualised, Inclusive, Non-technical, Accessible and Ease of proof.[3125] In his report, in rejecting a purely common law/ Irish based model of compensation, he based his opinion in no small part on what was likely to "meet their needs".[3126] It was not enough that the infected and affected who would be entitled to the payments which he deemed them entitled would be paid. His position was that the engagement of the community with that entitlement would in itself be part of the compensation, of giving them a sense that they had after so long been believed by the State and that they were receiving justice. This was consistent with the principle of self-assessment within some of the support schemes upon which so much of his logic appeared to be based. In this, the compensation scheme envisaged by Sir Robert served two purposes. It was a means by which the infected and affected could be provided with financial compensation which they deserved as a result of the cumulative breaches of moral duty by the State. In addition, the scheme itself was part of the compensation – being treated with respect by a State entity and being believed were part of the rightful recompense which the State was providing.[3127] In our submission, it is important that the compensation tribunal process does not involve the State further compounding the harms which have been suffered by the applicants. A process which does not respect their positions creates a real risk that the process will re-traumatise them and will compound as opposed to address the harms which they have suffered. The possibility that this may be the outcome of the SIBSS was a matter which was considered in detail as part of the Clinical Review group. The principle of self-assessment was therefore unanimously endorsed by that group (including the medical professionals who sat on it, whose endorsement of this approach was specifically recorded in the Group's report) as the most

---

[3125] RLIT0001129_0016 @ para 2.6
[3126] RLIT0001129_0022 @ para 232
[3127] It is submitted that this was why, from the outset of his report, Sir Robert spoke of the report being the beginning of a pathway to the "financial **and other** support they desperately need" - RLIT0001129_0008 @ para 1.2

appropriate means of weighing and balancing the various considerations relating to the approach which the scheme should take to assessment.[3128]

1.11 Thirdly, that the evidence which he had examined demonstrated that the existing support schemes which are predicated upon self-assessment and believing the applicants function well.[3129] We agree with this assessment and also with the importance of it in formulating the new compensation tribunal scheme. This is an important element of the Inquiry's consideration of how assessment should work within the new compensation scheme. Sir Robert appeared to be able to consult widely on how the current schemes function.[3130]

1.12 Fourthly, the basis upon which payments should be assessed should be a combination of (a) established common law principles which have evolved as the way that the law has seen fit to provide financial compensation for the variety of losses which tend to be suffered by individuals who have been harmed directly or indirectly as a result of medical treatment (b) a clear conclusion that the types of losses which have been suffered by this community have particular patterns and characteristics which means that the moral obligation said to be incumbent on the State means that additional heads of compensation are appropriate in this case. We agree that established legal principles should form the basis of the compensation mechanism, although we argue below that these need to take account of broader legal principles from across the UK as well as the moral obligations which we say arise from the particular circumstances of the disaster, if the logic behind the Sir Robert Francis analysis is to be properly implemented. We agree that a bespoke analysis of the types of loss which are common in this community require to be taken into account and that the effect of that is that certain bespoke heads of claim should be included in the new scheme. The clear objective of the scheme is to allow for all applicants to be compensated without the need to go to court. He proposes a surrogate for court award, based on the common law with bespoke heads of claim recognised where there is a moral case for them to be in this community. The scheme as proposed by Sir Robert is

---

[3128] WITN4081029, pages 8 to 9
[3129] IBI transcript for 11/07/22; 89 (1 to 19) (Sir Robert Francis)
[3130] RLIT0001129_0014 @ para 1.23

predicated on a moral duty incumbent on the State to make the payments. There is no pre-existing definition of the moral duty – it is bespoke to this situation. His evidence was clear in word and substance that the moral duty provided, in his view, a duty not only to compensate as the common law would but to compensate in ways which it would not. The law is a guide but the scheme must necessarily go beyond what the law would do if the moral duty of the state towards this uniquely impacted community is to be truly recognised and discharged. This is a principle which is expanded upon below – multiple harms, resulting in compounded losses requires a bespoke solution.

1.13 Fifthly, he recognised that there was a need to provide a system of compensation which operated on the basis of a settlement with a community whose loss had been caused by a similar route or, in our submission, similar routes based on the community of routes of loss (the direct or indirect effect of infection by blood or blood products within the NHS) as well as many other elements of the experience which were common enough to be deemed likely to affect all applicants or enough that it seemed equitable that they should be deemed to affect all applicants to a lesser or greater extent. We agree that this is a principle which ought reasonably to underpin the compensation tribunal system. This has important implications for the way that the tribunal ought to go about the assessment of the compensation payable. The reasonableness of the community approach to the settlement of the matter is also closely linked to the tariff based approach which he advocated. It would be impractical and unreasonable to expect that all cases would be assessed as in the Irish scheme which simply works on the principle of a normal civil law assessment of damages. In any event, by proposing his tariff system, Sir Robert deemed this to be unnecessary as certain heads of claim could fairly be categorised on the basis of the whole evidence heard by the Inquiry into bands, while others could be underpinned by such bands (such as average or tariff based rates of pay) into which individual could be allocated depending on their personal circumstances, with the possibility of a more individualised or bespoke approach, if that proved necessary in the interests of fairness.

1.14 Sixthly, connected to the above principle was the importance of parity. He was of the view that the same principles should apply to the scheme across the UK.[3131] The disaster has caused many and varied consequences across the country. Clearly, there have been some who have been more impacted and affected than others. The culpability of the State towards these individuals differs depending on the circumstances of the infections but the culpability and hence moral duty of the State remains nonetheless. It would undoubtedly be damaging if there were to be differences in the principles which were to underlie such a system would be impractical to operate. Sir Robert rightly recognised that there were common causes for what happened to the infected and affected, though their individual experiences and losses may have differed greatly. He acknowledged that to an extent the principle of compensation involved grouping individuals together.[3132] The is a principle which has been recognised by government in the changes to the support schemes which were put in place from around the spring of 2021, which sought to bring parity to the way that main support awards were made. In response to specific questions about the lowest common denominator approach, Sir Robert accepted that his approach had been informed by English law and not Scots law. He accepted that the need to keep the matter out of the court was a factor behind his thinking[3133]. However, he suggested that the approach as to the influence which one legal system should have over the UK wide approach should be a matter of discussion amongst the governments.[3134] These are matters which, in our submission, should not be left to such discussions, at least as far as the Inquiry's recommendations are concerned. Principles of parity and fairness require, we submit, that the Scots law approach, which is both rooted in the law and relatively easy to apply to fatal cases ought to be adopted in the UK-wide scheme, as is submitted below.

[3131] IBI transcript for 11/07/22; 62 (8 to 14) (Sir Robert Francis)
[3132] RLIT0001129_0013 @ para 1.20
[3133] IBI transcript for 11/07/22; 44 (Sir Robert Francis)
[3134] IBI transcript for 12/07/22; 92 to 94 (Sir Robert Francis)

1.15 Seventhly, the conclusions he reached were based on the evidence he had and the legal principles he applied. These were admittedly limited.[3135] We submit that these are important factors which ought to be taken into account when the Inquiry makes its final assessment of the way that the new compensation tribunal should work. Sir Robert's report was based on a limited time frame within which he required to work. The efforts made by him during that time are formidable. He had the advantage of being able to take account of evidence which had been gathered by the Inquiry. However, on his own admission, the Inquiry was better placed to be able to assess the full range of evidence to which it had access and which it had the opportunity to consider more directly (for example in its many oral evidence sessions) and more widely. Our interpretation of this is that the conclusions reached by Sir Robert regarding the important general features of the community which he deemed entitled to compensation on a moral basis were sound. However, we argue that in certain areas the disadvantage which he had, having been exposed to a large though not the full body of evidence available to the Inquiry means that in certain areas the additional evidence should lead the Inquiry to reach slightly different conclusions from those reached in the Francis study. In addition, as indicated above, we argue that the legal principles which can be drawn upon to ensure a fair settlement of the matter with the infected and affected communities, in particular the principles of Scots law.

1.16 Eighthly, and linked to the fifth principle above was the principle of simplicity. This is linked to the community settlement principle. He was against an adversarial scheme like the Irish scheme. In this regard, we note the evidence of Brian O'Mahony who gave evidence regarding the operation of the Irish scheme. Whilst we accept that he advised that the scheme was non-adversarial (albeit with a potential shift to a more adversarial position taken by the tribunal in more recent times), it was clear that the process required extensive reports being provided by the applicant, ahead of a hearing at which the Department of Health was represented and would play an active role in the proceedings.[3136] In those

---

[3135] RLIT0001129_0010 @ para 1.9

[3136] IBI transcript for 08/11/22; 38 (18) to 43 (14) (Brian O'Mahony)

circumstances, there appears to be at least elements of adversarial proceedings which, as Mr O'Mahony identified, might be increasing. To an extent, we agree with Sir Robert's principle of simplicity in this regard. It is important, we submit, for the scheme to be inclusive and based on engagement with the applicants. It cannot be overly forensic as that would (a) be very costly, diverting funds from the infected and affected communities to the administration of the scheme and (b) mean that the assessment element of the scheme may drag on for years, at huge cost and trauma to the applicants. Neither of these outcomes is desirable. A scheme which ran the risk of exacerbating or compounding the harms further must be avoided at all costs. It should be noted that one of the opening statements made by Sir Robert in his report was the need for a degree of compromise between the desire for a bespoke assessment of loss and the competing interests of the need to get payments made and lives to an extent settled, coupled with the variability of the losses suffered by the infected and affected.[3137]

1.17 Ninthly, he recognised that the system he was proposing should incorporate an element of presumption about applications. Ease of proof was one of the key principles upon which his scheme was built.[3138] At para 2.19 of his report, he stated in connection with proof of eligibility in the sense of infection having been caused by blood or blood products that "Generally, the recollections of the applicant should be accepted as true, unless there is overwhelming evidence to contradict them." This is a principle linked to the simplicity principle above, with which we agree. It is also linked to the need for the infected and affected community to have a degree of buy-in to the process, which we also think is of fundamental importance, in particular in light of the understandable scepticism which Sir Robert experienced amongst that community in the course of his work.[3139] We submit that there should be a general rebuttable presumption that factual matters advanced in support of an application, not just in relation to the circumstances of infection, are accurate. Given the fact that much time has passed since the events in question and since the time of evidence relevant to the assessment of a claim,

---

[3137] RLIT0001129_0011 @ para 1.12
[3138] RLIT0001129_0016 @ para 2.6
[3139] RLIT0001129_0010 and _0011 @ paras 1.11 and 1.12

it is likely that the testimony of the applicant on matters of fact is likely to be the most reliable source of information. This applies *a fortiori* in cases where medical or other State records have been destroyed, as has happened in many cases. It is assessed in detail below. This approach would respect the view expressed by Sir Robert in his oral evidence to the effect that there was a difference between matters of fact and matters of opinion[3140], though of course his simplicity principle and consequent tariff model meant that there should be little need for expert assessment in the compensation tribunal.

1.18 Tenthly, he recognised that the body of evidence which he had access to indicated that there was an equitable and reasonable basis for compensation being paid (a) for heads of claim which might not otherwise be recognised by the law and (b) to affected categories of people who had not been included in support schemes to this point and whose rights to compensation might not otherwise be recognised by the law. We agree with this principle. It is based on the unique circumstances of the blood contamination disaster and the very particular and complex harms which it has caused. Examples of such heads of claim are elements which reflect the loss of affected victims of the disaster which might not be available to them in law and also damages to reflect the unique harms caused by breaches of autonomy, such as being treated without consent and being unwittingly involved in medical research.

1.19 Eleventhly, he recognised the importance of timing, both in the need for interim payments (recommendation 14) but also more generally. Again, this is a sound principle, given the amount of time it has taken government to acknowledge and act upon its moral duty to the victims of the disaster. Further delay in recognising this duty and in implementing the compensation scheme would further compound the already significant harms.

The features of the proposed new compensation scheme

[3140] IBI transcript for 11/07/22; 176 (21) to 177(5) (Sir Robert Francis)

1.20 The Inquiry has heard a good deal of evidence which should inform its final recommendations about the financial support and compensation which ought to be made available to the infected and affected in the future. There are equally a number of features about the bespoke schemes which we submit should be recommended which need to be considered. As a general principle, we are of the view that the Inquiry has been able to amass a uniquely comprehensive body of evidence about matters which are relevant to precisely what the recommendations in this regard should look like. In the first place, we make the following submissions regarding what we say the evidence heard by the Inquiry should result in the support and compensation schemes looking like, before dealing below which the issue of a fair approach to quantification of compensation and support. It is submitted that these solutions are consistent with not only the very useful evidence heard from Sir Robert Francis but also the rest of the evidence heard by the Inquiry.

1.21 The evidence heard by the Inquiry clearly demonstrates that there has been inadequate compensation for those for who have suffered the greatest loss as a result of the infected blood disaster. It is clear from the evidence heard by the Inquiry that certain infected or affected individuals have suffered loss as a result of the infections which exceeds the support which is provided to them by the governments of the United Kingdom. As has been recognised by the UK government, the injustice which has been suffered by such individuals requires to be recognised by the availability of payments equivalent to damages which would have been available to such individuals, had they established liability in court.

Membership of the tribunal

1.22 As noted, the administration of the compensation tribunal should operate separately from the current schemes. A tribunal of independent, legally qualified members should be appointed by an independent panel made up of *inter alia* lay

representation, representation from the infected and affected community, the Dean of the Faculty of Advocates in Scotland *ex officio* and the President of the Law Society of Scotland *ex officio*.

The medical and legal panels and the Arms-Length Body

1.23 We broadly endorse the concept of tariffs for certain types of awards (as per recommendation 10). These tariffs seem best suited to the injury, social impact and autonomy awards. A more bespoke approach to more individualised awards, such as wage loss, bereavement financial awards (dependency claims), and care costs might be necessary although along with the use of tariffs to fix broad bands of wages which might be earned or care costs which might be incurred could be applied to make the process smoother and less adversarial. In setting tariffs, this Inquiry should provide guidance by way of principles to inform the approach of the panels. In order to pay due attention to the patient buy-in and simplicity principles, patient representation on them should be allowed so that the views of the infected and affected community can be properly taken into account. The lack of proper patient representation in previous trusts and schemes by liaison committees or user trustees provide a cautionary tale about what happens when the community is ignored. Patients and their representatives have shown themselves to be experts in the losses suffered by their community and the ways of addressing them. In addition, the Inquiry should stipulate that the medical panel should have regard to the need to avoid cruse categories such as the stage 1 and 2 in the Skipton Fund. It should be directed to have regard in its assessments to (a) the range of conditions said to have been suffered by the infected and affected and accepted by this Inquiry as the result of infection or its treatment (b) the evidence of the expert groups in that regard and (c) the results of research into the as yet less well known effects of treatment with blood or blood products which we have advised should be undertaken with money to be put in a research fund

for that purpose. The presumption below must be respected in the rulings as to how medical assessment will be approached.

1.24 In general terms, the role contemplated by recommendation 6 for the medical and legal panels in fixing the tariffs which will be fixed under recommendation 10 is an approach which we accept, subject to the observations above. As regards levels of payment which might be made, we think that in certain areas at least, this Inquiry could fix the type of payment to be made and, in places, the level of award or minimum award which should be fixed. For example, and as is argued below, tariffs for bereavement damages could be fixed relatively easily by this Inquiry (as set out below) in a way which would minimise uncertainty and allow progress to be made to payments being made. Other such area might include a basic award which could be made to HCV clearers, as is set out blow. On one view, the recommendation to have a compensation tribunal may mean little if the responsibility to set all the tariffs is abrogated to those who have not heard all the evidence. This Inquiry had access to a unique body of evidence, including expert evidence to enable it to assess these matters, in particular in line with the Francis principles, which are interpreted above and are key to the proper and fair operation of the tribunal scheme.

1.25 In addition, we disagree that the way that recommendation 10 is worded accords with the findings of the Francis report. The recommendation provides that the framework of compensation should be set "at rates which broadly reflect comparable rates of common law damages and other UK compensation schemes". It is important that the rates which are fixed have regard to all legal systems of the UK, including Scots law in accordance with the parity principle and also in accordance with guidelines or minimum amounts which we stipulate below can be set by the Inquiry. As Sir Robert recognised in his evidence, there are elements of his scheme which go beyond common law, such as direct awards made to the affected or the social impact or autonomy awards which are not recognised as separate heads of claim at common law. Some further guidance as to the rates which might be used for these awards or a way of fixing them should be proposed by the Inquiry. In addition, the unique circumstances of the blood contamination disaster make awards made under other UK compensation schemes largely

irrelevant to the bespoke circumstances which Sir Robert has so ably recognised in his report. Using other UK compensation schemes as a guide is vague and unnecessary. The panels should be directed to be guided by the findings of the Inquiry and the common law of the UK, recognising the law of the devolved nations in this regard. The "assessed basis for defined financial losses" should be subject to the presumption that factual matters asserted by claimants are accurate, in relation to all elements of their claims.

1.26 We agree with the concept of the Arms-Length Body, as set out in recommendation 16. The question of appeals is dealt with below. We consider that the principles by which that body is required to abide in its terms of reference can be expanded upon by this Inquiry, in accordance with the Francis principles set put above and the remaining principles set out in this part of our submission. The advisory forum should include representatives of Haemophilia Scotland and the Scottish infected Blood Forum. The accountability to Parliament should include accountability to the Health Committee of the Scottish Parliament and ultimately to the Scottish Parliament. Safeguards should be put in place to eliminate the chance of the accountability requirements being manipulated as a way of the government controlling the tribunal or the independent ALB.

Legal representation

1.27 The evidence heard by the Inquiry was that applicants to trusts and schemes had often suffered difficulty and hardship in seeking to engage them alone. There should be funding made available to applicants who wish to make an application to the compensation mechanism to seek and obtain legal advice in connection with the claim, which should include the ability to seek independent medical and other expert advice as necessary.

1.28 It is currently envisaged that a member of the tribunal would assess what expert evidence is likely to be necessary for (i) the initial presentation and (ii) the further determination of the claim, in particular where an attempt is made to rebut the

presumption by the State. Rules governing matters such as this would be laid down by statutory instrument in the normal way. Though there is a laudable aim contained in recommendation 16(a) for simplicity, accessibility and involvement, the past experiences of the traumatised community will not enable this to be achieved without trusted, independent advisors. The processes of the tribunal are necessarily complex, even though they have been carefully tailored not to be unnecessarily so. Funded legal representation for applicants is a necessary part of the process, even if its aims are to avoid adversarial approach. It will facilitate the aims of the tribunal to have legal representation, not undermine them. Though recommendation 17 contains otherwise important and laudable measures designed to support applicants and the process, it should be altered to include the right to paid legal representation. We respectfully submit that the analysis presented by Sir Robert has been influenced by how impressive he found similar procedural mechanism in the 9/11 scheme.[3141] Given the evidence which this Inquiry has heard about the experiences of the infected and affected community, along with the age of many applicants and/ or their ill health (including brain fog) and the likely complexity of the tribunal scheme, the comparison, though useful should not have been as persuasive. The differences were acknowledged by Sir Robert in his report.[3142] Legal representation will be essential.

1.29 Given the aspiration that claims made under the tribunal would be able to be quantified and agreed without the need ultimately to resort to the decision of the tribunal, the tribunal rules should provide for an opportunity for the parties to seek to discuss and resolve the issues in the application extra-judicially. The tribunal should be given case management powers to as to enable directions to be given as to how matters might be settled between the parties without the need to resort to a full tribunal determination of the application. During the course of his evidence, Brian O'Mahony noted that he had not heard of any 'settlement process' in the Irish Compensation Scheme.[3143] It is submitted that the need for the tribunal to hear each and every case may well have contributed to the length of time that

[3141] RLIT0001129_0091 @ para 8.9
[3142] RLIT0001129_0091 @ para 8.10
[3143] IBI transcript for 08/11/22; 43 (17) to 44 (11) (Brian O'Mahony)

applicants to that process have taken to receive their compensation. In accordance with principles espoused elsewhere in Sir Robert's report, there is a need to reduce the risks of unnecessary delays throughout the process. Delays that could be avoided by permitting settlement of applications by way of consent between the 'parties' cannot be allowed in a scheme recommended by this Inquiry. But, recognising the unique harms visited upon the community throughout their lives must also recognise the difficulties that at least some individuals will experience in trying to engage in any settlement process. Accordingly, this process would be likely to benefit from legal representation.

Structure

1.30 It could be suggested that the compensation tribunal could be operated wholly as part (though a distinct part) of the Redress Agency, as recommended by the Cumberlege report.[3144] The administration of the schemes across the UK could be shared, however, to minimise costs, though the principle of local delivery in recommendation 18 is important to maximise the chances of accessibility and effectiveness. The funding of the local delivery should also come from a fund ring-fenced for the purpose (in accordance with our general position on funding) so that health care delivery in Scotland is not undermined by the need to find funding for the operation of the scheme or the payment of compensation by it. As is argued elsewhere, it would seem to make little sense for Scottish patients to suffer as a result of the fulfilment of a moral duty to pay compensation to those who have suffered as a result of the state's past failings. In answering questions about the possibility that the tribunal service might be appropriate to administer the compensation scheme, as opposed to his ALB, Sir Robert made clear that he did not want the operation of the scheme to be undermined by its funding being diluted within the other considerations within Ministry of Justice budget.[3145] The

[3144] Appendix 3 to the Cumberlege final report, page 215 from para 13
[3145] IBI transcript for 11/07/22; 57 (3 to 7) (Sir Robert Francis)

same result would eventuate from the funding coming from the health budget. This must be avoided at all costs. The Inquiry should make a recommendation to that effect. In addition, Sir Robert made it clear that open-ended government funding would be necessary to underpin the compensation scheme.[3146] The Inquiry must recommend that the scheme have open-ended funding. Otherwise, it will not work and its principles and goals will be undermined.

1.31 It is important that there be a robust appellate procedure which should be judicially led as per recommendation 16(b). An ultimate appeal against the decisions of the compensation tribunal in Scotland should be available on matters of law to the Inner House of the Court of Session. It is important that matters are dealt with locally for Scottish applicants.

Legitimate concerns about lack of accountability and control

1.32 The decision making around the creation of parity amongst the UK schemes has led to the genuine concern that actual control over the operation of the regional schemes has been taken by the UK government which ultimately controls the funding the four schemes. For example, the Inquiry heard consistent evidence from the ministers in charge of the three devolved schemes that changes to the way that the schemes were to operate was announced unilaterally by the UK Government. It has proven important to the infected and affected on whose behalf this submission is presented that the control over financial support be exercised by the Scottish government, irrespective of the ultimate source of the funds. This has enabled meaningful dialogue with the infected and affected community as to the objectives of such financial schemes, the priorities of the local community for whose benefit it exists and the best means of achieving its objectives. This arrangement has also created a local political and administrative accountability for circumstances where things have not operated well. Such

[3146] IBI transcript for 11/07/22; 61 (7 to 18) (Sir Robert Francis)

engagement has been and would be unlikely at UK national level. Further, the administration of the SIBSS within Scotland has enabled those who are in charge of it on a day to day basis to gain an understanding of local problems and needs such as the particular needs of Scottish applicants based on geography or local care or treatment provision. This has rendered the system more effective than it would be, were it to be controlled or operated on a UK national level. It is imperative that the SIBSS continue to be controlled and administered in Scotland for the infected and affected in Scotland.

Concerns and considerations regarding the lack of future commitment and funding

1.33 The evidence heard by the Inquiry in connection with the support schemes was instructive in this regard and was to the effect that two broad problems arose. The first concerns the lack of commitment/ obligation on the part of the UK/ Scottish government to continue to fund the existing support schemes. The then UK health minister, Matt Hancock MP, gave public assurances to the Inquiry to the effect that the best assurance that the infected and affected community could be given was for the responsible health minister to provide a public commitment to the continued future existence of the schemes. Though the commitment which he demonstrated in his evidence to the ongoing support of the schemes was welcome, it was by its nature subject to the political whim of the day. It is imperative and proportionate that more of a commitment be given to putting the financial support schemes, including the SIBSS on a more secure footing for the stability and future protection of those who rely so heavily on them.

1.34 A second and related issue was the dubiety about the future funding of the schemes. The infected and affected communities have given powerful testimony throughout the UK, including in Scotland, about the uncertainty by which their lives have been characterised since the infections occurred. Certainty in the existence of a continued funding stream for the stability of the futures of the infected and affected is an essential feature of any civilised and functional support

scheme. There are two aspects of the current arrangements in this regard which have proven unsatisfactory, namely (a) the lack of certainty as to which government's health or other budget are to be used as the source of the funds for the schemes ("the source of funds problem") and (b) the apparent requirement that the funds be taken from the health budget (either on a national or regional level) such that funds required to be taken from current healthcare needs in other areas ("the health budget problem").

1.35 The source of funds problem was characterised by the evidence of Vaughan Gething who gave evidence about the source of funds for changes in the levels at which payments would be made under the WIBSS which had recently been announced by the UK government. He described funds for increased payments as having been found from the then current Welsh health budget, the extra funding for the increases having been found "down the back of the departmental sofa" within the existing UK Department of Health budget (which had therefore resulted in no Barnett consequential payment to the Welsh or other devolved administrations).[3147] This meant that changes at a political level had been announced and the money had been found to support those changes *ex post facto*. The changes included considerable uplifts in the regular payments to be made to those who had been infected, a feature which the changes in Wales shared with the changes announced for the other constituent parts of the UK, in particular for the large cohort of those who have suffered HCV infection but who have not reached the stage of cirrhosis of other similar condition (previously known as the "stage 1" applicants). It is submitted that this is hardly a sustainable model upon which to structure a stable and sustainable scheme of financial support for the future. The fiscal control of the schemes and the stability which the infected and affected so much crave and deserve necessitates a more coherent plan as to where the funding will come from in future.

1.36 The related health budget problem concerns the requirement at present that the funding for the financial support schemes be derived from the health budget either nationally or regionally. This creates the problem that money which is both

[3147] IBI transcript for 20/05/21 (Vaughan Gething); page 100 (22) to 101 (9)

needed and deserved for the infected and affected can be and often is characterised as detracting from the healthcare which the government(s) can provide to other users of the NHS. Though the contaminated blood disaster was caused by failings on the part of the NHS and the Departments of Health (as well as regional departments dealing with health matters) there is no need in logic or equity for the budget for the continued funding of the support schemes to be derived from health budgets. They are designed to deal with current healthcare provision. The schemes are not designed to deal with that. They are designed to deal with the financial consequences of the disaster and the financial need which it has created. Such a financial arrangement has allowed those who would seek to argue against the existence or extension of the schemes to define them as taking money away from the very legitimate needs of the rest of the NHS. This has, once again, added to the stigmatisation of the infected and affected who are thus seen, and more importantly often unjustifiably see themselves, as a burden on others relying on the National Health Service. This must stop. There is no need for the continued support of the infected and affected to be characterised as a drain on limited NHS budgets in future.

1.37 The suggestion that it would be appropriate for the Inquiry to recommend that all payments from the compensation tribunal and indeed from the support schemes should come from a ring-fenced fund from Westminster, outwith the normal arrangement whereby budgets are allocated for health matters within the devolved arrangements is not without precedent, even within this community. The evidence heard by the Inquiry was that HIV payments both before and after the creation of the current support schemes were paid by the UK government, for example to the Scottish government separately from the funding used for their normal health budgets.[3148] This arrangement should continue and be extended to all such payments in order to ensure that these payments do not impact upon the financing of healthcare and therefore the health and care of other patients.

[3148] IBI transcript for 18/05/2021 ; 45(11) to 48 (6)

1.38 Thus, we submit that the schemes (and the compensation mechanism set out below) should be funded separately from the Department of Health budget and from the budgets allocated to the Scottish Government to pay for health matters.

The compensatory mechanism – entitlement and calculation

General

1.39 The scheme should be open both to infected and affected people, who wish to assert an entitlement under the mechanism to payment in addition to the sums to which they are or will be entitled under the SIBSS.

1.40 The tribunal should have the power to award interest, which should in general terms be should be payable on past awards at half the judicial rate of 8% as is the usual position under Scots law. This is an important provision which seeks to rectify the injustice caused by the many years of government inaction in relation to the proper compensation of those who have suffered significant losses as a result of the contaminated blood scandal.

1.41 The tribunal should have the power to make lump sum payments or periodical payments to a successful claimant. Registrants of the scheme should be entitled to make an application to receive lump sum as opposed to future regular payments which the scheme will guarantee based on predicted life expectancy.

Eligibility – proving infection

1.42 In his assessment of this element of the compensation tribunal, Sir Robert Francis was of the view that an avoidance of legalistic concepts of standard of proof would be the most appropriate in the search to satisfy the standard that it is likely that

an infection have been caused by NHS blood or blood products.[3149] We agree. In this as in other elements of the tribunal the applicant's factual account should be rebuttably presumed to be true. It is fair to treat eligibility on a scheme for eligibility for the compensation tribunal. This should apply based on admission to any previous trust or scheme. It should also be recommended that the reverse be true – ie proof of eligibility for the compensation scheme with its proactive investigatory approach should result in eligibility being established for the purposes of the support schemes. Further, this should also be applied across cases arising from the same infection. Where there was eligibility on a scheme or for the tribunal in a case of infection, all applicants whose cases arise from that infection should be automatically entitled to be admitted. For example, it may be that an infected person, now deceased, was admitted to a scheme in life. His child may now be able to apply. The child should be automatically admitted to the tribunal scheme without the need to re-prove that the infection occurred as a result of NHS treatment. This should be a helpful step in reducing the administration associated with an individual being accepted onto the scheme. It may also allow for further interim payments to be made earlier than might otherwise be the case (see below).

1.43 The recommendation related to the proof of eligibility is recommendation 3. The addition of the words "or exposed to HCV as a result of treatment with blood, blood components or blood products during the course of NHS treatment" would clarify matters. This is because the scheme (as Sir Robert accepted in his evidence) should include natural clearers who were not infected but whose exposure has given rise generally to certain adverse consequences (see submission below). In accordance with the submission elsewhere the words "HBV of the defined level of severity" should be replaced with "chronic HBV". Also, the words "at any time" should be inserted at the end of sub-paragraph (b) and would remove the need for sub-paragraph (c). It does not lend itself to easy application and appears to have been based on certain assumptions about, for example, there being a cut off for HIV infection which does not exist within the schemes as they currently

[3149] RLIT0001129_0018 @ para 2.15

operate. The sub-paragraph also assumes a number of things which are not supported by the evidence, for example that technological advance was the only way that viruses could have been avoided. Informing patients of the risks, different treatment regimes and better use of lifestyle advice could all have had that result and are not to do with scientific advances like heat treatment. It is submitted that the proposed wording is much simpler and fairer. The consequent requirement would be the need (subject to the presumptions detailed elsewhere) for the tribunal to be happy that there was exposure or infection caused by NHS treatment. As a result, sub-paragraph (d) could be removed and replaced with the following to cover secondary infections, as follows "or (c) that their infection with HIV, HCV or chronic HBV was likely to have been transmitted to them by a person who fulfils conditions (a) and (b) above."

1.44 Recommendation 4 also deals with questions of eligibility, though its terms are somewhat confusing as to whether this is the extent of its application. The desire to avoid legalistic standards is laudable but where it may be necessary to establish that certain things were "likely" in cases where the State seeks to rebut the presumptions, it is submitted that it is somewhat unrealistic. We argue elsewhere that for this and other reasons, legal representation will be necessary. It is important to understand that, despite these very laudable principles in recommendation 4, the general past experiences of the infected and affected community have led to an understandable mistrust for State entities like the contemplated tribunal. It is agreed that eligibility should be automatic if already registered for a scheme (or indeed eligible within any previous trust or scheme) and collaboratively supported "in accordance with the principles out in recommendation 4 below. Eligibility is accepted if the information available points towards eligibility and there is no strongly persuasive evidence which contraindicates eligibility" This first section can be moved to be part of recommendation 3 which would then clearly just be to do with eligibility. The new recommendation 4 should contain the general principles which apply not just to questions of eligibility but also more widely, as follows:

"The scheme should (a) in general, apply a presumption that statements of fact made by an applicant are correct (b) sympathetically support the applicant by obtaining any required information and documentation (c) not require applicants to repeat information already provided to the support schemes.

1.45 The broad attempt to define the eligibility criteria to get access to the compensation scheme needs to be clearer, we submit than the current wording of the recommendation.

Eligibility – qualifying infections

HBV

1.46 The wording of recommendation 3 is considered above. Those infected with Hepatitis B and the victims of other pathogenic exposure from blood or blood products also merit inclusion in the schemes, as do those who have been affected by their infections and (in the case of HBV) those who are secondary infections, for example by sexual transmission (after proof of such transmission was likely). There is no reason in logic or equity why those who have been primarily or secondarily infected with HBV, CMV or other pathogens as a result of treatment with blood or blood products should be excluded from the compensation scheme. The Inquiry should recommend that provision needs to be made for their inclusion.

1.47 In his report, Sir Robert Francis had some difficulty in moving from the position previously adopted by the support schemes, namely that those who suffer from HBV infection alone should not be included as eligible for payments under the compensation scheme *per se*. The reasons which he gave for that were:

(a) That the effects of the condition were thought by him to be generally mild. This is neither consistent with the evidence, not does it sit well with his acceptance that it can cause serious disease, including cirrhosis.[3150] We submit that this is not a reason for excluding HBV infections from the scheme but is a reason why quantifications in individual cases might be lower than in the case of other infections;

(b) That treatment was available to suppress the most serious of infections. Again, we submit that this is a matter which should affect quantum and not eligibility (see below); and

(c) He acknowledged that the exclusion of HBV from his scheme should be reviewed in light of all of the evidence heard by the Inquiry on the consequences of the disease.

1.48 Though its investigation of these matters has been far more limited than the investigation of the circumstances in which individuals have become infected with HIV and/ or HCV from blood or blood products, the Inquiry has evidence of individuals becoming infected with both HBV and HCV from blood or blood products. It seems reasonable that the culpability of the State in relation to HBV infections in particular may be claimed to have been less than in relation to HIV or HCV as tests were generally introduced for the detection of the virus from around 1972 and a vaccine was generally available from 1982. Thus, it might be argued that the State did more to prevent these infections than it did in relation to HIV or HCV. However, it is neither fair nor reasonable that the severe consequences suffered by some should not be recognised as part of the scheme simply because others have not been affected very much. The very fact that these infections have been excluded from support schemes and ignored by government over the years will have, one can safely assume, had an impact on these individuals. The fact that HBV is transmitted by similar routes to HIV means that it seems reasonable at

[3150] RLIT0001129_0017 @ para 2.8

assume that these individuals will also have suffered a degree of the isolation and stigma associated with that condition, both within the NHS and more generally. The same applies to CMV, to the extent that it is blood borne and poorly understood. All of the patient who have been infected with these conditions have been infected at a time when they needed State care and were in a vulnerable state. Given that harmful Interferon based therapies have been used in the treatment of HBV and HCV, it is reasonable to assume that the effects of those treatment well-known to the Inquiry in its examination of HCV, will also have afflicted HBV infected individuals.[3151]

1.49 Further, the Inquiry does have evidence of individuals having suffered serious consequences as a result of HBV or CMV infection. Some individuals who fall into this category have been infected as a result of blood or blood products received in Scotland. One CMV infection in an immuno-suppressed patient occurred as a result of a blood transfusion in Aberdeen. As a result, the patient in question went blind. The statistical information available to the Inquiry suggested that 90% of children who were infected with HBV went on to develop chronic disease (with a lifetime risk of cirrhosis of 15 – 40%)[3152] and in those who were infected as adults, liver disease can develop, though only in under 5% of cases.[3153] Thus, it would be inaccurate to assume that HBV infection via blood or blood products cannot become chronic and indeed serious in a large number of cases.

1.50 In his report, Sir Robert Francis recommended that the entry point for those infected with HBV should be that an applicant would have to show that he or she fell into the category of "defined serious cases".[3154] This is too nebulous a term and is based on the limitations of his understanding of the potential consequences of the condition. In the same way as the use of the "stage 2" criterion for qualification for certain awards under the Skipton fund, was, in time, deemed to be too crude a measure of the potentially serious impacts of the disease, a clearer and fairer entry point is merited. A fairer entry point would be the development

---

[3151] EXPG0000001_0006 (hepatitis expert group report)
[3152] EXPG0000001_0028 (hepatitis expert group report)
[3153] EXPG0000001_0075 (hepatitis expert group report)
[3154] See recommendation 2

of chronic disease, which is a medical concept well recognised by the expert evidence available to the Inquiry. The limitation of payment to chronic cases seems to adequately reflect a balance appropriate to the moral duty to make payments in respect of HBV infection, though severe illness can occur in acute HBV infection.[3155]

1.51 Those who are chronically infected with HBV alone or other pathogens alone (such as CMV) should be able to access the schemes and be entitled to the same payments as those infected with HCV (including relatives and carers claims for the affected). Anyone chronically infected with both HBV and HCV should be entitled to claim the "co-infected" payments currently available to those infected with HIV and HCV (including relatives' and carers' claims for the affected).

vCJD

1.52 The possibility of patients being exposed to or infected by the causative agent of vCJD is another matter which is considered and rejected by Sir Robert Francis, on the basis that there is a separate scheme for infection with that virus and also that he deemed there to be no difference between those with whom this Inquiry is concerned (otherwise infected as a result of exposure to contaminated blood or blood products) and others who may have been exposed to it by blood or blood products.[3156] It is submitted that though his reasoning for not including this element in his scheme appears attractive on these grounds, his assessment gives insufficient weight to the "thin skull" created in the otherwise infected community. Their reaction to the possibility of having been infected with vCJD needs to be understood in the context of having already been infected with one potentially fatal virus, with all of the natural consequences which that would reasonably have entailed including fear that the medical profession, having infected the patient once, may have done so again. This background puts those

[3155] EXPG0000001_0026 (hepatitis expert group report)
[3156] RLIT0001129_0017 @ para 2.10

already infected in a different category to those simply exposed to the risk of vCJD by blood or blood products who have not been so infected. Their natural concern and anxiety would not have been an exacerbation of the pre-existing infection.

1.53 Thus, it is submitted that the Inquiry should recommend that the compensation tribunal should make lump sum awards to those who are otherwise infected by blood or blood products in respect of this. It is suggested that a standard lump sum award should be made and that an enhanced award (of a higher lump sum) might be made where the patient is able to speak to particularly harrowing stigma or other consequences, including the effects of having received a vCJD warning letter.

Entry point for the calculation of loss

1.54 The compensation scheme should assess the losses of the applicant on the basis of common law and statutory damages under the law of Scotland which would be payable to the applicant (i) without the need to establish breach of legal duty and (ii) on the assumption that the applicant had not received blood products infected with the viruses or other pathogens which infected the applicant or the person in connection with whom the application is made in the case of an affected person. The moral duty explored above extends, we submit, to compensating the infected and affected for the consequences of the infections. Thus, there would be no need for legal duty to be established. It is logical that for the tribunal to function in a way which seeks to achieve this aim, the assessment must be done (subject to certain further rules about causation which are explored below) on the basis that the State must assess cases on the basis that the infections did not happen at all. To do otherwise would introduce unnecessary complication and would not end up with the State fulfilling the moral duty which we have argued is incumbent upon it.

Provisional awards

1.55 The evidence available to the Inquiry is to the effect that those exposed to infective blood and/ or blood products may, in addition to the pathogens with which they are acknowledged to have been infected, also have been exposed to pathogens whose effects are not yet known. The possibility that infected applicants may be infected with vCJD or other pathogens, the effect of which are currently not known is a realistic possibility. It should therefore be the norm that any agreement or award under the compensation mechanism should be made provisionally, with the option remaining open to the applicant to present a fresh application in future should it become apparent that the application has also suffered loss as a result of infection with pathogen or pathogens, such infection of the applicant not having been known to the applicant at the time of the original application. The possibility of serious deterioration in a person's health or a material change in their circumstances should also be a trigger to returning for a further assessment. Sir Robert contemplated in his oral evidence that future deterioration in a person's condition may mean that a re-appraisal of losses would be necessitated. One example of this which he considered (in a different context) might be that circumstances meant (due to deteriorating health and/or changing family circumstances) that professional care may become necessary at considerable cost.[3157] This is a realistic prospect as people with HIV and/ or HCV in this community are now living into old age. If the intention of the tribunal is to replace the need for parties to go to court[3158], functions like the ability to deal with these changing circumstances (as courts can perform with their ability to award provisional damages) require to be replicated for fairness and proper compensation.

1.56 This approach would be at odds with the approach of Sir Robert Francis in his report, who favoured finality – see recommendation 12(a). Though this is an understandable factor of which to take account, we submit that it is outweighed

---

[3157] IBI transcript for 11/07/2022; 169 (20) to (23) (Sir Robert Francis)

[3158] IBI transcript for 12/07/2022; 42 (21) to 14 (25) (Sir Robert Francis) – payment of compensation as a basis for removal of the need to litigate was stated to be one of the objectives of the scheme

by the medical evidence available to the Inquiry that there is a real risk of material harm due to blood or blood products materialising in the future, either as a result of existing or as yet unknown infections. Without such a provision, Sir Robert's first recommendation which includes the need for infections eligible for compensation to be reviewed on a regular basis would make little sense. The reason for so doing would be to keep the door open to the recognition of future harm being caused in the future as a result of infection not known about or fully understood now. It is notable that certain of the *A v NBA* cases appear to have been resolved provisionally.[3159] We do agree with recommendation 12(b) which allows payments to be made as a lump sum or as periodical payments, in accordance with the wishes of the applicants. That is another matter on which independent legal advice will be necessary.

Assessment

1.57 The evidence heard by the Inquiry is to the effect that (i) the effects of infection as a result of the contaminated blood scandal have been many and varied and (ii) the nature and extent of the harms suffered and the needs thereby created have been repeatedly compounded and exacerbated by inaction on the part of the NHS and the government to deal with the consequences of this national scandal. The practical result of these two facts has been that an analysis of the extent and causation of the *sequelae* of infection can be complex and multi-factorial. Infection has made a material contribution to the totality of the outcome in every case. As a result of this, it is submitted that applications to the tribunal should operate on the basis that there is a presumption that the loss asserted to have been caused by infection has been so caused. That presumption will be able to be rebutted by the State in the event that it chooses to seek to do so. In the event that the State did indicate an intention to seek to challenge the presumption in respect of all or

[3159] *A v National Blood Authority (No 2) [2002] Lloyd's Rep Med 487*

any part of a claim, it would be necessary for the applicant to have access to funded legal advice and expert assistance in order to be able to contest the claim properly.

1.58 The mental and physical consequences of the infections are acknowledged in the evidence available for the Inquiry to be complex and wide ranging, stretching far beyond the most obvious consequences associated with them, such as liver disease resulting from HCV. In HIV, the physical consequences are by their nature varied due to the immunosuppressant nature of the condition and the possibility that infection could impact on any number of parts of the body. As is submitted in some detail above, in addition to this, the treatment received by haemophiliacs caused immune suppression not associated with HIV infection, wither as a result of antigen overload and/ or hepatitis exposure, as per the Ludlam et al research on this published in The Lancet in 1984. This is likely to have had an effect on their resistance to other infections and indeed conditions. This supports the argument that the harm, inflicted upon them by the State and the consequent ill health which they have should be viewed as indivisible.

1.59 The mass of mental consequences is also apparent in the evidence which the Inquiry has heard. This may be in the form of the physical consequences, as described to the Inquiry by its expert groups, for example resulting from HIV or HCV per se[3160] or its treatment.[3161] In the case of HCV infection, a large array of extra-hepatic manifestations was recognised as resulting from the infection, beyond the well known liver damage.[3162] This may equally be in the form of the psychological consequences so ably explained by the psychosocial expert group[3163] and/ or resulting from organic damage to the brain caused by the infection, described in the evidence of Professor Howard Thomas. In his evidence to the Inquiry, he described the fact that a special category for mental problems

---

[3160] See from EXPG0000004_0029 (HIV expert group report) re the conditions and consequences of HIV; See from from EXPG0000001_0024 (Hepatitis expert group report)
[3161] See EXPG0000004_0052 (HIV expert group report), table 4 with the known side effects of HIV treatment; See from EXPG0000001_0039 (Hepatitis expert group report) regarding the many and varied recognised effects of HCV treatment, in particular Interferon
[3162] See from EXPG0000001_0060 (Hepatitis expert group report)
[3163] EXPG0000003

was added for stage 1 applicants to the Skipton Fund. This was introduced as his research had shown that the HCV was present in the brain and that interferon caused long term effects on mental function. He stated that the main manifestations of the infection of the brain were depression and cognitive problems which were difficult to differentiate from mental problems unrelated to HCV and interferon.[3164] Thus, the infections or their treatment were responsible for organic brain injury, psychological effects which were hard to disentangle from mental injury caused by other factors. In cases of co-infection, the position is even more complex, with the risk of consequences like hepatic decompensation being all the higher.[3165]

1.60 The combination of the multiplicity of harmful acts referred to above has led to multiple harms which have exacerbated and compounded each other in multiple complex ways. For example, the ethical breaches on the part of the State have led in many cases to a reasonable and understandable mistrust of the medical profession. This has been exacerbated further by stigma, whether at the hands of the State or otherwise. The psychological consequences have been exacerbated in many cases by the failure of the State to believe the victims or to allow an inquiry into how they or their loved ones came to be infected. This has led in many cases to a breakdown in the relationship between the infected or affected person and the State, including a scepticism about taking treatment or seeking State assistance. This has led in many cases to conditions being rendered worse than they would otherwise have been but for infection. By way of example, the Inquiry has heard evidence – dealt with in more detail elsewhere in this submission – regarding the difficulties many individuals have faced in accessing dental treatment as a result of their infection. As a result, some individuals have suffered considerable issues in relation to their oral health, whether because the stigma they experienced when trying to obtain dental treatment rendered them unable or unwilling to access such treatment, or whether because treatment was refused by dentists. Such issues must be seen as a natural consequence of their infection.

[3164] WITN3824007 _0026, para 100 (Professor Thomas); See also IBI transcript for 26/02/2020; 76(16) to 77(5) (hepatitis expert group – Professor Cooke) on the recognised neuro-cognitive consequences of HCV infection
[3165] See EXPG0000004_0059 (HIV expert group report)

In addition, in many cases the reasonable and natural consequences of the infections also include many complex physical and mental consequences of the treatments for the infections which in some cases have had life-changing effects even where the treatment has been successful.

1.61 The Inquiry has also heard evidence from its expert groups that the infections render more complex and difficult the underlying conditions for which treatment was sought in the first place, be that haemophilia or a condition which resulted in a patient receiving a transfusion. The HIV expert group opined that "the impact of HIV on people with haemophilia, their families and the services providing specialist care has been profound and multifactorial".[3166] The HCV expert group confirmed that alcohol use was common in HCV infected patient and that it would be difficult to determine what element of the liver damage was caused by the alcohol and what by the virus.[3167] It is submitted that such a high prevalence of alcohol use is likely to be a by-product of infection anyway. Thus, the "harm" suffered by the infected and affected communities is highly complex and indivisible. This is akin to the legal analysis applied in cased where loss is said to have been caused by a number of factors where medical science cannot determine what element of the loss is caused by the negligent source and what element is caused by the non-negligent source. In such, circumstances the law deems that loss to be invisible and the whole harm to have been caused by the negligence.[3168]

1.62 The harms which have been suffered result from multiple wrongful acts. They are complex and exacerbate each other. The loss which might be said to have been caused is not easily divisible. Harms have been caused by patients not being

---

[3166] See EXPG0000004_0060 (HIV expert group report); See EXPG0000001_0055 (Hepatitis expert group report) where the group recognised that poor liver function resulting from HCV could have an effect on the patient's bleeding disorder

[3167] See EXPG0000001_0028 (Hepatitis expert group report)

[3168] Bonnington Castings v Wardlaw [1956] AC 613 per Lord Reid @ 621 and Lord Keith @ 626 - 627 – where the loss has been caused by the cumulative whole of more than one source of harm the pursuer proves his case by showing that the negligent cause made a more then de minimis, or material contribution to the causation of the loss; AW v Greater Glasgow Health Board [2017] CSIH 58 per LJC Dorrian @ para 330 – where due to the inadequacies of medical science, the traditional "but for" test of causation could not be satisfied, where there were multiple competing causes, the pursuer could succeed where he proved that the negligent cause had made a material contribution to the loss; Williams v Bermuda Hospitals Board [2016] AC 888 per Lord Toulson @ para 38 (successive events are capable of triggering the principle of material contribution as much as concurrent ones) and para 47 (re-affirmation of principle that tortfeasor takes the victim as he finds him)

believed in the past, such as when they have made claims about how their infections were caused in seeking government inquiry or when they have sought to make legitimate claims to trusts designed ostensibly to help them. Thus, the Inquiry should recommend that a fundamental principle of the compensation tribunal.

1.63 As a result of this situation, which can be said on the basis of the evidence to have affected the entire infected and affected community in this way, though to different degrees it would be very difficult and complex to try to unravel the causation of the losses and detriments suffered by the infected and affected communities. In fact, the complexity of the standard position would make it impossible for the precise causes of the totality of the loss to be understood or proven. Evidence heard by the Inquiry was consistent with this conclusion. For example, in relation to the Caxton Foundation, evidence was heard from its former trustee Charles Lister who explained that the approach which ultimately required to be adopted was to pay financial support to assist to lift people out of poverty, whether the matters in respect of which assistance was sought was caused by HCV infection or not.[3169] It is submitted that this was a figment of the fact that establishing causation in most cases was impossible. Support needed to be given for the whole and not try to tease out what could be said to have been caused by the infection.

1.64 The presumption was a principle which was supported by Sir Robert Francis. It assisted with the buy-in and self-assessment principles set out above. The presumption is an important feature of such a scheme. It is consistent with the findings of Sir Robert about the way that the self-assessment schemes work that claimants are genuinely honest and accurate on the way in which they assess their own cases. Thus, it should be an essential principle of the compensation tribunal that matters of fact (not just about eligibility but in connection with any aspect of claim) should be presumed to be true. It will assist with simplicity also if this approach is taken. If the State wishes to incur the cost of making a challenge to assertions made by an individual, it will incur the cost of doing so for both sides of

[3169] IBI transcript for 26/03/2021; 91(13) to 92(1) (Charles Lister)

the argument. If any other approach were adopted, the Irish model which Sir Robert Francis was keen to avoid due to its delays and adversarial nature will ensue.

The tribunal's approach to assessment and quantification

1.65 In addition to the presumption, we endorse the principles which are set out in the Sir Robert Francis report. A constructive and reasonable assessment of past losses will be necessary in circumstances where the ability to vouch any such loss (such as care or other expenses) will not be able to be vouched by documentary evidence due to the passage of time. The presumption along with the reasonable and constructive approach advocated by recommendation 6 will be likely to be the best way to deal with such situations. As is argued elsewhere, legal representation is necessary to help as opposed to hinder that process.

Account to be taken of payments from support schemes

1.66 A basic principle of its separation from the existing support scheme in Scotland will be that the support scheme will continue to be about providing support for the needs of the applicant. The compensation scheme will be about providing compensation over and above the needs of the applicant. For example, an individual may assert that he has suffered significant past loss of wages as a result of his or her infection. Such loss would not have been accounted for by the support schemes, whose object has been to provide support for the needs of the applicant from the date of their inception. This principle with regard to past payment was endorsed by Sir Robert Francis as regards past payments.[3170] It is just that the State provide a mechanism whereby such loss be made good. This system will enable

[3170] RLIT0001129_0026 @ para 2.52

the applicant to seek to make an application to the compensation tribunal without any concern that the sums being paid to him or her under the support scheme might be jeopardised.

1.67 We agree with the rationale advanced by Sir Robert Francis in support of his recommendations 15(a) to (c) regarding:

(a) the suggestion that there be legislation to secure future payments under the support schemes at current rates, though uplifted for inflation and in accordance the other uplifts recommended by Sir Robert, analysed below (recommendation 15 (b)):

(b) the suggestion that no account be taken of past payments under the support schemes or other trusts in the calculation of past compensation (recommendation 15 (a)); and

(c) the suggestion that future compensation assessments takes the support scheme payments into account in the assessment (recommendation 15 (c)).

1.68 As regards recommendation 15(b) we agree that the past payments (made in small amounts and only regularly since around 2017) were for support and not for compensation. They should be discounted as *ex gratia* support payments which were not compensatory in nature. The changes recommended to the future change the character of the future payment to an extent, and the discounting of future scheme payments (uplifted as set out blow) seems a fair way to approach the calculation.

Interest on past awards

1.69 For many years, legitimate appeals have been made by campaigners to the various governments of the UK for compensation to be paid to the infected and affected in accordance with what they have correctly asserted to be the moral duty of the

State. The delays in the acknowledgement by the State of that moral duty have caused widespread hardship. As indicated above, both the Paymaster General and the minister responsible for the SIBSS at the time agreed in evidence before the Inquiry that payment of compensation was long overdue.[3171] As a result the tribunal ought to pay interest on past awards. The basis upon which this should be calculated should be that interest should be payable at 4 percent per annum, in accordance with the normal practice of the Scottish courts for past awards which have represent loss over a long period of time.

1.70 In Scotland judicial interest on a court decree would currently run at 8 percent per annum[3172], though historically over the period with which the losses to be awarded under the contemplated compensation tribunal are concerned these rates have run much higher.[3173] The court has power to award interest on any sum paid by way of damages at whatever rate as it sees fit, from the date the cause of action arose to the date of the court decree.[3174] It shall do so on past awards of solatium (PSLA) unless it considers there to be special reasons for not doing so.[3175] The court requires to include interest on past elements of loss in a damages action arising out of personal injury or death unless there are special reasons for not doing so.[3176]The rate of interest applied is the current judicial rate[3177] which is often discounted to reflect the fact that pain, or wage loss, or loss of services, are not suffered all at once, but from day-to-day.[3178]

1.71 This is a general proposition which is supported by Sir Robert's recommendation 13. His alternative that such awards are updated for inflation seems to be acceptable. The recommendation appears to limit the awards on which interest

---

[3171] IBI transcript for 18/05/2021; 73 (15 to 23) (Mairi Gougeon)

[3172] Court of Session, Rule of Court 7.7: "Where interest is included in, or payable under, a decree, it shall be at the rate of 8 per cent a year unless otherwise stated."; Section 9 of the Sheriff Courts (Scotland) Extracts Act 1892 and S.I. 75/948, 93/769: "Where interest is included in a decree or extract, it shall be deemed to be at the rate of eight per centum per annum, unless otherwise stated."

[3173] From 1975 to 1993 it ran at between 11 and 15% - see McEwan and Paton, Damages for Personal Injuries in Scotland, chapter 3-01

[3174] Interest of Damages (Scotland) Act 1958, section 1(1A) (as inserted by the Interest on Damages (Scotland) Act 1971

[3175] Ibid, section 1(1B)

[3176] *Smith v Middleton, 1972 S.C. 30,* at 35

[3177] McEwan and Paton, Damages for Personal Injuries in Scotland, chapter 3-04

[3178] McRae v Reid & Malik Ltd 1961 SC 68

should be paid to wage loss and care cost awards. As these should have been awarded many years ago, interest should be payable on all past awards as a matter of course, unless they can be uplifted for inflation. In cases of non-patrimonial loss (i.e. general damages under English law) the interest award should date from the point of infection to the date of the award. In cases of patrimonial loss (special damages in English law) which has continued this should run at the rate of 4% per annum from the date when the loss commenced (for example the date a person would have started working). In cases of patrimonial loss which has ceased, interest should be applied at the rate of 4% per annum during the course of the loss being incurred and 8% per annum from the date that the loss ceased.[3179] On one view, this might be taken to be a conservative approach to interest as Scottish courts have awarded higher rates in cases where higher judicial rates have been relevant in the past or where the period of past loss straddled different judicial rates.[3180] In fatal cases, interest would normally be awarded on the past element from the date of the death until the date of decree at a rate equivalent to about half the judicial rate.[3181]

1.72 Though these rates of interest may be deemed generous compared with the equivalent rates which might be paid under the law of England and Wales, the same arguments apply here as are advanced above for loss of society/ bereavement awards to be paid at rates equivalent to what might be awarded under the heads in fatal claims in Scotland. As the principle lying beyond the Francis report was to be able to keep cases out of court and/ or be guided by legal principles, this could only be achieved for Scottish applicants by awarding what would be awarded in a Scottish court in fatal claims. The parity principle means that these rates are then paid UK-wide. Alternatively, these higher rates could also be justified as fair by the unnecessary delay caused by the government's failure to recognise its moral duty to pay compensation, which has caused unnecessary hardship and, as argued above, by the fact that the rates are lower than would

---

[3179] McEwan and Paton, Damages for Personal Injuries in Scotland, chapter 3-09
[3180] McEwan and Paton, Damages for Personal Injuries in Scotland, chapter 3-08
[3181] McEwan and Paton, Damages for Personal Injuries in Scotland, chapter 3-08; *Prentice v Chalmers, 1985 S.L.T. 168; 1984 S.L.T. 63* - One-third of loss of society was allocated to the past with interest at 6 per cent.

have been paid historically in cases which had been determined at the time of the infections.

Benefits, tax and IHT

1.73 For reasons set out elsewhere in this submission, we agree that the current annual payments under the support schemes should be continued, increased according to Sir Robert's analysis and guaranteed for life, underpinned by legislation to ensure the security of the payments for all who are entitled to them. This certainty and security are of fundamental importance to those in receipt of the payments, as recognised by Sir Robert.[3182]

1.74 In his statement to the Inquiry in response to a Rule 9 request for clarification of his recommendations in respect of the relationship between compensation, support payments, and benefits, Sir Robert requested that his report be amended to clarify the position.[3183] Sir Robert noted that *"it would be wrong"* for past support payments to be subject to claw-back provisions that might otherwise exist pursuant to the Social Security (Recovery of Benefits) Act 1997. To an extent, we agree. Given that (as submitted) the evidence shows that they were support payments, paid on an *ex gratia* basis and the fact that they have thus been paid to date without regard to benefit entitlement, to suggest that past payments should, contrary to past assurances, be subject to some sort of claw back provision would be morally and ethically wrong, as well as being impractical.

1.75 In any event, however, the Social Security (Recovery of Benefits) Regulations 1997 expressly provide[3184] that payments made from the SIBSS administered by the Common Services Agency are prescribed payments for the purpose of exemption under the Social Security (Recovery of Benefits) Act 1997. We agree that, in circumstances where the payments made under the support schemes to date are

---

[3182] RLIT0001129_026 @ para 2.52

[3183] WITN7413001

[3184] Social Security (Recovery of Benefits) Regulations 1997, reg 2(2)(n) (added by Social Security (Scottish Infected Blood Support Scheme) Regulations 2017/329 reg.2 (April 3, 2017))

expressly not compensation or compensatory in nature (as set out elsewhere in this submission), there can be no offset.

1.76 As regards the future position, there appears to be potential for confusion. On the one hand, Sir Robert recommends that *"support payments made after the compensation scheme is set up, but before the compensation award is made, should be subject to those* [Social Security (Recovery of Benefits) Act 1997] *provisions"* [3185]. However, he goes on to recommend that *"the existing position should continue in relation to entitlement to existing benefits. That means that they should be disregarded in the assessment of entitlement to such means tested benefits and remain irrelevant to assessment for non-means tested benefits"*[3186]. It appears that it is only in respect of means-tested benefits for the future where Sir Robert envisages any change being made to the offset of benefits against support payments. We endorse that position. Similarly, we endorse the recommendation that non-means tested benefits should be awarded without regard to the support payments.

1.77 We accept that, in the course of assessment of compensation for past and future losses, provision should be made for 'offsetting' the relevant benefits in line with the Social Security (Recovery of Benefits) Act 1997 principles. However, in order to avoid under-compensation, and for consistency with Sir Robert's principles espoused throughout his report and statement, the application of the Social Security (Recovery of Benefits) Act 1997 ought only to apply to a claim for compensation, as opposed to future support payments.

1.78 For clarity, we accept the contention that "*The requirements of overall fairness and proportionality mean that it would be wrong for past support payments to be taken into account to reduce entitlement to compensation for past financial losses or the value of past gratuitous care [*apparent typing error corrected*] provided"*. We also agree that, having regard to the changing nature of the support payments would mean that support payments made after the compensation scheme had been set up (assuming such a scheme was in line with Sir Robert's

[3185] WITN7413001_004 @ para 5.
[3186] WITN7413001_004 @ paragraph 7.

recommendations and the submissions contained herein) would be subject to provisions regarding offset of future losses. However, we submit that this could only be on the basis that the support schemes were increased in line with his recommendations (including the additional sum for extra expenses) for the reasons set out elsewhere in this submission.

1.79 We agree that awards of financial loss should not be liable to taxation in order to ensure that a recipient is not in a worse position in accepting a compensation payment through the tribunal than they would be in receiving compensation in litigation. This principle was recognised by the Chair when recommending interim payments for those infected and those bereaved partners registered on a UK infected blood scheme[3187] and should be extended to all payments of compensation.

1.80 As Sir Robert identified, given the adverse effects that the infections had on the family lives of the infected and affected communities, compensation awards should be exempt from inheritance tax. At paragraph 10.9 of his report, Sir Robert suggests that the lump sum award amount should be added to the IHT allowance for a deceased infected recipient. In Recommendation 15(f) there is no reference to that IHT allowance only applying to an infected recipient. We submit that all lump sum awards, whether to infected or affected, should be exempt from IHT (whether by increasing the IHT allowance or by other means).

The interaction between scheme and court awards

1.81 This is addressed in recommendation 11 of the Francis report, where it is recommended that:

[3187] INQY0000367_016 @ 36

(a) eligible infected and affected persons should not be required to accept the offer of an award in full and final settlement of any right to pursue legal actions related to the infection;

(b) any accepted scheme award should be set off against any entitlement to damages for the same subject matter; and

(c) the availability of an award under the scheme should be a factor to which the court could have regard when determining liability for costs in any court proceedings related to the infection.

1.82 In his evidence Sir Robert was of the view that dealing with the compensation within the tribunal and keeping damages claims out of the courts was a laudable aim. We agree that if for whatever reason a person is dissatisfied that the award of compensation at the tribunal represents what might be deemed full compensation by a court that that person should be entitled to pursue their legal claim to seek the balance (head (a)). This is important for the sake of fairness but also so that engagement with the tribunal is not undermined by the feeling that it comes with a waiver of other legal rights as in the HIV litigation settlement. Given the nature and extent of the compensation being made available under the tribunal scheme, it should not be necessary for claimants to do that.

1.83 We agree that the clarity with which the scheme awards have been framed would allow sums awarded to be offset against damages awarded by a court, such that court actions would be able to relate to the balance which a claimant thought could be recovered via a court in addition to the tribunal award. For the sake of clarity, we think that the Inquiry should clearly recommend that any such recommendation to the opposite effect could not realistically be enforced. Therefore, awards made in settlement of court actions should not be taken into account for the purpose of the calculation of a tribunal award. This is because in the normal case a settlement would have been reached on a global basis without clarification as to which head of claim were being paid and which were not and why. Many of the settlements of which the Inquiry is aware (such as the settlement of the HIV litigations) were of relatively small sums and were, in that

case made in part due to the duty of the State to support those infected with HIV (both to litigants and non-litigants) under the MFT Special Payments vehicle. In Sir Robert's report, he states that the average pay-out in these cases was £12,790.[3188] These should all be regarded as support payments for present purposes.

1.84 Although we have no real view on paragraph (c) it may be necessary for legislation or at least the rules of Court in Scotland to be changed to enable paragraphs (b) and (c) to acquire force.

A) The infected and estates

Entitlement – general

1.85 The estate of a deceased individual should be entitled to make a claim for the losses which would have been available to be claimed by a deceased person in life. This should not depend on whether the death was caused by the infection. The payment to the estate is in recognition of the fact that the moral duty of the State was to make such payments in circumstances where the moral duty to do so should have been recognised many years ago. The State had a moral duty to make the payment decades ago which would only be acted upon now. The payments should be made now. The principle that a claim which would have been available to the deceased is in accordance with English law pursuant to the Law Reform (Miscellaneous Provisions) Act 1934. In Scots law such claims could be made in fatal cases under section 2 of the Damages (Scotland) Act 2011. This would allow claims to be made in respect of patrimonial and non-patrimonial losses attributable to the period before the death. This would include past PSLA awards and so should include awards for injury, social impact and autonomy (including any exemplary element) in the tribunal. It should also include wage loss which the

[3188] RLIT0001129_0056 @ para 4.53

person suffered in life, reasonable expenses including professional care costs incurred. In law this would also include necessary services which were rendered to the deceased/ personal services which could not be rendered by the deceased before death in terms of sections 8 and 9 of the Administration of Justice Act 1982 but in the tribunal this would be more appropriately claimed by the person or relative who had rendered these services under the provisions for affected people who were carers to make claims. Interim payments of £100,000 should be made to estates, as is set out below. These do not need to await the setting up of the mechanisms of the tribunal.

Heads of claim

1.86 The features of such heads of claim to which the claimant should be entitled should include awards for the injury, social impact and autonomy awards in accordance with recommendations 8 (a) (b) and (d). By recognising the need for separate awards to be made for these components of the loss suffered by the infected community, Sir Robert has adeptly interpreted the evidence to which he had access concerning the heads of claim which arise most often and most strikingly in the testimony of the infected and affected. These are losses which arise consistently amongst the community. That this is a community-based settlement is linked to the need to provide a relatively simple, workable and fair settlement with the infected and affected. We support a tariff-based system which allocates different categories and awards for each of these elements. Allocation of an individual to a particular category or tariff should most fairly and workably be based on the presumption that factual matters relating to the nature and extent of the loss are presumed to be accurate. We think that figures could be fixed by the Inquiry or, alternatively, left to the medial and legal panels. In this regard, we consider it important that the evidence heard by the Inquiry demonstrates that the losses flowing from infection are many and varied in type, and compound each other, as is explored elsewhere in this submission. The Inquiry ought at the very

least to recommend that the categories for these elements of the quantification of loss need to reflect this in their sophistication. They must not be assumed to be linked to crude measures of loss, such as the level of liver damage, as was the flaw of the stage 1 and 2 measures adopted by the Skipton Fund. A balance should be recommended by the Inquiry between this extreme and the use of so many categories or tariffs as to make them of little difference from a wholly individualised system of assessments. The categories need to be capable of being explained to infected and affected applicants and their representatives in a way which is not overly medicalised or complex. Case studies might be used as a means of demonstrating the type of case which would be deemed to fall into a particular category or tariff and why.

1.87 One of the main impressive features of the Francis report is the fact that it has so clearly identified common feature of the loss within the infected or affected community which are unusual to these groups, when compared with typical losses which might be expected to have been suffered and hence are more generally recognised at common law. Examples include (a) those who have suffered the survivors' guilt of those who avoided infection in a group or who have survived where others are not, for example amongst haemophiliacs who did to die in the first wave of AIDS deaths (b) mothers who have guilt for having been the cause of the child's haemophilia and then having "caused" their infection by injecting factor concentrates (c) those who infected or could have infected loved ones (d) those who have suffered stigma as a result of their infection or the possibility of infection (e) the opposite of that, those who have suffered detriment in silence and loneliness in fear of stigma (f) family members who inflicted stigma in ignorance on loved ones who were infected (g) those who suffered detriment (either through stigma or through not engaging with medical treatment) as a result of their further contact with medical professionals post-infection (h) those whose family lives have been tainted by the effects of campaigning for others or (i) those who, as part of a similarly afflicted group suffered the fear that the effects of those around them would at some point become their fate (eg related haemophiliacs or groups of boys, friends infected with HIV at Yorkhill). These are all types of loss or detriment which would be unusual to find in normal cases of negligence bot which are

common in the evidence heard by the Inquiry due to the nature of the underlying condition which gave rise to the need for the treatment (eg haemophilia), the fact that there was a community of infected people and/ or the nature of the diseases caused by infection. Given the unusual nature of these losses in other such cases and their relative prevalence in these communities Sir Robert was right, in our submission, (a) to recognise these as being losses sufficiently common to the community that they should give rise to a head of loss which should generally be available to members of this community and (b) that the head of loss which should be recognised go beyond the bounds of what would normally be experienced and so what would normally be recognised at common law.

1.88 As regards the injury element, it should include an element in living cases for loss of expectation of life to reflect the period in which it is expected that the applicant will not be alive due to the consequences of infection (such as under section 1(1) to (3) of the Damages (Scotland) Act 2011). For the avoidance of doubt, this should also be part of the assessment of future wage loss, insofar as earning capacity will be diminished in the projected lost years (such as under section 1(5) to (8) of the Damages (Scotland) Act 2011).

1.89 As regards the social impact element, we agree that this should be capable of being assessed as a lump sum and that, subject to input from the medical panel, the Inquiry might provisionally recommend that such sums could be put into brackets. However, we do not agree that the awards under this head should be deemed to be commensurate with the extent of the injury impact, as social stigma would in general be greater, depending on the extent of the injury, as Sir Robert opined.[3189] The evidence does not support this contention. Though it might seem logical that the extent of the stigma would mirror the extent of the injury, there is good deal of evidence to support the contention that this is not the case. Haemophiliacs were often assumed to have AIDS. Those with HCV were often assumed to have AIDS. Stigma suffered by patients in hepatology clinics at the hands of the NHS occurred based on assumptions about mode of transmission occurred irrespective often the severity of the disease. The Inquiry even has

[3189] RLIT0001129_0025 @ para 2.43 – 2.45

evidence of people with sustained virological response to HCV after treatment continuing to suffer stigmatisation based on past infection. Sir Robert even noted in his report that people who were had no symptoms suffered stigma. In many of these unusual and tragic cases, social consequences followed irrespective of the severity of the underlying disease.[3190] The stigma having been caused in large part in the first place by misguided or inadequate public information about the diseases, the consequences were rendered all the worse by the lack of support and assistance offered by the state. In many cases, the State (in the form of the NHS) was the source of the stigma. This would seem to us to be an area where the damages award could be safely assumed on the evidence to apply to all of those infected and to have applied in a way that could justify a broad community-based award at the same level, or at limited differentiated levels. It also demonstrates why what one might assume to be the likely position is not borne out by the evidence heard by the Inquiry.

1.90 Limited tariffs (or maybe a single tariff) could be allocated for social impact, with the ability for an individual to claim to be in a higher enhanced bracket based on particular evidence of social impact/ stigma, particularly if that was at the hands of the NHS, with lump sum uplifts for the inability to have long term relationships and the loss of a chance to have children.

1.91 In addition, care and financial awards should be made as recommended by Sir Robert Francis in recommendation 8 (c) and (e). These are addressed in more detail below.

1.92 The approach to the assessment of these heads of claim should be in accordance with the presumptions about matters of fact, as set out above.

Natural clearers

[3190] RLIT0001129_0105 @ para 9.39

1.93 There has been a lack of recognition for the loss suffered by those defined as "natural clearers" of HCV. Those who have been infected as natural clearers of HCV have been left without recourse to any financial support from the existing schemes. The evidence heard by the Inquiry as to the effect that the original planning for the payments to be made to victims of the disaster after the Ross committee report in Scotland had intended that a payment be made to such individuals.[3191] The Inquiry has heard evidence that they have generally suffered loss. In most cases they found out about their exposure to the hepatitis C virus many years after the event. Many had inadequate explanations of what a historic antibody test would mean for them. Many have suffered and continue to suffer from uncertainty about the implications of what previous exposure to this potentially lethal virus would mean for their health or in the future. This has and continues to cause understandable anxiety. Those who have been so exposed have inevitably also experienced sensations of survivor's guilt and suffered stigma as a result of the positive test appearing in their medical records leading to speculation about how they might have come into contact with the virus. There appears to be little logic in providing considerable financial support to individuals who have been chronically infected with HCV but who self-identify as minimally impacted but at the same time excluding this group from the schemes. Though their loss has not manifested itself medically in the same way as others who went on to suffer from chronic infection, this group deserves financial recognition for the loss which it has suffered. Some "natural clearers" claim that their infections have caused much more serious loss, either in the form of significant psychological distress or on the basis of a claim that their more serious physical ailments or conditions are causally linked to their exposure to HCV. Such natural clearers could have open to them the ability to make an application for compensation over and above the award made under the scheme.

1.94 Sir Robert Francis made clear in is evidence that such individuals who clear the virus at the acute stage should not be excluded from his compensation scheme but that payment which might be made to them would naturally be at a lower

---

[3191] RLIT0001129 para 4.17

level than those who went on to develop chronic infection.[3192] Those who were infected with HCV contracted from blood or blood products who are deemed to be "natural clearers" of the virus should receive a standard lump sum of £20,000. The evidence heard by the Inquiry (which will be examined more fully in the submission to follow hereafter) is to the effect that these individuals have generally suffered as a result of their diagnosis, as set out above. If any of those wish to assert greater loss than that, they should be entitled to do so. As they are not "infected" claims should not extend to the affected.

Campaigning

1.95 Those who are able to assert that they have been campaigners or who have otherwise provided services to the infected and affected community other than themselves or their own family should be able to present claims for additional awards. It is likely that these should be additional awards which could be claimed under the injury and family awards. The additional injury award which is likely to have been suffered by these claimants is akin to an affected award – they will have suffered as a result of their proximity to others and the vicarious effects of that. The Inquiry has heard voluminous evidence about the impact of campaigning on family life. This should be capable of being recognised as a separate award, the level of which should be assessed by the medical and legal panels. Of course, those entitled to claim such an award may come from the infected or affected communities.

1.96 In certain circumstances, the Inquiry should recommend that such an award should be capable of being assessed as a percentage uplift on another award. For example, the family consequences might be able to be said to have been exacerbated above and beyond the consequences of the infection *per se* by 50% of what that award would otherwise have been. The power should be given to the

[3192] IBI transcript for 11/07/22; 94 (10 to 18) (Sir Robert Francis)

tribunal to assess awards for injury and for family impact in this way. Further, such considerations should be ale to play a part in the assessment of other claims such as claims for wage loss caused by the effects of campaigning on mental health or family.

1.97 That such an aspect of the compensation scheme is recognised specifically in this way is an important part of the community buy-in principle. The additional harms caused by those who have been required by the State to fight to get to this point on behalf of others, to personal detriment, needs to be recognised. That the State required them to do so for so many years and caused harm as a result has resulted in a loss which the State has a moral duty to address.

Quantum

1.98 The Sir Robert Francis approach to the quantification of the various tariffs which he thought could be devised as the framework within which his compensation tribunal model could work was to leave the analysis of the medical (physical and psychological) and legal (quantification) to the independent medical and legal panels. Whilst we entirely respect that determination, we submit (a) that it was based in part on the limitations of the Francis reporting exercise, as set out above and which were very fairly accepted by him (b) that the Inquiry does not suffer from all of the same limitations and (c) that the decision to leave these matters to these unidentified panels is limited by some conceptual anomalies and potential pitfalls. As such, we advocate an approach whereby the Inquiry, with its access to volumes of medical evidence about the basis of the moral duty to compensate, the guidance which it has been able to obtain from independent expert medical panels and the unparalleled body of evidence from the infected and affected about the many and varied impacts of the disaster ought to provide some degree of guidance within which the medial and legal panels can work on the detail. In his evidence to the Inquiry, Jeremy Hunt MP stated that the recommendations of a public inquiry deserve to be treated with great respect due to the detail into which

an inquiry can go, that they have great moral authority and are very hard to ignore as a government.[3193] The corollary of that position is that the government which set up the Inquiry expects that the investment in it will result in as many of the questions it has been asked to address being as comprehensively answered as possible. To leave much if not all of the decision-making around the amount of money which might be paid under the compensation tribunal might be seen to be an abrogation of the inquiry's responsibility. It might even be said to make the entire system devoid of meaning, if the kinds of figures arrived at by the panels were woefully out of kilter with what the well-informed Inquiry or indeed Sir Robert might have expected. This needs to be balanced against the desire not to go too far too quickly, which may result in injustice. Conceptually, we are concerned that without further detail about quantum being incorporated into the compensation tribunal recommendation, there is a very real risk of the value of the tribunal being lost. There is also a very real risk that the tribunal may take a long time re-inventing the wheel. Sir Robert was rightly concerned about the possibility that his model may take a long time to get to the point of making payments. Efforts made by the Inquiry to fix quantum would mitigate against that legitimate concern materialising. In any event, leaving too much to the panels to do appears to have the following conceptual flaws:

(a) Though we have no doubt that the panels could involve eminent leaders in their fields, the Inquiry is as well placed as any body to make judgements about how the tariffs ought to be framed. The Inquiry has the expertise based on the evidence to which it has access. Asking any other body to make these important decisions might be seen to an extent as abrogation of its responsibilities arising, as Mr Hunt said from the detail in which the Inquiry has been able to investigate matters (which could never be replicated by the panels) and the moral authority which is has thus acquired;

[3193] IBI transcript for 27/07/2022; 117(3 to 16) (Jeremy Hunt MP)

(b) The legal panel is being appointed to come up with figures based on its experience of awards which might be made at common law. Thought it makes sense to use existing common law quantification as a guide or starting point as to how much might be awarded under the various tariffs, Sir Robert's analysis involves awards being contemplated for matters which he thinks there is a moral duty to include but which are not recognised, or not separately recognised at common law (such as the social stigma award, the family/ autonomy award, awards for affected people in their own right and possibly other areas such as awards for the exacerbation caused by campaigning or exemplary/ aggravated damages, to which Sir Robert himself had opined the tribunal would be unsuited). Indeed, in many ways the Sir Robert model is based on a view that courts/ the common law would not be well suited to assessing the loss suffered by the infected and affected, hence why a bespoke tribunal model has been advocated. There are concepts which we propose in this submission, such as the presumption about factual matters, which are not familiar to the common law, where the claimant would generally bear the burden of proof of such matters. The ability of lawyers expert in the common law approach to such matters but not to the more nuanced and complex issues arising in respect of the infected and affected communities may therefore be limited and certainly not as well-informed in the particulars of the disaster as the Inquiry;

(c) There is a possibility that the "buy-in" principle may be undermined by ultimate control being given to panels which have been appointed by the ALB, which (though independent) would be a body appointed by the government. The trust which the community has in the Inquiry has been hard-won though well-deserved. Infected and affected core participants were able to express views on the composition of the expert groups in this Inquiry. These views were listed to and acted upon. It would not be possible for such trust to exist in panels appointed as Sir Robert has contemplated. The absence of such trust would undermine the core principles on which Sir Robert's recommendations are founded.

1.99 There are many ways in which the Inquiry might go about exercising an appropriate degree of influence over the quantification of the compensation claims. It might set the tariffs itself. It might leave all of these matters to the expert panels, as Sir Robert has suggested. We submit that there may be ways in the middle in which the Inquiry's responsibility might best be discharged. We suggest elsewhere in this submission that certain minimum figures might be recommended for payments to be made. This may have the effect which Sir Robert contemplated would happen if interim payments were made to the infected of discharging many claims, as claimants may think that what they had received was sufficient to satisfy them that they had received adequate compensation. We make suggestions elsewhere in this submission as to what those minimum figures might be for, amongst others, natural clearers and the relatives of deceased persons. The Inquiry may take the view that those figures should have interest applied to them by a pre-set average formula but those figures are proposed as a starting point. In all cases, individuals would have the right to make further claims if they wished to assert that these payments were not an accurate quantification for them, whether that be due to the possibility of claiming for the more bespoke elements, like wage loss or care costs, or otherwise.

1.100 Similarly, some guidance might be given to the panels as to the parameters within which the Inquiry expects that awards might be made. The interim payment of £100,000 might be seen as basis for the lower end of the spectrum, encompassing what the lowest awards for the injury awards, social stigma award and family/ autonomy awards might be. The Inquiry might also go about setting what might be anticipated to be the upper level award, in the most serious of cases (subject to the possibility of a further awards for injury and family/ autonomy for campaigners and an uplift for exemplary damages as well as an average interest award for the past, as set out elsewhere in this submission). This may have the effect of assisting the panels to set levels of awards in between. We submit that such an top-bracket award would be best set at no less than £350,000 for the injury, social impact and family/ autonomy awards. This is based on the following analysis and the evidence of impact in the most serious cases set out above:

- The most serious types of case might be seen as one of co-infection, leading to painful, distressing death or years of debilitating and harrowing illness, along with the debilitating and compounding effects of debilitating and often unsuccessful treatment. These elements are hard to quantify as a matter of normal legal analysis as they are so multi-factorial. The psychological elements are likely to fall into a high bracket as they involve the compounding of the harms over decades in many cases in the various ways described elsewhere in this submission or the mental agony of an impending, painful, desperate and isolated death. If one were to look at the Judicial College Guidelines (16th ed), headline figures of assistance might include:

(a) Chapter 1 - Injuries Resulting in Death, Section (A) - Full Awareness - Severe burns and lung damage followed by full awareness for a short period and then fluctuating levels of consciousness for between four and five weeks, coupled with intrusive treatment or significant orthopaedic/physical injuries followed by death within a couple of weeks up to 3 months - £12,540 to £23,810. Clearly these awards go nowhere near the kind of prolonged death with consciousness of the likely consequences of infection with HIV and/ or HCV.

(b) Chapter 1 - Injuries Resulting in Death, Section (E) - Mental Anguish - Fear of impending death/reduction in expectation of life. For the parent of young children suffering such mental anguish for a period of around 3 months - £4,760 – as above.

(c) Chapter 2 - Injuries Involving Paralysis, Section (A) - Tetraplegia (also known as Quadriplegia). The typical case of tetraplegia attracting an award in the mid-range of this bracket is appropriate for cases in which the injured person is not in physical pain, has full awareness of their disability, has an expectation of life of 25 years or more, has retained powers of speech, sight, and hearing but needs help with bodily functions. At the top end of the bracket will be cases where physical pain is present or where there is a significant effect on senses or ability to communicate. Such cases often involve significant brain damage where degree of insight is a

relevant factor: see 3(A)(a). Lack of awareness/significantly reduced life expectancy will justify a below average award. Other factors bearing on the award include age, the extent of any residual movement, the degree of independence or pain relief (if any) whether through the provision of aids/equipment, treatment, or otherwise, the presence of respiratory issues, and depression. - £324,600 to £403,990. Though not directly comparable, cases of this nature involve all-consuming damage to the body and a total transformation of the person's life which is comparable to the worst cases of infection of which the Inquiry has heard evidence.

(d) Chapter 4 - Psychiatric and Psychological Damage, Section (A) - Psychiatric Damage Generally. The factors to be taken into account in valuing claims of this nature are as follows (i) the injured person's ability to cope with life, education, and work; (ii) the effect on the injured person's relationships with family, friends, and those with whom he or she comes into contact; (iii) the extent to which treatment would be successful; (iv) future vulnerability; (v) prognosis; (vi) whether medical help has been sought. (a) Severe - In these cases the injured person will have marked problems with respect to factors (i) to (iv) above and the prognosis will be very poor - £54,830 to £115,730. It would require to be borne in mind that, unlike in the paradigm personal injury case where there had been one traumatic event causing the reaction, the re-traumatising effect of multiple wrongful acts or omissions the State over many years will have compounded and exacerbated the harms.

(e) Chapter 6 - Injuries to Internal Organs, Section (H) – Kidney - Serious and permanent damage to or loss of both kidneys - £169,400 to £210,400

- In such circumstances, it might perhaps be inevitable that high levels of award for the social stigma and family autonomy elements might also be expected, though the family impact can to an extent be reflected in an award for psychiatric damage (see above). These elements are of course hard to quantify as they do not have a

clear, separate basis at common law. It might be inevitable in such a case that family and personal relationships would normally be strained to the maximum by the desperation of the situation. It was almost universally the case that patients had some element of breach of autonomy involving treatment, testing or diagnosis and to be given clear answers by any emanation of the State, which could to an extent be reflected in this award (though would also, in our view, attract a separate award in some cases, considered below). An additional £50,000 under this head would not seem to us to be unreasonable in such a case.

1.101 Of course, our position is that the further the Inquiry can go into setting the tariffs for these heads of claim, the more informed the outcome is likely to be and the speedier the resolution of claims are likely to be.

Wage loss

1.102 Previous past support schemes, including the SIBSS were not designed to compensate applicants for past of future loss of wages but to help them with their day to day living costs.[3194] Claims for loss of wages under the compensation tribunal should be assessed in accordance with the general presumption that all factual matters presented by the applicant in support of a claim for wage loss should be assumed to be true (discussed in detail above). Where no evidence is able to be presented, due to the age of the applicant or the passage of time, the applicant should not be penalised in that regard and median figures should be used, as proposed by Sir Robert Francis.[3195] This approach as supported by Sir Robert Francis in his report, where he opined that the period of presumptive loss should be the adult life of the infected person and apply to each year of that person's working life "unless the State proved on convincing evidence that for

[3194] IBI transcript for 18/05/2021; 20 (8) to (13) (Sam Baker)
[3195] RLIT0001129_0027 @ para 2.55

reasons not associated with the infection, the claimant would have been incapacitated from work in any event".[3196] The applicant's claim should be presumed to be true and the loss suffered due to infection. Though rebuttable by the "State" the rebuttability of this presumption must be based on the need for convincing evidence to rebut it. This process must be done at the expense of the State. It may prove hard to do this in many cases due to the absence of evidence upon which the claim might be rebutted. It is hoped and anticipated (in line with Sir Robert's impression of the effectiveness of the self-assessment system in the SIBSS) that this system will work well and fair claims will be advanced and accepted in most if not all cases. In this regard, we note the importance of legal representation. The idea that the "State" will be responsible for rebutting a presumption about wage loss means that there is a potential at least for the process to become adversarial. Legal representation as to the extent of the claim which can be fairly presented and in any dispute will be necessary and also likely to make the process work more fairly and efficiently. As explored elsewhere, it is imperative that this process occur locally, in Scotland for those on whose behalf this submission in presented.

1.103 Loss of earning capacity for those in work should also be payable, again based on the rebuttable factual presumption.[3197] A multiplier/ multiplicand approach should be used to calculate losses in accordance with normal personal injury practice.

Care and other costs

1.104 Care costs should include claims for what would be deemed to be service claimable under sections 8 and 9 of the Administration of Justice Act 1982 and professional care costs. Actual care received should be calculated on the basis of

[3196] RLIT0001129_0027 @ para 9.96
[3197] RLIT0001129_0027 @ para 2.56

the principles set out in the Robert Francis report.[3198] Unlike at common law these should be payable to the carer or relative who has provided the care.

1.105 In addition, relatives should be entitled to claim for personal services which would have been rendered to the (either due to incapacity or death) in terms of section 9 of the Administration of Justice Act 1982 and/ or section 6 of the Damages (Scotland) Act 2011, based on similar tariffs. These should be payable to the relative in question or based on detailed assessment, as Sir Robert proposed for the analysis of care costs above.

1.106 Other additional costs (such as household renovation costs for the infirm) over and above these claims should be paid as compensation to the infected person or the estate. The costs of reasonable treatment including therapies in addition to treatment which would be available to an applicant on the NHS should also be claimable, as they would in a civil action.

Additional elements

1.107 Costs of administration or investment of ultimate awards should also be available to those for whom it is required, above a certain level where advice would be deemed necessary for the proper protection and assistance of the applicant and where independent, confidential advice was thought to be appropriate in cases where the financial advisory service to be provided by the tribunal were deed to be inadequate.

<u>Exemplary and aggravated damages</u>

Exemplary damages

[3198] RLIT0001129_0025 to _0026 @ paras 2.47 to 2.48 and 2.50 to 2.51

1.108 The tribunal should also include a scheme of exemplary damages, which should be able to be awarded either as a lump sum or as a percentage of the total damages or support payments to which an applicant is entitled, depending on the circumstances of the case. Sir Robert appears to have recognised that the matters being considered in this Inquiry might give rise to a moral entitlement exemplary damages, leaving this a matter to be reviewed in light of the findings of this Inquiry.

1.109 We submit that, in light of the evidence heard by the Inquiry, and analysed in detail elsewhere in this submission, that the 'threshold' for exemplary damages has have been passed in some cases. Thus, the compensation scheme should include the ability to award such damages. We accept that not all of the infected will be able to establish that their treatment at the hands of the State would fall within the scope of exemplary damages, as defined at English common law. However, in some cases we would argue that the conduct of those responsible for the treatment (whether medical, ethical, or political) of individuals by state actors might warrant exemplary damages consistent with English legal principles. The Inquiry should give guidance at least as to the types of conduct that it considers would warrant an exploration and assessment of exemplary damages in light of the evidence it has amassed.

1.110 In his analysis of the possibility of the scheme providing for exemplary damages, Sir Robert voiced concern that, in addition to it being "*premature to propose such awards being included*"[3199], it was difficult for such awards to be assessed in the course of the tribunal. He did not exclude the possibility of such damages being awarded, however. It is accepted that there is likely to be real difficulty if the issue of exemplary damages (rather than aggravated damages) is left to the scheme assessors alone. This is precisely why we would advocate that the Inquiry should in its final report set out the basis upon which matters should be judged. The Inquiry ought, having regard to the detailed evidence it has heard, set out clear guidance regarding the potential applicability of exemplary damages within the

[3199] RLIT0001129_086 @ oara 7.38

scheme on the basis that that evidence reveals conduct which equivalent to conduct which would give rise exemplary damages in a court action, in certain cases.

1.111 In circumstances where Sir Robert was evidently concerned to ensure that there was a 'buy in' from the infected and affected communities, ignoring or excluding the possibility of exemplary damages for those who have experienced oppressive, arbitrary or unconstitutional treatment on the part of an agent of the State for example, would likely serve to undermine this key tenet of the proposed scheme, given that it will itself be constituted by the State. Providing clear guidance regarding possible elements of qualifying conduct that could give rise to exemplary damages will assist in giving credibility to the scheme. How this should operate is set out below.

Aggravated damages

1.112 As regards aggravated damages, Sir Robert appears to consider the position less complicated. We agree. However, he suggests that an award might form part of the autonomy award. This is already considered within his scheme to be "additional redress for the distress and suffering caused by the impact of the disease, including... personal autonomy, the right to informed consent, and candour from healthcare professionals and providers". Whilst the recognition of the additional losses and harms caused to the infected and affected as a result of the disaster is welcome, the tenor of Sir Robert's evidence regarding the autonomy award generally appears to be the regard he has had for the damage to family life that has been spoken to by many witnesses in this Inquiry. The loss of autonomy element had such significant and wide-ranging consequences in many cases that it should be considered separately, in our view, based on all of the evidence in that regard available to the Inquiry. We submit that incorporating an equivalent of aggravated damages into the award for interference with autonomy and private life risks eliding different and wide-ranging effects into a single concept

which fails to recognise the specific harms they experienced as a result of their treatment(s) at the hands of the state.

Conclusion

1.113 We submit that the purpose of a separate award would be to compensate those involved in non-consensual treatment, or otherwise had their autonomy infringed (relating to testing or not knowing about elements of their medical condition or treatment) and/ or research with a sum to reflect the insult and affront to their autonomy which such an experience involved. The loss which is to be reflected here is the consequence of the all-consuming, all-exacerbating "domino effect" of keeping patients in the dark described above. Such damages (for affront to autonomy *per se*) would not be available at common law and so would not be included under the rest of the scheme which seeks to award compensation for common law and statutory damages. [3200] The Inquiry has heard evidence to the effect that these breaches of individual autonomy have had substantial effects on the psychological condition of claimants due to the fact that the relationship between doctor and patient (in particular in patients with chronic conditions like haemophilia) has been seriously undermined and the treatment of the underlying condition(s) rendered less effective as a result. It is submitted that the effects for those who have experienced this are wide-reaching. The practices in this regard which have been uncovered by the Inquiry are also wide-reaching and ought to be seriously condemned. Lack of patient involvement in decision making, testing and diagnosis in many cases went on for years. Separately, those who were involved in research, without their knowledge or consent have had their harm exponentially increased. As is submitted elsewhere, they have legitimately called

[3200] Under the Administration of Justice Act 1982 and/ or the Damages (Scotland) Act 2011; See *Shaw v Kovac [2017] 1 WLR 4773* – though if a patient's suffering was increased by the knowledge that his personal autonomy had been invaded through want of informed consent, it could be reflected in the award of general damages for pain, suffering and loss of amenity, such an element is not currently included within the lump sums awarded to claimants under the schemes.

into question the motivation of their treating clinicians. In such cases not only has this confidence in the medical profession been irreparably shaken but also the State has benefited from the knowledge which it has gained or the research which is had been undertaking. The complex and all-encompassing effects mean that those who have been subject to these should be reflected either (a) by a separate lump sum award for aggravated damages for loss of autonomy or (b) as per the Irish scheme by an uplift being made on the total damages awarded to an individual who qualified, to reflect the all-encompassing nature of the harms suffered and the need for the State-wide action in this regard to be condemned. The degree of the uplift could be fixed by the medical and legal panels, though the Inquiry should provide guidance based on its experience of the evidence and the approach of the Irish scheme as to the kinds of cases to which these uplifts should apply. Case studies may again be helpful to help define the kind of case that would qualify. For those individuals subjected to *inter alia* a loss of autonomy and involvement in research without consent, exemplary and/ or aggravated damages would (a) recognise the unconscionable treatment that they have endured and its long-lasting and far reaching consequences on their lives, and (b) go some way to seeking to deter those who were involved and who might in the future consider being involved in such practices from repeating the horrific mistakes of the past.

1.114 It is important to note that this system requires to be supported by a right to access information about what research or other similar study a patient may have been involved in, which is addressed elsewhere in this submission. As this is often based on a situation where things have happened of which the claimant may not have been aware for many years or indeed now, it may be necessary for the mechanism to incorporate a degree of presumption, based on the circumstances of the infection.

B) Compensation for the affected

General

Eligibility

1.115 The types of relatives who should be entitled to claim are as listed by Sir Robert Francis in his report. There is ample evidence available to the Inquiry to suggest that losses have been suffered by these classes of individuals generally. That these losses have been incurred by these classes of relatives is understandable in the circumstances of the blood contamination tragedy. There has been a lamentable and complete lack of recognition for those affected by and who have suffered as a result of the blood contamination disaster in the former trusts and schemes or even the current schemes. It is clear that the current schemes have failed to recognise the significant loss and hardship, suffered by the close family members and carers of those who were infected by blood or blood products in the UK. The very significant effects of the blood contamination disaster on parents, children, siblings and carers require to be recognised and made good by the governments of the United Kingdom.

1.116 Recommendation 5 contains the various classes of affected beneficiaries which it is proposed be admitted to the scheme, as follows:

a) Spouses, civil partners and long term cohabitees (for at least one year) of living or deceased eligible infected persons;

b) Children of an eligible infected person;

c) Parents of eligible infected persons whose eligibility started in childhood;

d) Siblings living, while under the age of 18, as a family with an eligible infected person;

e) Providers of care to an eligible infected person, as a result of the infection;

f) Members of the family, or friends of an eligible infected person, whose relationship with them was so close that it could reasonably be expected that their mental or physical health would be seriously affected by the consequences of the disease, and who has in fact suffered a mental or physical injury as a result;

g) The estates of deceased affected persons who would, if alive, have been an eligible affected person for the compensation to which they would have been entitled during their lifetime; and

h) Fatal cases - Dependants (as defined by the Fatal Accidents Act) of deceased infected persons whose death was caused by the infection or its consequences. This is discussed in some more detail below.

1.117 We agree that the estates of affected persons who would have been able to bring claims under the tribunal scheme in life should be able to bring such claims on behalf of the deceased affected person.[3201]

Proposed modifications to the Robert Francis criteria

Wage loss

1.118 One area where we take the view that the Francis tribunal criteria should be re-considered is the availability to affected people of wage loss claims. Qualifying individuals would have the ability to qualify for loss of support claims (see below). The Francis report makes clear that he was satisfied on the evidence available to him that relatives and others should qualify for awards in their own right, which may not be available at common law, due to the particular types of losses which have been caused to the affected community and his interpretation that the State has a moral duty to pay compensation in respect of those losses. We agree that that was an entirely appropriate interpretation of the evidence available to the Inquiry. In our submission, it follows from that recognition that financial loss suffered by those individuals should be included as well where it be established (with the benefit of the factual presumption) that such loss was caused by the

[3201] RLIT0001129_0019 @ para 2.20

infection. It is possible that there are families would stand to lose out significantly otherwise as a result of the current proposals. This would be unfair. It may be that the infected person was not the main breadwinner in the family or that he or she did not work at all and thus that wage loss or loss of support could not legitimately be claimed or could only be claimed in a limited amount. In such families, it may have been the spouse or other family member who suffered loss of income which resulted in a lesser amount of income being available to the household/ family as a whole due to the need to care for the infected person, due to psychological injury to the affected person or social impact elements, which are otherwise claimable by the affected person under the scheme. If these losses are available as compensation under the scheme, wage loss which is a consequence of those losses should also be claimable by the affected person. To do so would be consistent and fair, in our submission. Individuals who can claim affected awards for injury, social impact or family/ autonomy or who qualify for carer awards should also be entitled to be paid compensation for wage loss resulting from these claims.

Cases where the infected person is still alive

1.119 The classes of those entitled to non-fatal damages are listed under recommendation 5(a) to (f) above. The heads of claim to which they would be entitled are to be found in recommendation 9(a) to (d). A confusion about the way in which fatal claims are categorised by the Francis evidence is listed below. As far as claims for non-fatal cases are concerned, the individuals listed above are entitled to claim for an injury impact award, under recommendation 9(a). This includes the right to claim for "physical and mental injury caused by their experience of the effect of the infection". In recommendation 5(f) the requirement for the residual category of those who can claim is restricted to those who have suffered "mental or physical injury" and whose relationship was so close that "it could reasonably be expected that their mental or physical health would be

seriously affected by the consequences of the disease". It is unclear why the terminology here is different or the precise ramifications of the words chosen. The following principles should instruct the approach to the physical element of the classification:

- Those who fall within relationships listed in recommendation 5(a) to (e) should be assumed to have a relationship such that they may be deemed entitled to a certain minimum award based on the nature of the relationship and on the timing of that relationship at the time of infection in the case. A minimum level of award might attract a lump sum award to be paid to those individuals without the need for further proof based on the likely effects on these groups. This might be fixed by the panels or by the Inquiry. A figure of not less than £20,000 might be recommended with the option to apply for more in cases where there is a basis for doing so (to cover all heads (a) to (d) under recommendation 9);
- In other cases, in category (f) there would be a need for an application to be treated on its merits, both as regards eligibility and extent. To be clear, this category should include the ability of relatives and non-relatives to make an application where they can assert a basis for doing so. For example, grand-parents (who it is argued below should be included in fatal case claims) may have had a particularly close relationship with an affected child, or a cousin with an affected individual, or a close friend. Such categories would not benefit from the presumption or the minimum payment. That would be the advantage of being in the listed categories between recommendation 5(a) to (e);
- Wording should be careful to include all of the consequences of infections which would be likely in the normal course of events to cause such individuals loss. Also, the suggestion that it would only be in cases of diagnosable mental or physical injury that such claims can be made should be discounted. This might be as a result of infection itself or in other cases due to other infection-related events, such as the treatment for infection. In addition, the evidence available to the Inquiry suggests that affected individuals may well have suffered considerable psychological loss, which in many cases remained hidden due to stigma or the

priority given to the infected person. The idea that proof of a diagnosed psychiatric condition might be necessary seems unreasonable and unrealistic on the evidence, if that is what was intended by Sir Robert. The wording "who have suffered mental or physical loss as a result of the infection or the consequences of infection" would seem apt. In his evidence Sir Robert seemed to suggest that this would be an appropriate definition and that he was not too hung up on psychiatric illness, as understood in the common law as being a precondition of receiving damages in cases where there is no physical injury. In that regard he was struck by the psychological *sequelae* which had been opined upon by the Inquiry's psychosocial expert group, which extended into the subtle psychological consequences of infection on both the infected and affected.[3202]

1.120 We agree that the evidence supports claims being made for the social impact, family care and autonomy awards to claimants under recommendations 5 and 9.

1.121 Though this was ultimately the position accepted by Sir Robert in his evidence, sub-category (a) should include former partners who can assert that they have suffered loss.[3203] This is because marital breakdown was a common and understandable consequence of infection in evidence heard by the Inquiry. Former partners therefore suffered in many cases and they should be assumed to have eligibility. They would not qualify for the loss of society (bereavement) award under the Damages (Scotland) Act 2011 (as they were not married to the deceased at the time of death, by definition) and so should be entitled to an award which reflects their own losses and also an element to reflect the bereavement, which many would also have felt, calculable by reference to what a spouse would get as damages in the more usual case. Former spouses would be entitled to an award under section 8 or 9 of the Administration of Justice Act 1982 (necessary services rendered to the injured person or personal services which would have been rendered to them by the injured person) under section 13(1) of the

[3202] IBI transcript for 11/07/22; 103 (5 to 17) (Sir Robert Francis)
[3203] IBI transcript for 11/07/22; 97 (Sir Robert Francis) – he mentioned former spouses only but the logic, we submit must be for former partners

Administration of Justice Act 1982 if they were in a relationship with the injured person at the time of the act or omission giving rise to liability. Given the long-term effects of infection in the current circumstances, former partners should qualify for their own injury or as carers. Under section 14 of the Damages (Scotland) Act 2011, sub-para (h) former spouses or civil partners would qualify as relatives in fatal cases but not immediate family and hence would not qualify for a loss of society award. Such an award would be justified as an extension to the normal principles of bereavement or fatal damages, due to the unusual circumstances of the disaster and the likely effect on these individuals. They should be entitled to the £20,000 referred to above as a minimum payment to reflect the minimum they are likely to receive as a combination of the non-fatal and, if appropriate, fatal elements of the award.

1.122 Children should be given a wide definition and should include step-children and children who are accepted as children of the infected person as per the definitions under section 14(1)(c) and 14(2)(b) of the Damages (Scotland) Act 2011. The same should apply to the definition of parents, siblings and grand-parents/ grand-children *mutatis mutandis* under sections 14(1)(a) to (d). This should apply to fatal and non-fatal cases.

Fatal cases

1.123 In fatal cases where the infection has been the cause of death, the estate should be entitled to payment under recommendation 5(g) to what the person would have received in life. As per the interim report, where widows were deemed entitled to a payment of £100,000, it should be assumed that such entitlement arises where the family is already registered for a bereavement award or the widow is already registered for payments under a support scheme. In cases where the case was registered or deemed eligible by a trust or scheme before, qualification on proof of relationship should be automatic.

1.124 The position as regards eligibility for bereavement compensation in cases of fatality is not entirely clear from the Francis report. In recommendation 5(h) he suggests that bereavement awards should be open to those who could make claim for such an award under the Fatal Accidents Act. Recommendation 5(h) thus constitutes a separate category from those listed as relatives under categories, who appear in that recommendation to be those entitled to make claims arising from their own loss as opposed to a fatal award (in categories (a) to (e). However, in recommendation 9, those entitled to make bereavement claims (both as a result of bereavement and also what are called financial dependency claims) are defined by reference to categories 5(a) to (c) (spouses, parents and children but not siblings) and not by reference to the Fatal Accidents Act classifications. It is far from clear why Sir Robert has sought to categorise those entitled to make claims under the heads of claim this way. He appears to have wished to follow the categories known to English law. There is an apparent indication in recommendation 5(h) that he intended to follow the English law rules on dependency. However, in recommendation 9, the ultimate classes of claimant who are entitled to claim do not replicate that law. Children are included in the bereavement award and would not be under section 1A of the Fatal Accidents Act 1976. For example, siblings appear to be included in the entitlement to bring a claim as a dependent pursuant to recommendation 5(h) under the Fatal Accidents Act provisions regarding eligibility[3204] but they are excluded under recommendation 9 which provides for a bereavement financial loss award only for spouses/ civil partners/ long term cohabitees, children, and parents (where the infected person's eligibility started in childhood). Indeed, under section 1(3) of the FAA, there are far more individuals who would be eligible to be admitted to the Scheme under Recommendation 5(h) as dependents than would be entitled to claim a bereavement financial loss award under Recommendation 9(e). It is far from clear why these discrepancies exist.

1.125 It is submitted that the claims for these heads of claim should accord with the way that fatal claims operate in Scots law, as defined below. As is argued elsewhere in

---

[3204] Fatal Accidents Act 1976 s1(3)(g)

this submission, Sir Robert wished to be guided by established legal principle as to the categories of claimant who should be allowed to claim in fatal claims at the tribunal. The principle behind this was that the moral duty was said to have the purpose of precluding the need for claimants to go to court. In accordance within the parity principle, this would mean that all possible claims in law would need to be covered in Scotland and that these would need to be replicated UK wide.

1.126 Under English law, those entitled to the statutory bereavement award are limited to the spouse/ civil partner/ long term cohabitee of the deceased or the parents (or mother if the child was illegitimate) of an unmarried minor. The statutory sum (currently £15,120) is to be shared amongst the eligible recipients. The position in Scotland is very different. There is no statutory bereavement damage award. Rather, a broader group of relatives is recognised as being entitled to bring claims for their bereavement in their own right, including children, siblings, grandparents and grandchildren. Sir Robert Francis appears to have extended the scope of who would be eligible for a bereavement award (as recognised in English law) to include children and parents having regard to Recommendation 9(e). We submit this does not go far enough.

1.127 As a result, grandparents and grandchildren should be entitled to be added to the list of those who can qualify for a fatal award, though they are not generally deemed to be entitled to a bereavement award under the Fatal Accident Act. Sir Robert made clear that he had drawn the line for the category of those who would be entitled to a bereavement award to those who were entitled to such an award in English law. Beyond that he struggled to see that there could be a moral case made for them to be included. [3205]In Scots law, grandparents and grandchildren would qualify under 2011 Act. The moral case must therefore be deemed to extend to them also in cases of fatality. Indeed, like siblings, they would qualify as member of the deceased's immediate family under sections 4(3), 4(5) and 14. Thus, both siblings in general (not restricted to situations where they had shared a house with the infected child at the time of infection) and grandparents would qualify for a loss of society award under section 4(3)(b) of the Act as well as a loss

[3205] IBI transcript for 11/07/22; 101 to 102 (Sir Robert Francis)

of support claims under section 4(3)(a), if applicable. They are included within that category as part of the grouping who would be likely to suffer that type of loss on the death of their grandparent or grandchild or sibling, as appropriate. In the interests of parity, we suggest that such relatives should be automatically deemed to qualify for an awards of this nature in the compensation scheme (as detailed below). It is a safe assumption that given the circumstances of the deaths about which the Inquiry has heard, some level of grief and distress would be likely to be felt by these relatives in most if not all cases. Their entitlement to qualify for awards on their own right in non-fatal cases would only arise (a) in the case of grandparents and grandchildren if they were carers or could otherwise prove their own loss and (b) in the case of siblings, only in limited circumstances as defined by recommendation 5. We are unable to point to significant volumes of evidence from these groups as the Inquiry has focussed on closer relatives in Scotland, though some evidence is referred to above in the cases of siblings of those infected. Others beyond Scotland might have evidence such as to enable the Inquiry to draw the conclusion that this class broadly has suffered such that there is a moral duty that they should as a class be compensated across the board. It is noted that they could claim if they are able to demonstrate their own individual loss within the scope of Recommendation 5(f). For the sake of clarity, like siblings, parents would only qualify for an award in their own right in non-fatal claims if their child was infected as a child and if they can prove their own loss. They too should be entitled to the undernoted awards in fatal cases, in accordance with the law of Scotland.

1.128 Affected relatives in fatal cases should thus be entitled to claim:

(a) A sum to reflect the loss of society of the deceased person. This should be available to the deceased's immediate family, defined in accordance with the Damages (Scotland) Act 2011 – spouses etc, parents, children, siblings, grandparents and grandchildren.[3206]

[3206] As per section 4(3)(b) of the Damages (Scotland) Act 2011

(b) A sum in respect of the services which they required to render to the infected person in life (akin to necessary services under section 8 of the Administration of Justice Act 1982 – these should also be claimable in living claims)[3207];

(c) The loss of personal services (as defined by section 9 of the Administration of Justice Act 1982) which the infected would otherwise have been expected to render to them, but for the death – these should also be claimable in living claims [3208];

(d) Funeral expenses incurred – a certain minimum amount (around £5,000) should be nominated with the ability to claim for more if more was incurred reasonably[3209];

(e) Care costs for their infected relative in the event (with adequate provision to avoid double counting with estate claims, where patrimonial loss for cost of care incurred by the deceased could also be claimed);

(f) Costs of administration or investment of ultimate awards. This is an award which also ought to be made in cases where the investment of funds is something which the tribunal, along with legal advice can achieve for the individuals in question and should also be claimable in non-fatal claims. The evidence which the Inquiry had heard relating to the ways in which monies awarded for support from trusts and schemes were sometimes lost by those who were not used to having the money indicates that such support is merited. It would be expected that damages to cover such expenses would be awarded in large damages claims. The level of the support awarded in this regard should be provided would depend on the level of the ultimate award;

(g) If they can establish loss of support (dependency) any family members as defined above should also be entitled to make claims for loss of financial support.[3210] There

---

[3207] This would normally be claimable by a deceased's estate in Scotland under a combination of section 8 of the 1982 Act and section 2(1) and (2) of the 2011 Act but under section 8, there would be a duty for the estate to account to the relative for the sums paid in respect of such necessary services rendered by that (section 8(2) of the 1982 Act). This sum would best be claimed by the relative in question in these circumstances as they would be best placed to provide evidence as to the extent of those services.

[3208] Part of the English dependency award and claimable in Scotland in fatal cases by the family members under section 6 of the 2011 Act

[3209] Which could be claimed in Scotland in fatal cases under section 4(3)(a) of the 2011 Act by a relative of the decease who had incurred the expense

[3210] Damages (Scotland) Act 2011, section 4(3)(a), 4(5) and 14(1)

claims are similar to the claims which could be made in fatal cases in Scotland under the Damages (Scotland) Act 2011, section 4(3)(a). The tribunal could allocate an assumed percentage which would have been used for the expenses of the deceased.[3211] Notification provisions should be incorporated in the scheme to make sure that all relatives with a claim under recommendation 8(f) may also have the opportunity to apply for their share of the financial dependency claim; and

(h) Their own wage loss in appropriate cases, as argued above.

Amounts

1.129 The Robert Francis analysis leaves the calculation of precise categories and tariffs to the medical and legal panels. However, given the Inquiry's access to so much of the relevant information and evidence, we submit that its recommendations should provide some greater guidance as to how these sums might be calculated by those bodies. In making the interim award to the infected, the Inquiry was likely to be acting on safe ground in terms of that being a minimum injury award which most infected people would be entitled to received, as per recommendation 14. By awarding £100,000 to widows, however, the Inquiry went further. It is submitted that the Inquiry can go further and is well placed to do so, given its ability to analyse the extent of the moral duty owed to wider relatives, considering the culpability of the State and the extent of the loss which these affected relatives have suffered. In doing so, the Inquiry can and should be guided by the law as it appears to have been in awarding the £100,000 to widows. That is the sum that would be appropriate for this Inquiry to order that widows or other partners (as listed by Robert Francis in his report) be paid, before interest. This would be a typical award in Scotland in fatal cases[3212];

[3211] Such as the 25% used as the default position under section 7(1)(a) of the Damages (Scotland) Act 2011

[3212] See Anderson v Brig Brae Garage Ltd (Lady Stacey and a jury, 25 June 2015): Partner (aged 35 at the trial): £140,000 (E20,000 to the past). Spray painter aged 33 had to move a quad bike from a garage. Lost control of

1.130 That a lump sum payment of not less than £80,000 (before interest) should be made to the parents of those who died as a result of being infected with HIV and/ or HCV as a result of the contaminated blood scandal. This payment should be made to them (akin to the lump sum payments made to the infected and widows of the affected) to reflect the loss of society and guidance which they suffered as a result of the loss of their children to the scandal and/ or the practical and emotional burdens which they will inevitably have incurred as a result of the infection of their child whether alive or deceased. This would represent a typical award which would be made to a parent in a fatal case in Scotland[3213];

---

it and hit a wall, sustaining a fatal head injury. A good partner and father. Surviving partner (aged 35 at the trial) was devastated by his death. Their daughter was only 6 weeks old at the death, and would never know her father. Deceased had been particularly close to his father, being an only child whose mother had died when he was in his teens.

Stanger v Flaws and Proctor (Lord Clark and a jury, 17 June 2016): Widower (aged 68 at the death, and 72 at the trial): £120,000 (£60,000 to the past); two sons (aged 49 and 46 at the trial): £50,000 each (£25,000 to the past) - Woman aged 64 was a passenger in a car involved in a head-on collision in Orkney on 26 February 2012. Killed instantly. Had been married for 46 years. Was the central and supportive figure in a close family, described as a home-maker and a traditional housewife. Family suffered deep feelings of grief and sorrow. Husband devastated by her loss.

Manson v Henry Robb Ltd, 2017 S.L.T. 1173; 2017 Rep. L.R. 118 (Lord Clarke) - Widow (aged 79 at the proof): £75,000 (2/3 to the past. Company director developed mesothelioma and died aged 81. Had been a fit, active man with a life expectancy of 5.8 years, living with his wife and two sons, and helping with household chores. A "solid rock" in a close family unit.

Andrews v Greater Glasgow Health Board, 2019 S.L.T. 727 (Lord Pentland): Partner - £75,000 (£60,000 to the past) - woman aged 77 died of acute mesenteric ischaemia, having suffered stomach pains (latterly agonising), severe diarrhoea, and vomiting. With appropriate surgery, would have had a life expectancy of 7.5 years. McCulloch & Ors v Forth Valley Health Boards [2020] CSOH 20 (Lord Tyre — obiter) — award would have been made of £120,000 to the widow (agreed by the parties) respect of death of 39 year old of pericarditis shortly after hospital admission

[3213] Ryder v Highland Council 2013 SLT 847 (Lord Tyre) — award of £40,000 to child 17 year old at proof

Scott v Parkes (Lady Stacey and a jury, May 23, 2014): Mother - £86,000 (£40,000 to the past) Deceased (aged 19) died in a car accident. An only child. Had lived at home with his mother, who had brought him up and with whom he had a very close relationship. Devastating effect on mother (aged 51 at the trial) who described herself as "lost and broken" and who was described by others as "different from before". Unable to return to work as a staff nurse; began working in a shop.

Young v MacVean, 2014 S.L.T. 934; 2014 Rep. L.R. 113 (Lady Rae) (not altered on appeal: 2016 S.C. 135 (IH); 2015 S.L.T. 729 (IH); 2015 Rep. L.R. 110 (IH)): Mother - £80,000 (1/2 to the past): Pedestrian (aged 26) fatally injured when struck by a car driven by a dangerous driver. Mother witnessed immediate aftermath (damaged car and rescue workers) and after a period of increasing anxiety was told that her son had been killed. Mother and son had had a very close relationship.

1.131 That a lump sum payment of £80,000 (before interest) should be made to the children of those who died as a result of being infected with HIV and/ or HCV as a result of the contaminated blood scandal, for the same reasons as are set out above. This would represent a typical award which would be made to a child in a fatal case in Scotland[3214];

1.132 That a lump sum payment of £35,000 (before interest) should be made to the siblings of those who died as a result of being infected with HIV and/ or HCV as a

---

Anderson v Brig Brae Garage Ltd (Lady Stacey and a jury, 25 June 2015); Daughter (aged 3 at the trial): £80,000 (£10,000 to the past); father (aged 56 at the trial): £80,000 (£10,000 to the past). Spray painter aged 33 had to move a quad bike from a garage. Lost control of it and hit a wall, sustaining a fatal head injury. A good partner and father. Surviving partner (aged 35 at the trial) was devastated by his death. Their daughter was only 6 weeks old at the death, and would never know her father. Deceased had been particularly close to his father, being an only child whose mother had died when he was in his teens.

McArthur & Ors v Timberbush Tours & Anr [2021] CSOH 75 (Lord Armstrong) — awards of (a) £100,000 to each parent and (b) £70,000 to step-father in respect of death of a 26 year old killed in an accident at work;

McCulloch & Ors v Forth Valley Health Boards [2020] CSOH 20 (Lord Tyre — obiter) — award would have been made of (a) 80,000 in respect of each child (young at death) and (b) £70,000 to stepson and (c) £30,000 to each parent (agreed by the parties) in respect of death of 39 year old of pericarditis shortly after hospital admission

[3214] McCarn v Secretary of State for Business Innovation and Skills, 2014 Rep. L.R. 138; 2014 G.W.D. 26-519 (Lord
Bannatyne): Five children aged 40, 38, 37, 36, and 31: £35,000 each (1/2 to the past). Deceased aged 69 died of mesothelioma.

Anderson v Brig Brae Garage Ltd (Lady Stacey and a jury, 25 June 2015); Daughter (aged 3 at the trial): £80,000 (£10,000 to the past); father (aged 56 at the trial): £80,000 (£10,000 to the past). Spray painter aged 33 had to move a quad bike from a garage. Lost control of it and hit a wall, sustaining a fatal head injury. A good partner and father. Surviving partner (aged 35 at the trial) was devastated by his death. Their daughter was only 6 weeks old at the death, and would never know her father. Deceased had been particularly close to his father, being an only child whose mother had died when he was in his teens.

Stanger v Flaws and Proctor (Lord Clark and a jury, 17 June 2016): Two sons (aged 49 and 46 at the trial): £50,000 each (£25,000 to the past) - Woman aged 64 was a passenger in a car involved in a head-on collision in Orkney on 26 February 2012. Killed instantly. Had been married for 46 years. Was the central and supportive figure in a close family, described as a home-maker and a traditional housewife. Family suffered deep feelings of grief and sorrow. Husband devastated by her loss.

Manson v Henry Robb Ltd, 2017 S.L.T. 1173; 2017 Rep. L.R. 118 (Lord Clarke) - Two sons (aged 59 and 55 at the proof): £30,000 each (1/2 to the past). Company director developed mesothelioma and died aged 81. Had been a fit, active man with a life expectancy of 5.8 years, living with his wife and two sons, and helping with household chores. A "solid rock" in a close family unit.

McCulloch & Ors v Forth Valley Health Boards [2020] CSOH 20 (Lord Tyre — obiter) — award would have been made of (a) 80,000 in respect of each child (young at death) and (b) £70,000 to stepson and (c) £30,000 to each parent (agreed by the parties) in respect of death of 39 year old of pericarditis shortly after hospital admission

result of the contaminated blood scandal, for the same reasons as are set out above. This would represent a typical award which would be made to a sibling in a fatal case in Scotland[3215]; and

1.133 That a lump sum payment of £25,000 (before interest) should be made to the grandparents and grandchildren of those who died as a result of being infected with HIV and/ or HCV as a result of the contaminated blood scandal, for the same reasons as are set out above. This would represent a typical award which would be made to a sibling in a fatal case in Scotland[3216].

[3215] McArthur v Timberbush Tours Ltd, 2021 S.C.L.R. 598; 2021 Rep.L.R. 124; [2021] CSOH 75; 2021 S.L.T. 1021; 2021 G.W.D. 23-318 (Lord Armstrong): Parent/child; half-sister (aged 12 at the death); step-father. Young man aged 26 died when a tour bus collided with his cherry-picker, throwing him to the ground. Conscious and in significant pain for about 50 minutes before death. Particularly close family, who were distraught with grief and shock, and finding it difficult to get over their loss. Distress, grief and loss of society: Parents: £100,000 each; half-sister, whose relationship with the deceased had been "an extraordinarily close and loving one": £45,000; step-father: £70,000. (One half of each award to the past, with interest at 4 per cent.)

Currie v Esure Services Ltd, 2014 S.L.T. 631 (OH); 2014 Rep. L.R. 57 (OH); 2015 S.C. 351 (IH); 2015 Rep. L.R. 28 (IH) (Lady Wise and the Inner House): Parents, brother. Pedestrian fatally injured when struck by a car at a pedestrian crossing. His death caused deep grief and upset. Distress, grief, and loss of society: Father and mother: £42,000 each; brother: £22,500.

[3216] Stuart v Reid, 2014 Rep. L.R. 107; 2014 G.W.D. 25-493 (Lord Woolman): Grandparent/grandchildren. Man aged 60 died as a result of a car driving into him as he stood at the rear of his parked vehicle intending to let out his dogs. Two grand-daughters, N aged 5 and E aged 3. Grandson H born five months after the death. Deceased and his wife ran a guesthouse at the family home in Aberdeen. Both devoted to their family. Closely involved in their grand-daughters' upbringing, including holidays. Deceased had a life expectancy of 15 years. Following the death, N very upset, E noticeably quiet. Distress, grief, and loss of society (taking into account inter alia (i) the very close bonds of love and affection; (ii) the deceased's material involvement in their upbringing; (iii) the conclusion that he would have enjoyed a similar relationship with H; and (iv) his state of health and his life expectancy of 15 years): Grandchild N (5): £18,000 (1/3 to the past); grandchild E (3): £16,000 (1/3 to the past); grandchild H: £14,000 (no allocation to the past).

Gallagher v S C Cheadle Hume Ltd, 2015 Rep. L.R. 33; 2014 G.W.D. 23-435 (Lord Uist): Spouses; parent/children; grandparent/ grandchildren. Deceased died of mesothelioma as a result of negligent exposure to asbestos during his employment. Distress, grief, and loss of society: Widow: £80,000; four children: £35,000 each; grandchildren: £25,000 each for two; £12,000 each for three; and £2,500 each for two aged 2 years and 3 months respectively at the death.

McGee v RJK Building Services Ltd, 2013 S.L.T. 428; 2013 Rep. L.R. 59 (Lord Drummond Young): Spouses; parent/children; grandparent/grandchildren. Man aged 71 died after falling downstairs. Happy marriage, close relationship with wife, active social life. Distress, grief, and loss of society: Widow: £80,000; daughters B (44) and C (37) close relationship with deceased: £35,000 each; son D (43) not such a close relationship but greatly upset by death: £27,500; granddaughter X (9) close relationship: £20,000; grandson W (17) deceased had been a father figure: £25,000; granddaughters Y and Z (13 and 10) close relationship but no special factors: £12,000 each.

2 CHANGES TO THE SUPPORT SCHEMES

Evidence about the existing schemes available to the IBI

2.1 The evidence heard by the Inquiry in connection with the support schemes has led to certain deficiencies and principles emerging, as is submitted above in connection with the rationale behind why there should be a compensation tribunal in addition. These apply *mutatis mutandis* in connection with the rationale behind the continuance of the need for support and thus for the schemes to continue, broadly as they are constituted.

Alterations to the existing support schemes

2.2 Sir Robert Francis was charged with reporting to the government about a possible compensation scheme for those infected and affected as a result of the contaminated blood scandal. This is presumably why his commentary on the need for changes to the support schemes does not feature amongst his recommendations. However, in exercising his functions he deemed it necessary to make recommendations about the schemes as well. It would be impossible fully to understand or to implement the recommendations he has made about compensation without also implementing changes he has recommended to the schemes. Indeed, it would be fundamentally to misunderstand and leave unfulfilled his overall vision for the future, if these elements were left unimplemented. In broad terms, we submit that they should be, for the reasons given below.

Lack of parity in the existing schemes

2.3 The UK government has given the impression to this Inquiry that recent efforts have resulted in parity between payments made under the four support schemes. This is not the case. Ongoing harm is caused to those in receipt of payments similar to that described in correspondence prior to the recent uplifts in the amounts paid under the schemes.[3217] The discretionary payments made under the EIBSS enable greater payments to be made to registrants with that scheme than are currently made to the registrants of the Scottish scheme. Few discretionary payment have been made in Scotland.[3218] Parity of payments has been limited to the lump sum and regular payments to which applicants are entitled. It is therefore necessary that changes be made to the framework and administration of the SIBSS to facilitate discretionary payments (such as child payments[3219] and winter fuel payments[3220]) being made to those who would be so entitled under the EIBSS scheme.

Increased regular support payments

2.4 The Inquiry has heard that the payments made under current schemes for those infected with HIV and/ at the "stage 2" of HCV infection receive inadequate support to provide for their needs under the current scheme arrangements. This is because the basic regular payments which are received by such individuals often do not cover the significant increased costs associated with these more advanced conditions and the associated disability and dependency which they create. This is particularly the case as a result of those infected as a result of the contaminated blood disaster now reaching old age in many cases. The increased disability of the more severely infected community as the cohort grows older leads to significant

[3217] WITN4506014 – letter from Dr Caroline Coffey to Catherine Cody dated 11 March 2021
[3218] IBI transcript for 18/05/2021; 171(15) to 171(23) (Martin Bell)
[3219] IBI transcript for 18/05/2021; 174 (19) to 175 (16) (Martin Bell) – child payments available under EIBSS were not available in Scotland
[3220] IBI transcript for 18/05/2021; 173 (14) to (17) (Martin Bell) – there was a non-means tested living costs supplement which made up for some of the winter fuel payment available elsewhere

financial need in areas such as care, significant home adaptations, the requirement to move accommodation etc.

2.5 This is to cater for the fact that the evidence which has been heard by the Inquiry has shown that for such registrants, the current annual entitlement is inadequate to meet their considerable needs. This increased sum could and should be fairly applied across the board without the need for resort to be had to the compensation tribunal and is commensurate with the increases to the "stage 1" payments announced by the government in 2021.

Mechanics of the changes

2.6 The proposals which are made by the Francis evidence are to be found in 2.53 of his report. He has proposed that (a) all annual support payments (which include the heating allowance) should be brought up to at least a level 5% above net national median earnings, and those already at that level should be increased proportionately to maintain the differential between categories of award and (b) a lump sum supplement should be added to all annual payments of £10,000, to cover other items such as increased insurance costs, additional transport costs and so on. It was revealed in the evidence to the Inquiry that costs like insurance costs had been considered as part of the Scottish Financial Review, had been recognised as an area which needed to be addressed but has not been.[3221]

2.7 These changes are, it is submitted, entirely sound in principle, consistent with the evidence heard otherwise in the Inquiry, consistent with the principle of providing proper support via the support schemes and sensibly aligned with and complimentary of the principles which underpin the compensation tribunal. It appears to be beyond dispute that the moral duty to provide support via a

[3221] IBI transcript for 18/05/2021; 39 (16) to 42 (6) (Sam Baker and Mairi Gougeon)

mechanism such as the schemes exists in these circumstances. No government minister who spoke about the operation of the schemes claimed otherwise.

2.8 Change (a) addresses to an extent the need to address the fact that the nature of the future payment would change to an extent to be compensatory in part, due to the fact that future loss would take these payments into account. They would tend to assist with the simplicity principle as they would remove the basis for future claims for wage loss in most cases and would promote finality in a way which is fair to the whole community. The change would incorporate a community based approach to recognising the need to provide a degree of future wage loss (which is likely to be accepted in most cases) in order to settle the claims and allow people to move on. Those who wish to claim above this level could do so but such claims would be likely to be few in number. This logic of this proposal is set out in the Francis report. He was of the view that past payments were not compensatory in nature (as had been confirmed by ministers in other evidence) and that they had the intention of lifting people out of poverty. In that latter assessment, he had some support of the Financial Review group report which had formed the basis upon which the SIBSS was formed.[3222] The continued regular payment of these sums was deemed important to Sir Robert and to the community.[3223] We share this view. His oral evidence made it clear that he had thought long and hard about the need for these support payments to continue in light of the compensation tribunal. His position, we submit, constitutes a reasonable balance between (a) the need for there to be regular payments to maintain security and the need for people who have been recognised by the schemes not to receive less due to the compensation scheme than they otherwise would and (b) the need to recognise that compensation tribunal changes the landscape to an extent.[3224] This is why (in the absence of any clear explanation to the contrary in his researches) Sir Robert concluded that the support schemes should continue for the purposes of security and support but that future payments should be deductible against future wage loss claims in appropriate cases. In addition, the abolition of the support schemes

[3222] IBI transcript for 18/05/2021; 19 (22 to 23)
[3223] RLIT0001129_0115 @ para 9.87
[3224] IBI transcript for 11/07/2022; 168 (16) to 170 (10) (Sir Robert Francis)

in favour of then national compensation tribunal would have many consequences which should be avoided. The SIBSS has the benefit of locality and hence accessibility. It has built relationships with registrants. It performs functions other than simply providing financial support, including signposting to support services in connection with psychological issues, benefit queries and more, as were spoken to in the evidence to the Inquiry of Sam Baker and then minister Mairi Gougeon. Sir Robert was correct, in our submission, in his analysis that the past payments could not be viewed as compensatory based on the evidence from ministers and his interpretation that they had been limited in time, sporadic at times and intended to lift people out of poverty, to an extent. The balance that was struck between these competing considerations was to change the interpretation of these payments in the future. All of this was part of his analysis of the extent of the moral duty to support but also to compensate, both of which were merited. We agree.

2.9 Change (b) reflects the fact that infected individuals incur increased costs due to their illness and disability, such as accommodation or travel costs. Indeed, the current payments do not account for certain additional costs which are suffered in day to day life and the current issues with lack of parity in the way in which discretionary payments are dealt with under the current schemes. The increase of £10,000 would remove the need for these discretionary elements and address parity issues. The cost of living crisis is also likely to be more acutely felt by the infected and affected than others. These changes address that element fairly as well. In addition, the likelihood that many infected people are now more elderly and will live into old age will mean that the expenses associated with their infections in addition to natural infirmity will only be likely to grow. We appreciate that the changes which are proposed are broad brush. They are justified in so being in order to provide a community based approach to future support/ compensation and which avoids dealing with the complex subject of future loss, which would otherwise involve a good deal of speculation about the future. In his evidence, Sir Robert clarified that this approach had the advantage of people needing to prove future expenditure of a standard, routine nature which is likely to be incurred due to infection, which was something people had had great

difficult and suffered distress in having to do under previous trusts and schemes. This also provided certainty for those funding the scheme and the possibility of spreading such payment evenly into the future.[3225] The increased payments to cover insurances would avoid the need for there to be a complex underwriting scheme for insurances such as in Ireland. In evidence to the Inquiry the representatives of the Scottish government accepted the need for these extra cost issues to be addressed by the schemes. We submit that the Inquiry should recommend that these changes should be implemented immediately.

Ancillary elements

2.10 There are various submissions made above about the need for various steps to be taken based on arguments and principles which apply equally to the future basis and operation of the compensation tribunal which apply equally to the future of them – such as the need for legislation to provide a greater level of security for the safeguarding of future payments and the need for local administration with which claimants can interact. Insofar as the steps which we submit should be taken in accordance with principles apply equally to the support schemes, we have made clear where they should apply above.

2.11 In particular, the SIBSS should be put on a statutory footing creating an obligation on government to continue to make the payments which are due under the scheme for the remaining lives of those who have a right to claim, including both the infected and widows.

2.12 The payments under the scheme are designed to provide support to the individuals with an entitlement to them for the needs created by the infections. In order that the payments continue to do that, the statutory regime should provide for payments to increase year on year in accordance with inflation. Otherwise, the value of the payments made would decrease in real terms.

[3225] IBI transcript for 11/07/2022; 12 (22) to 14 (14) (Sir Robert Francis)

3 CONCLUSION

A new statutory regime

3.1 It is therefore submitted that the Inquiry should make the following recommendations:

(a) That the governments of the UK and Scotland should seek to introduce legislation underpinning the existence and operation of the current support schemes, including the SIBSS, as well as the compensation mechanism described below. Though it is true that legislation could in theory be undone by future legislative measures proposed by a future government, it would be far more burdensome for a future government to take the necessary steps and gain the requisite political support for the necessary legislation to be introduced and enacted than would currently be necessary for the schemes to be dismantled or significantly changed.

(b) Such primary legislation should commit to:

- The continued existence of the support schemes;
- A recognition that the purpose of the schemes is to cater for the needs of those infected and affected by the contaminated blood scandal;
- The setting up of a compensation tribunal in accordance with the principles above to provide compensation in addition to support payments to those who qualify;
- Payments being made under the schemes being be free from liability to taxation, exempt from inheritance tax and discounted for the purposes of benefit entitlement, except as otherwise indicated in this submission, and increased annually in accordance with inflation;

- Payments being made via the compensation tribunal being free from liability to taxation, exempt from inheritance tax and discounted for the purposes of benefit entitlement, except as otherwise indicated in this submission;
- The obligation on the UK government to funding the schemes and the compensation mechanism;
- The obligation on the UK government to ensure that funding for the schemes nationally and for the compensation tribunal is allocated to a budget administered separately from the national and regional health budgets;
- The ability of the Scottish government to independent retain control over the operation of the SIBSS, including the determination of the qualification criteria in order to maintain local responsibility and accountability for the operation of the Scottish scheme;
- There being no time limit on the application. This is to cater for the possibility that infected people who qualify may only learn of the fact of their infection or of the fact that it was caused by a blood transfusion some years into the future. They may also be legitimate personal reasons why an applicant does not wish to apply at a given time, which he should not be required to explain or justify if an application is made "late";
- The removal of the September 1991 time window which to applies to the schemes or the compensation tribunal. The reason for this is that it remained possible that infections could occur after this date, in particular from HCV as a result of receiving unscreened blood collected before that date but also as a result of blood or blood products which have proved infective despite measures taken to minimise the likelihood of their infectivity. Given this possibility and the requirement still to prove that it is likely that the infection was caused by blood or blood products - this arbitrary deadline should be removed;
- The right to legal representation in the compensation tribunal and in appeals under the SIBSS scheme, the prejudice suffered by those representing themselves within that process having been made clear by evidence heard by the Inquiry;
- The introduction of requirements (both for the compensation tribunal and the SIBSS) (a) that the testimony of the applicant or other supporting medical or lay

witness testimony as to the causation of the infection by transfusion must be considered in the determination of whether a person was likely infected by blood or blood products and (b) that reasonable steps must be taken by the tribunal and the SIBSS to ascertain local transfusion practice at the time of the alleged transfusion infection; and

- The ability of any devolved government to undertake any additional financial obligations in connection with the blood contamination disaster to cater for circumstances in which they saw fit to introduce unilateral further payment in the future (such as, for example, the introduction of payments to deal with the emergence of damage as a result of pathogenic exposure which had not been foreseen or the introduction of new classes of qualifying affected applicant).

Delay

3.2 As a result of submissions made on behalf of core participants and in light of recommendation 14 in the Francis report, the Chair produced an interim report which recommended that interim compensation payments of £100,000 should be made to infected people and the widows of deceased infected people, if they were already registered with a support scheme, which meant that they had already satisfied the eligibility criteria for payments to be made to them under those schemes. One of the main reasons why these payments were thought appropriate was in recognition of the fact that if a compensation scheme were to be set up along the kind envisaged by the Francis report, it would take some time for the mechanisms to be set up (including the Arms Length Body and the medical and legal panels) with the result that it would take some time for cases to be processed and payments to be made. Sir Robert gave clear and compelling evidence that the earlier compensation could be awarded, the more effective it would normally be.[3226] This statement needs to be considered in light of the considerable delays

[3226] IBI transcript for 11/07/22; 21 (1 to 7) (Sir Robert Francis)

(which have gone on for decades) which have been occasioned by the State in recognising the moral duty to pay compensation, the fact that certain clearly affected groups have never received any compensation or support, and the fact that despite the SIBSS existing since 2017, some of the worst affected still live in financial hardship which needs to be addressed as soon as possible. It was thought appropriate that interim payments were made at this stage, in particular as there was a pressing moral need for payments to be made in light of the age of many of the applicants, the general evidence about heard about the ill health of many, the possibility that many may die before the compensation tribunal can be set up, the pressing need for these individuals to be able to settle their affairs and, by clear implication, the benefit which these interim payments are likely to have on the mental well-being of the applicants.[3227] The entire purpose of the government setting up the Francis study was to seek to minimise delay between the report of the Inquiry and the introduction of a compensation scheme.[3228] However, it was also planned, according to the Francis report, that the government's response to the study would be issued to the Inquiry along with its report, so that both could be subject to the scrutiny of the Inquiry.[3229] No response to the Francis report has ever been released by the Government. Therefore, there must be a real risk that the delay which the study wished to avoid will occur. It is submitted that the Inquiry must do all that it can to avoid or at least mitigate the effects of such delay.

3.3 In light of these same considerations, both for those who have already received interim payments and would be entitled to claim for further payments and also for those who would be entitled to such payments but did not receive interim payments it is imperative that further delays are avoided. Elsewhere in this submission, we have submitted that a task force should be set up to monitor action being taken consequent upon the recommendations of the Inquiry. We consider that that body should be expressly provided with the power to seek responses from the government as to how it intends within reasonable deadlines. As submitted elsewhere, that body should include representative bodies from the

---

[3227] RLIT0001129_0010 @ para 1.10
[3228] RLIT0001129_0010 @ para 1.9
[3229] Ibid.

patient community (such as Haemophilia Scotland and the SIBF) to ensure that the legitimate and reasonable expectations of the infected and affected community are heard and acted upon.

3.4 As indicated above, an important part of the alleviation of the suffering and financial hardship of many infected or affected individuals that should be recommended is that the changes to the support schemes (which do not rely upon any substantial administrative action to be taken, as per the interim report on compensation) should be implemented within a specified timescale. It should also be recommended, if the Inquiry accepts and recommends that step, that the payments should be backdated to the date of the Francis report. The government has chosen not to act upon those recommendations which were actionable immediately without the need to await the outcome of the Inquiry as they did not rely on substantive administrative changes or even acceptance of the moral duty underpinning the compensation tribunal. That is precisely why Sir Robert recommended that those increases be made through the schemes as opposed to being part of the compensation tribunal system.

3.5 In addition, it is submitted that there are still significant categories of people who have been left without support, to whom it is argued above and accepted by Sir Robert Francis, the State owe a moral duty to provide compensation. These include:

(a) Estates of a deceased person who did not receive a compensation payment in life;

(b) The parents, children and siblings of deceased infected persons;

(c) Wider relatives and others connected to the case of a deceased infected person; and

(d) The relatives (other than widows) of and others connected to an infected persons who is still living.

3.6 The principles underpinning the Sir Robert Francis report included the need to alleviate suffering by way of interim payment, as it set out elsewhere in this

submission. As far as interim payments are concerned, the Inquiry needs to consider (a) the practical impediments which would exist if interim payment to some or all of these individuals were to be made and (b) the extent to which the Inquiry supports awards ultimately being made to these classes of persons and how much those awards might be.

3.7 We have already made a submission to the effect that a payment of £100,000 should be made to infected persons (as per the Francis recommendation 14) and to partners. It was argued primarily that such an award would be roughly what might be awarded (before interest) to partners in normal fatal cases in Scotland for "loss of society" under section 4(3)(b) of the Damages (Scotland) Act 2011. That submission was accepted by the Inquiry. The possibility that interim payments might also be made to bereaved parents and children might was also considered. Though the case for this was recognised as compelling, the question of how much might be awarded was something on which the Chair invited further submission.[3230] We have presented above a case for payments to be made for payments to be made to bereaved relatives who would be entitled to payments in fatal cases (and the levels at which such payments might typically be made) under Scots law. This is a sound basis upon which such payments should be made, along with the preceding submissions which constitute the basis upon which it can be asserted that there is a moral case for so ordering. The Inquiry should, in the first instance, consider a further interim report ordering that interim payments be made to these bereaved relatives, or at least bereaved parents and children as soon as possible. The same arguments relating to the likely impacts of delay apply to these individuals who have waited so many years for any form of recognition of the effects of the disaster on them.

3.8 In any event, if the Inquiry accepts in its final report the principles of Sir Robert Francis which are also supported in this submission, there would have been a change of position since the interim report was drafted, in that the moral case argument would have been accepted to a greater extent than was inherent in the decision reached to recommend that interim compensation be awarded only to

---

[3230] Interim report of the Inquiry, para 33

the infected and to partners. Further, if the Inquiry endorses sums suggested as being applicable in certain types of cases (as it is urged to do in this submission) there would be little need to wait for the process of application or indeed assessment by medical and/ or legal panels. In effect, tariffs commensurate with the law would already have been set and there would be little benefit to delaying payment unnecessarily. There would also, it is submitted, be less practical impediment than might at first be thought based on current registration with the support schemes and their capacity to undertake any administrative work involved.

3.9 In the case of estates, the Inquiry should recommend an interim payment of £100,000, which would represent the same approach to an injury award that the deceased person would have received in life. The estate would be entitled to that payment under Scots law under section 2(1)(a) of the Damages (Scotland) Act 2011 or to a similar awards under the Law Reform (Miscellaneous Provisions) Act 1934 in England and Wales. It is understood that some such estates may already be registered with the support schemes in order to receive the bereavement payment made on the death of an infected person.[3231] The SIBSS also has experience of registering estates in cases where lump sum payments which would have been made to a deceased person which were not claimed are now made.[3232] If not, registration with appropriate vouching should be fairly straightforward. Further, payments should be made to parents, children and siblings in fatal cases in the sums suggested above. These are payments to which the individuals would be likely to be entitled under section 4(3)(b) of the 2011 Act. Though these would not be tariffs as under the Fatal Accident Act 1976 in England, it is submitted above that judicial authority in effect ascribed tariffs to these figures meaning that they are awards which could be safely deemed to be what a court would order in most if not all cases. If further claims are to be made beyond these sums or by others, these would require to be made in accordance with the normal processes of the tribunal. The administration involved in these individuals registering with the

[3231] See RLIT0001498 and IBI transcript for 18/05/2021; 79(11 to 15) – see reference to the bereavement payments made in cases where death has been since the scheme began to be made to "families"
[3232] IBI transcript for 18/05/2021; 129(8) to 130(3) (Martin Bell)

schemes or the tribunal would be minimal, in particular in cases where the infection were already registered (ie where the infected person had registered or been deemed eligible in life or where a widow is estate is already registered).

3.10 In any event, whether the Inquiry take the view that interim awards can be made without the setting up of the Arms Length Body and/ or the medical and legal panels, we renew our submission made at the stage of the interim report that these bodies should be set up without delay.[3233] This was a view which was endorsed by Sir Robert in his evidence to the Inquiry. The Inquiry ought to recommend that these steps be taken as soon as are practically possible.[3234] The progress of these matters should be monitored by the task force which were have suggested should be set up to monitor the implementation of the Inquiry's recommendations. Timetables should be set for these measures to be taken.

3.11 In addition, for those who have already had interim payments from the tribunal it may become apparent relatively quickly once an application for compensation has been made that that their claims are likely materially to exceed the interim awards which they had already been given. For example, it might become apparent quickly that a person had suffered a wage loss, at least to a certain extent, which was not rebuttable or that the injury award made to that person would be likely to exceed the payments already made by some distance. In such cases, the tribunal should have the power to make further interim awards in accordance with normal civil law principles regulating the making of interim payments. The fact that a person has a large and complex claim should not be an impediment to securing a reasonable proportion of that claim quickly. All of these proposals are consistent with the eleventh of Sir Robert Francis' principles relating to timing and the avoidance of delay.

3.12 The evidence given by Sir Robert Francis to the Inquiry and the basis upon which the Inquiry determined that interim payments of compensation should be made to the infected and to widows acknowledged rightly that delays from this point require to be minimised so that the harms caused by the disaster are not further

---

[3233] See para 2(b) and para 37 of our interim submission

[3234] IBI transcript for 12/7/22; 94 (22) to 96 (15) (Sir Robert Francis)

compounded by a compensation scheme which is designed to alleviate them. It was accepted that the amount of taken which would be taken for these mechanisms to be put in place would be likely to run into years – time which many do not have.[3235] As such, we submit that the Inquiry should recommend that, in light of the practical steps which will have to be taken for the ALB and panels to be put into place which may run into years that priority should be given to those with the most pressing need in having their cases assessed. These might include applicants with a terminal diagnosis[3236], those who require full time care and those who are aged 70 years or older. These groups are those who are likely to have the most pressing need for access to funds, given in particular the likely significant costs associated with advanced disease and/ or age and those who are most likely to need to have their cases assessed in order to be able to settle their affairs before their deaths, which was such an important factor in Sir Robert's assessment of the need for interim payments.[3237]

O. CONCLUSIONS

1.1 The importance of this Inquiry cannot be over-stated. Its wide remit enables it to present a unique analysis of the factors which caused and the effects of the biggest treatment disaster in the history of our National Health Service since its inception over 70 years ago. It has heard copious evidence which enable it to draw robust conclusions about things that have gone seriously wrong, which should enable it to make clear and informed recommendations from an objective perspective and constituting a blueprint for how things need to work better in the future. Though the significant delays caused by the State in having the matters which are within the Inquiry's remit looked at have created challenges for the Inquiry, if it adopts

---

[3235] Interim report, para 32 (c)

[3236] Social Security (Scotland) Act 2018 - "Does the patient have an advanced, progressive and incurable condition, which may be associated with other conditions and which could include severe frailty, indicators of deterioration, where death will be an inevitable consequence of that condition?"

[3237] See recommendation 14 and IBI transcript for 11/07/22; 20 (3 to 10) (Sir Robert Francis)

the approach to the evidence which is advocated above, clear systemic patterns and failings are apparent from which clear messages emerge.

1.2 Though it concerns matters which had their origins many years ago, the Inquiry is not solely an historic analysis. The current relevance and importance of the Inquiry was recognised by Lord Owen in his evidence near the start of the oral hearings into what went wrong. The evidence heard by the Inquiry has allowed the universal themes and fundamental principles which do and will always be part of the effective functioning of the NHS to be re-analysed in a modern context. The Inquiry has more recently heard scientific evidence that the next pandemic could be blood borne. This is indeed a timely opportunity for a clear and comprehensive statement of those fundamental principles to be made, set in the context of real, contemporary threats to the very essence of the NHS. At the time of writing, the press is littered with examples of funding issues, which have provoked more than just speculation about the possibility that a State-funded NHS is no longer sustainable without further private investment. Staffing issues linked to Brexit or otherwise have caused industrial action resulting from the intolerable pressures imposed in modern day on NHS staff and real concerns about the sustainability of the NHS model. These very real and pressing concerns threaten the existence or at least the essence of the national health service model. The COVID crisis has shown the importance within Society of effective health services and the need for a cohesive and effective system by which the country's governments and its citizens can access and rely upon advice from its medical experts without any hesitation that it is given in the best interests of those who are in medical need and without influence by any other factor than that. The evidence heard by the Inquiry in connection with what is undoubtedly the biggest treatment disaster in the history of the NHS shows unequivocally what happens when the interests of patients and their engagement with decision making about their medical care are not at the forefront of decision making about clinical care. It had shown that a domino effect of secrecy and mistrust can flow from ineffective patient engagement in decision making, a lack of partnership, leading to lack of trust, leading to breakdown of individual relationships and ultimately of the whole system of medical care. The importance of effective collaboration between the

medical profession and patients and their families, encouraged and supported has never been more important in the post *Montgomery* world. The pressing need for practical engagement as opposed to mere theoretical involvement has been emphasised again and again in the evidence. At an organisational level, the need for clear and transparent medical advice being provided to government from appropriately qualified experts has been apparent. The need for candour and accountability in the activities of public servants, be they part of government or in the medical profession cannot be in doubt.

1.3 It is important that where the Inquiry finds there to have been wrongful action or inaction that the individuals who are responsible are identified. In many cases individuals were charged with responsibility – clinicians who had almost total freedom and little accountability, ministers who were elected, civil servants who were allowed the freedom to make key decisions despite not being so. In some instances, where not clear who was responsible, often the State should be held to be responsible as nobody was. In such instances, a lack of clear responsibility and thus clear accountability was the problem. Where not clear which department, entity or individual was responsible for acting or not acting as they should, more than often lack of responsibility/ accountability is the answer to what went wrong in the system. In some cases, nobody took control of events as nobody felt that it was their ultimate responsibility to do so. It is essential that the Inquiry be clear in its final report as to where the system failed and who or what entity was responsible, as we have sought to do in this submission.

An analysis of the key features of the infected and affected community

1.4 In our submission, the commitment of the Inquiry to start and finish its consideration of its terms of reference with the infected and affected is laudable and absolutely the correct way to go about its business. Our submission ends with some reflections on the unique nature of the community of infected and affected people who have suffered so greatly at the hands of the State. Above, we submit

in detail that the infected at affected form a unique group of victims. Unlike victims of other medical disasters, they have been exposed to repeated harms over decades at the hands of the State. It is this fact which makes them stand out and which make bespoke government compensation/ financial support schemes necessary and appropriate, as well as the non-financial mechanism which we have also recommended be put in place to help and support them. The moral culpability of the State makes these solutions entirely appropriate.

1.5 There are many common characteristics which the evidence has shown to be characteristic of the infected and affected communities, whether they or their loved ones became infected as a result of treatment for a bleeding disorder or as a result of a blood transfusion. These are as follows:

(a) All of those who were infected were vulnerable and considerably reliant on the medical profession at the time of the infections. They suffered from chronic diseases or their conditions were at least serious enough to require considering transfusion. Being in a vulnerable state meant that they had relied on the State, the State had accepted responsibility for them and they were liable to greater physical and psychological damage of things went wrong. They all had a "thin skull" in legal terms.

(b) The fact of their infections or other medical requirements for these underlying conditions meant that they frequently had an ongoing reliance on medical profession. This ongoing reliance for care, along with the stigma associated with their infections have led to normal situation where the mistrust created by the infections has caused an additional detriment in the form of the deficit in that care. For the bleeding disorder community, the reliance of the patients on the medical profession for the care needed for their chronic conditions led to a significant breach of trust and impacted on their ability to seek out care for those conditions in future. Many bleeding disorder patients were infected as children, when they were at the most vulnerable. This has led to complex physical sequela which remain poorly understood in patients explored to potentially deadly pathogens in their growing bodies. It has had uniquely complex results for family

relationships, in particular between parents and their infected children. Many were infected in families where others were also infected. This has led to uniquely complex sequelae for infected persons both in their relationships with the medical community and their families, the places where they would normally have expected unconditional care;

(c) Many of those with underlying conditions which caused the need for transfusion also needed ongoing care for those; for the transfusion community, the sense of abandonment by the State which in many cases did not inform them of their infection or trace them as having been infected by a blood transfusion for many years undermined their ability to accept care when their infection were eventually identified. In many cases, opportunities to investigate HCV as a possible consequence of blood transfusion was not investigated as a possible cause of medical problems meaning chances to treat were missed. This rendered them more ill by the time they were diagnosed, lessening their chances of treatment being successful. The resultant feeling that little was done to identify them as it would have cost the State money to do so. Even the Penrose Inquiry made tracing them its one recommendation;

(d) In addition to the multiple harms perpetrated by the State over many years, the subsequent actions of the State have had a uniquely compounding effect on the original harms including:

- The causation of the infections in the first place. This is addressed above.
- The failure of the State to recognise the harm which had been caused. Very few witnesses spoke of the medical profession accepting or recognising the harms or explaining how they had come to happen, invariably without any explanation of the risks in advance. Little psychological or other medical support was given to assist with coping with this situation, even in the case of children.
- The lack of answers being forthcoming for the medical profession led to a need for State engagement and answers from other emanations of the State. No answers were provided by the multiple government

investigations in Scotland, which had the inbuilt limitations which are hallmarks of a cover-up. The lack of public inquiry also compounded the harms – the State and the medical profession being allowed to mark its own homework also had a compounding effect. Answers were not found elsewhere in State-provided mechanisms, such as litigation, the criminal law or the GMC which were also characterised by obstruction and resistance of truth and justice.

- The stigma associated with the infections was both at the hands of the State and the fault of the State. When presenting for treatment, many treated like IVDUs and/ or alcoholics. In their communities, the fear and alarm which State-sponsored advertising around disease (in particular AIDS) increased public assumptions about the innocently infected victims, compounding their harms further.
- The lack of financial support drove many into poverty. Financial support was inadequate when it did come, forcing those infected to come to the State with a begging bowl. There was a lack of appreciation for the difficulties in applying, making applications dependent on medical opinion when there was a clear lack of trust in the medical profession. Financial solutions were always based on what could be afforded.
- Even when public inquiries did come, they were inadequate and provided a paternalistic response for those responsible. The Archer Inquiry was limited in its powers, the Penrose Inquiry limited in its compassion and analysis. Like all of these factors, they were common to the whole community, whether infected due to treatment for bleeding disorders or transfusion. Further, many also caused harms for the affected who at no stage were ever considered.

(e) Infection and treatment were like separate harmful incidents. What was eventually offered by the medical profession by way of treatment to try to cure or alleviate the original infections actually made their position considerably worse. For some, the consequences of treatment were far worse than the

consequences of infection. Again, State care seriously compounded and complicated the harms,

(f) The State response in many of the areas listed above created a sense of not being believed or having been stripped of not only health but also dignity and self-respect was also common to all of the victims.

(g) The diseases which were involved were diseases which were shrouded in mystery in terms of their aetiology and prognosis. These were diseases (both HCV and AIDS) which were latent/ had lengthy prodromal periods. They were thus by their nature hard to predict. The treatment which had led to the infections had involved widespread denial of choice and denial of freedom. This left the infected without any means of knowing what would happen to them and whether what they were being told was accurate or trustworthy. The diseases being ones which were slow to manifest themselves left the infected and their families in state of uncertainty without medics whom they could trust, a form of psychological torture. The diseases manifested themselves in losses which were (i) hard to see or understand from the outside and (ii) similar in symptomology associated with other diseases increased the stigma and lack of sympathy from other people.

(h) All have been blighted by the effects of secrecy. The greater the secrecy and the suspicion, the greater the mental health consequences. In both communities patients told of not being told about their infection, there being no discussion about how they had come to be caused, no acceptance of culpability, acknowledgement of harm or apology which led to mistrust, suspicion and psychological harm. The psychosocial expert group has spoken at length about the complex nature and extent of the psychological harm caused by such a response which is analysed in detail above. It is notable that no clear apology or sign of contrition has ever been issued by or on behalf of the NHS in Scotland, other than general expressions of regret, such as David Cameron's vague and hence meaningless apology in the aftermath of the Penrose Inquiry, which formed a unique opportunity which was not taken to address the Scottish elements of what went wrong on a national level. By way of contrast, apologies have been offered to this Inquiry by other such bodies in the UK. No clear or

specific apology has ever been offered by the Scottish government to the infected and affected of Scotland. It should have been. The continued defensiveness and lack of compassion and contrition on the part of the Scottish NHS to the infected and affected in Scotland have been significant element of compounding the harms of the disaster. They continue to this day to constitute a barrier between those infected and affected by the disaster and the NHS upon which they continue to rely;

(i) Given the nature of the way in which all of the patients have been infected (insidious viral transmission through blood and blood products), there exists a constant threat that it will be revealed that their treatment has not only caused the infections of which they are aware but also infections of which they are not yet aware, the existence of which is not yet known or the consequences of which have not manifested themselves. The most obvious manifestation of this phenomenon is CJD/ vCJD/ nvCJD. The extreme consequences of the contraction of the disease (ie death), the knowledge that those who have died have been blood donors, the fact that some have received products made from their donations, the fact of detailed and again secretive ongoing surveillance (CJD unit in Edinburgh) and the entirely understandable the mistrust of the reassurances given by the government/ the NHS all contribute to this element of the harm.

(j) The secrecy around the risks and the fact of infection in the context of infectious disease created amongst the infected a sense of considerable guilt that (though no fault of their own) they had or may have exposed loved ones to risk of infection, serious illness and death. For many this was described as the worst part of the disaster.

(k) The way in which campaigners were treated with suspicion and derision by the State as a result of their efforts in the face of the constant rebuttal of responsibility by the State led to greater suspicion and a further breakdown of the trust between the State and the community whom they represented. For the campaigners themselves (from all parts of the community) this had the knock-on effect of a further assault to already fragile social and family relationships;

(l) The effect of delay has had a further adverse effect on all. There has been an unprecedented delay in the acceptance of responsibility, apology or providing any explanation which has led to compounding of harms. The delay in holding a public Inquiry (addressed above) which should have been held nearer the time has diminished the quality of the evidence which can be uncovered the likelihood of finding the truth/ responsibility, not to mention the loss of life and the lack of justice for so many. Lord Fowler said in that regard that "There was a question of justice here that I hope will be addressed";

(m) The survivor guilt of the remaining infected and the affected is a common feature in both communities. The psychological trauma based in the conception that being dead would be better than being alive. The guilt of the parents, often the mothers, who injected lethal doses of the products they had been promised would minimise the effects of a genetic condition they had unwittingly passed to their sons. Even for those whose loved ones are not dead, the guilt of having administered the life altering drug which turned out to lead to a life not of freedom and happiness but of pain and illness. There was a tragic and painful irony that products derived from blood (whether red cells or plasma derivatives) which were meant to be life giving turned out to take or seriously impair life, in connection with which there was no strict liability protection;

(n) The scale of the disaster has been to the detriment of the individuals who have suffered harm on all communities. They may well have been treated differently by the State, had it not been the fact that to make a concession to one would open to the door to concessions to others. The evidence of litigations is demonstrative of this. The entire State response was predicated upon not allowing a chink of the light of truth to be allowed to shine through, given the potential ramifications caused by the scale of the disaster; and

(o) All patients were the victims of the lack of government responsibility taken for the administration of its public health responsibilities and the deference allowed to doctors in the exercise of their clinical freedom which allowed a system of anarchy.

1.6 There are other features of the evidence available to the Inquiry which may suggests that there are differences between the bleeding disorders and the transfusion communities. Important aspects of these elements are as follows:

(a) The effect of pooling and the increased risks which that created for the bleeding disorder community is addressed above. However, it must be borne in mind that transfusion patients were also the victims of exposure to the high risk donors as they were permitted to make their blood donations (generally not by plasmapheresis but by whole blood donations where the red cells were also used) into the system due to the need for plasma to treat the haemophiliacs.

(b) Many of those were either surrounded by death and serious disability in communities where they had been treated along with others, like the Yorkhill children or the being amongst a family of infected haemophiliacs. This led to the need to stare a possible unimaginable future in the eye. The same was true of campaigners who selflessly surrounded themselves with the horrors of others' experiences, knowing that they could become their own. The ongoing dependency of the bleeding disorder patients on the haematologists for their treatment meant that a sense of suspicion that they were not being provided with the best/ most informed treatment available and a sense that they may still be subjects of medical research.

(c) The fact that the State has benefitted from the harm occasioned to the infected and affected is also a material feature of the disaster which predominantly affected the bleeding disorder patients, as follows:

- Patients were used as a basis for increasing knowledge about diseases from their "canaries" for the benefit of society generally to the benefit of the NHS in providing better care. The State advanced medical knowledge based on the vulnerability of the canaries and their reliance on their doctors and trust that they are acting only in their best interests.

- Bleeding disorder patients reasonably believe that they were used as a basis for harvesting viruses from those who were known or likely to be infected for the development of vaccines domestically and avoided the need for them to be purchased commercially from abroad. They also believe that they were used as a basis for harvesting other immunoglobulins from communities known to be infected.
- It should also be borne in mind that the transfusion community, those identified by Lookback were (without their knowledge) included in the HCV Register. This created issues about trust and suspicion as to what information about them had been used for.

(d) In the case of those multiply exposed to pooled blood products or multiply transfused, it remains unknown to medical science what pathogens have or might still cause them harm and thus which aspect of adverse medical conditions is caused by what virus or pathogen. This has created greater uncertainty about future, in particular in circumstances where the medical profession has a vested interest and track record of keeping the cause and extent of the infections secret.

(e) On the other hand, those infected by transfusions had almost the opposite, horrible outcome. They were often left alone with no explanations. They thought in many cases that they were the only ones to whom this had happened, a kind of solitary confinement despite having committed no crime and with no clear definition of sentence.

1.7 The detriments which have been suffered are unique as a result of these factors and do not fit into any normal system or pattern of analysis. As is argued above, most have suffered so many consequences and harms that the injuriae are hard to define. Most have suffered repeated harms at the hands of those who were charged to care for them. The argument is made above for the need for presumption that loss they assert was caused by their infection or by the State. These patterns of harm and loss identified above are sufficient to allow general conclusions to be drawn and general solutions to be recommended. As a result,

the Inquiry needs to look at unique solutions which reflect the complexity and multiplicity of the unsurpassed harms, all of which stem from the iatrogenic injury occasioned to the infected and affected by the State.

1.8 As was set out near the start of this submission, the evidence heard orally by the Inquiry relating to Scotland has been characterised by a significant degree of evasiveness on the part of clinicians, ministers and officials who are (as a matter of fact at least) responsible for the occurrence of the blood contamination disaster in Scotland. They have, on many occasions, failed to answer questions, the answers to which only they can know. If this is due to matters not being remembered, that is the consequence of the failure to have a public inquiry into these matters on a national level earlier. Though this Inquiry has, as we have submitted, found many answers, they have rarely been forthcoming from those who are the most responsible. They have shown little contrition, if any. As a result, many have thus been denied clear explanations of why infections occurred, why their loved ones were lost and on various other matters. They have been denied a sense of justice and closure from those responsible. In this submission, we have made it clear that many important matters were never explained to patients or their parents adequately at the time of their infections or subsequently. We have also submitted that this was one of the main reasons why a public inquiry at the earliest possible stage was necessary, to achieve clear and essential explanation as to how and why this tragedy had happened. The State's failure to recognise this need and order a public inquiry was culpable. If it is correct to say that the clinicians or others who must at one time have had the answers to these unanswered questions or at least a reasonable basis for knowing where they might be found cannot remember, the culpable delay has had the effect of denying to the truth to those who so richly deserve it. If those clinicians have chosen to portray their positions as being that they cannot remember the answers, they have merely repeated and compounded their or their profession's failures at the time. Either way, the State has denied what the infected and affected have always wanted, the truth. We hope that in its independent capacity, the truth can be revealed by the Inquiry's final report. We hope that this submission assists the Inquiry in its remaining work and in achieving that aim.

James T Dawson K.C.

Heather Arlidge

16th December 2022