CLOSING WRITTEN SUBMISSIONS

on behalf of

NHS SCOTLAND TERRITORIAL HEALTH BOARDS

in the matter of

THE UK INFECTED BLOOD INQUIRY

CHAPTER 1: INTRODUCTION

1. At the outset, the NHS Scotland Territorial Health Boards wish to express their sorrow for this tragedy; and their sincere contrition for the failures and shortcomings on their part, which contributed to the suffering experienced by those infected and their loved ones. In the submission which follows, the Boards seek to identify, acknowledge, describe and explain the general and specific respects in which they consider that they fell short of the standards of care and treatment that patients were entitled to expect. To all those who have been affected by any of these failings, the Boards would like to say that they are sorry.

2. This Inquiry is tasked with investigating a treatment disaster of unprecedented magnitude within the National Health Service in the UK. The evidence from the Inquiry's expert group on statistics brings home in stark terms the enormity of the scale of the suffering and loss.[1] In Scotland, the Penrose Inquiry found that 60 patients were infected with HIV from blood products therapy; and 18 through blood transfusion. It was estimated that 478 people acquired Hepatitis C from blood products therapy and 2,500 through blood transfusions. Many of those infected have since passed away. Those who survive continue to suffer from the life-changing consequences of the diseases. Moreover, when one takes account of the impact on patients' families and others affected, the true number of victims is much greater.

[1] The expert group concluded in its report that between 1970 and 1991 1,250 people with bleeding disorders became infected with HIV from their treatment; and at least 79 people, and possibly up to about 100 people, became infected with HIV from blood transfusions. They estimated that 26,800 people have contracted HCV through blood transfusions; and between 2,400 and 5,000 people with bleeding disorders were infected with HCV, excluding those infected with HIV.

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3. In her evidence, Dr Anna Pettigrew, a junior doctor at Yorkhill Hospital, where 21 children were infected with HIV, said simply: *"it was just an awful, awful, awful tragedy."*[2] The written and oral evidence given by those infected and affected reminds us that every life lost or ruined in consequence of these infections is a profound tragedy in its own right. Those who gave evidence to the Inquiry have powerfully expressed their suffering and loss, and each and every one of those witnesses has contributed to the significant and important body of evidence which is now before the Inquiry. The Boards wish to express their gratitude to those witnesses for giving their evidence, and to acknowledge their courage in doing so.

4. As has been said before, the Boards place great value on their relationship with all patients from the infected and affected community. Strengthening that relationship is a paramount objective of the Boards in participating in this Inquiry. During this Inquiry they have listened to, and reflected upon, what their patients, clinicians and other witnesses have said in evidence about the Boards' role in the tragedy and what lessons can be learned. The Boards welcome the opportunity to set out their own conclusions in this submission.

5. The Boards come to this submission determined to approach matters afresh, and to put out of their minds assumptions and beliefs that may have been formed during the Penrose inquiry on the basis of evidence led before it. The conclusions arrived at in this submission are based upon their reflections on the very different evidence led before this very different Inquiry. They have sought to approach that evidence fairly and in good faith, and to draw what they sincerely believe are appropriate conclusions based upon their understanding of the evidence. Insofar as this submission proceeds to invite findings and conclusions which differ from those of the Penrose Inquiry, or indeed from their own submissions to that Inquiry, that is a necessary consequence of this approach.

[2] Dr Anna Pettigrew [Transcript 07.12.2020, p88-89]

6. Towards the end of his evidence to the Inquiry, Professor Ian Hann said: *"The final thing I want to say is you have already heard a lot of people say that the worst thing you can do, if you are in your right mind as a doctor, is to do harm to people. Unfortunately, harm does occur. A tragedy such as this is not absolutely unique but it was unique in my experience and it was a terrible thing and it caused terrible suffering to the families."*[3] The Boards are profoundly aware of the fact that this Inquiry is concerned with investigating how patients came to be harmed by treatment given to them by their doctors acting with the opposite intention. In these circumstances, the Boards believe it to be absolutely right that they focus their submission upon issues relating to what went wrong and why, rather than seeking to highlight positive accomplishments. That said, however, the Boards also consider it is important for them to acknowledge their many excellent and dedicated employees, both past and present, involved in the care of patients requiring blood therapy or transfusions. The Boards recognise, and pay tribute to, the dedication and commitment of their staff, who worked tirelessly to serve their patients in extremely challenging circumstances, often at personal and professional cost. In saying that, the impact of these events upon the healthcare professionals involved, however significant, cannot be compared to the enormous suffering experienced by the patients and their families.

7. Consistent with the Inquiry's Statement of Approach, this submission is primarily addressed to the factual findings and conclusions which the Chair should make on the matters within the Terms of Reference of most importance to the Boards. In this regard, the submission gives priority of focus to issues having the most direct bearing on the Boards' involvement in, and responsibility for, the circumstances in which patients acquired viral infections and their diagnosis and treatment. Recommendations are also addressed separately. The scope and breadth of the Inquiry's examination of its terms of reference has been vast. Accordingly, the Boards do not seek to address every topic and issue relevant to their position. Insofar as certain topics or issues are not expressly considered here, that should not be taken to infer, in any way, that these are not considered important.

[3] Professor Ian Hann [Transcript 08.12.2020 p160 – 161]

8. Finally, it is important to state that the conclusions set out in this submission constitute the views of the current Scottish Health Boards. These conclusions include an evaluative assessment of the Boards' historical performance in relevant areas, and also the actions of senior clinicians that held appointment at the material times. It is distinctly possible that some of the clinicians who have given evidence to the Inquiry will disagree with the Boards' judgments and conclusions in these regards. In the Boards' view, it is therefore important that the clinicians' opinions and perspectives should be given equal consideration by the Inquiry. While individual clinicians cannot make formal submissions, they have been given an opportunity to set out their position in their oral and /or written evidence. The Chair is respectfully invited to have regard to that evidence, insofar as relevant, alongside these submissions so as to ensure that any contrary position may also be fully considered prior to making any determinations.

9. This submission comprises 7 chapters as follows:-

   i. Introduction
   ii. Knowledge of Risk – NANB hepatitis
   iii. Knowledge of Risk – HIV/ AIDS
   iv. Consent
   v. Response to Risks of Viral Infection
   vi. Response to Infections
   vii. Recommendations.

CHAPTER 2: KNOWLEDGE OF RISK – NANB HEPATITIS

Introduction

10. The issue of knowledge of risk presents foundational questions for the Inquiry to determine. In relation to NANB hepatitis, whether the risk arising from the condition was sufficiently appreciated by the medical profession based on the information available to it at the time is clearly an important question in and of itself. However, the Chair's conclusions as to what was (or ought to have been) known about the risks of viral infections at all material times will also serve to inform the analysis of a whole host of other matters, perhaps most significantly: 1. the adequacy and timeliness of organisations' response to risk; and 2. the extent to which patients were properly informed and warned by their doctors of the risks of their treatment.

11. In this submission we do not attempt to describe a comprehensive chronology of events relative to developing knowledge of NANB hepatitis. The Inquiry has that evidence and we do not repeat it here. Instead, we seek to highlight certain events and facts at particular points in time which seem to us to be of importance, where appropriate under reference to the timeline of events. It is submitted that in their examination in evidence, Counsel to the Inquiry were correct to focus on how and when it first came to be appreciated that NANB hepatitis might be a serious condition with possible long-term consequences in the form of progressive liver disease. Identifying the answer to this particular question is important to enabling a wider consideration of the response of the medical profession and others to the emerging risks. For this reason, we focus our submission on the critical period between the late 1970s and mid-1980s, when evidence as to the nature and severity of NANB hepatitis first began to emerge in a meaningful way.

12. This chapter of the submission considers in isolation the issue of developing knowledge of NANB hepatitis, so as to avoid any conflation with other logically separate issues. For example, potential risks from treatment would have to be viewed in the context of its extraordinary benefits in addressing the known risks to patients caused by the life-threatening condition which haemophilia therapy was

designed to treat. Related questions, such as whether or not the emergence of a *possible* risk of progressive liver disease was such as to require modification of treatment policies, with its own attendant risks, also arise for the Inquiry to consider. In that regard, it will be very important to bear in mind that the risks, as they were understood at the time, needed to be balanced, with the caveat that, at that time, the risks were not clearly understood or agreed. We address these matters separately later in the submission (see Chapter 5 below).

13. Finally, by way of introductory comment, we note that during the Inquiry we have closely examined a wide variety of articles and papers about NANB published in the 1970s and 1980s to try to gain a better understanding of what was known at the time. It goes without saying that we have carried out this task with the benefit of substantial hindsight. We have read these publications against a backdrop of the now considerable understanding of NANB/hepatitis C resulting from years of further research after many of the articles were written. Furthermore, we have had the luxury of time to carry out a detailed and comprehensive comparative review of the publications - something that would not have been practically possible for most, if not all, medical professionals at the relevant time. On reading our analysis of events below, if we inadvertently give the impression of there having been a coherent narrative, clearly discernible from the publications referred to, which should have been obvious to clinicians and others reading the publications, that is not our view. The Boards wish to make clear that they do not believe this would have been the reality or experience of those reading them in "real time". The challenges faced by the profession at that time, including working in a pre-internet era and the associated difficulties in relation to the gathering and reviewing of evidence cannot be underestimated.[4] Moreover, the practical reality is that changing views held within the medical profession takes time. That is especially so when there is a prevailing view that has been held for some time and endorsed by persons viewed as

[4] The situation in relation to accessibility, modes of knowledge transfer and dialogue is very different nowadays compared to the 1970s, 1980s and 1990s. The internet has provided unparalleled access to information. Email has provided the ability to communicate at speed across wide networks, and to facilitate, promote and encourage conversations and rapid exchanges of information. This was a resource clinicians didn't have in the 70s and 80s.

being of high authority in the field.[5] There requires to be a balance of evidence against the prevailing opinion. These comments certainly apply in relation to the 1970s, 1980s and 1990s when processes of evidence gathering, dissemination, and learning took longer than they do today. We would wish our conclusions set out at the end of this paper to be read with these comments in mind.

Discussion

14. At the outset, it is important to acknowledge that the general propensity for blood and blood products to transmit hepatitis was known even since prior to the introduction of cryoprecipitate as a therapeutic in haemophilia.[6] The risks of Hepatitis B were well known. However, the evidence indicates that it was not until the early 1970s it came to be recognised that Hepatitis B[7] only accounted for a small proportion of post-transfusion chronic hepatitis. The introduction of RIA screening of plasma donations for HBsAg in 1975,[8] and consequent reduction in infections with HBV, appeared to give rise to an increasing appreciation that most of the post-transfusion chronic hepatitis seen in haemophiliac patients was a sequel to infection with *"Non-A Non-B hepatitis"*.[9] That this somewhat curious term was

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[5] See for example the seminal textbook published in 1981 by Dame Sheila Sherlock discussed below. For examples (of which there are many) of judicial views expressed about these principles see the following. *"The dissemination of new literature takes some time, and a medical doctor is not expected to react immediately, or change standard practices, in response to every new article that is published. Often new studies and recommendations are received with some scientific scepticism, while replication of the results is awaited. Immediate response to every publication is unrealistic": Nattrass v Weber 2010 ABCA 64; (2010) 316 D.L.R. (4th) 666; [2010] 12 W.W.R. 36 at [31]. In Gascoine v Ian Sheridan & Co [1994] 5 Med. L.R. 437 at 447 Mitchell J commented that a "shop floor gynaecologist" had a responsibility to keep himself generally informed on mainstream changes in diagnosis, treatment and practice through the mainstream literature, such as the leading textbooks and the Journal of Obstetrics and Gynaecology.*

[6] Albeit there has been evidence to the effect that the near 100% infection of first time recipients with NANB was realised only in 1983 after prospective ALT studies, as discussed below.

[7] It was by then known that Hepatitis B could lead to cirrhosis see i.e.: Prince et al, 'Long-Incubation Post-Transfusion Hepatitis Without Serological Evidence of Exposure to Hepatitis-B Virus', *The Lancet,* 3 August 1974.

[8] It became known that despite the introduction of screening, a significant amount of both symptomatic and symptomless Hepatitis B still occurred associated with commercial and NHS Factor 8 transfusions. (see i.e.: what was reported by Dr Craske in *Unresolved problems in Haemophilia Proceedings of an international symposium held at the Royal College of Physicians and Surgeons*, Glasgow, September 1980. Charles D Forbes and Gordon D O Lowe (Eds) (FN9, p6)

[9] Dr Craske told the Glasgow Symposium that *"since less than 5% if British haemophiliacs are carriers of HBV, it is likely that most of the chronic hepatitis is a sequel to infection with non-A non-B virus(es)….there is, therefore, a high risk from the use of Factor VIII or IX concentrate that the patient will contract non-A, non-B hepatitis and a 20-30% chance of resistant chronic hepatitis, together with a smaller risk of hepatitis B….until*

coined by reference to what the condition was *not*, might be said to encapsulate the poor understanding of the epidemiology and natural history of the condition at that time.[10]

15. From the outset, the issue was not ignored and considerable effort was directed towards understanding the causes and consequences of the abnormalities found in liver function tests in patients, reflecting longstanding medical interest in the subject of post-transfusion hepatitis. However, the dramatic increase in use of factor concentrates in haemophilia treatment from the mid-1970s onwards came at a time when knowledge of Non-A Non-B hepatitis was still in its relative infancy. That fact alone gave rise to very significant difficulties for the clinicians then involved in haemophilia care. The evidence indicates that the condition was very incompletely understood at that time: the cause was unknown; it was a diagnosis of exclusion; there was evidence it might be due to more than one virus or indeed no virus at all;[11] and the clinical spectrum indicated by liver function tests varied considerably.[12]

16. At the same time, however, even such significant uncertainty ought not to be allowed to obscure one point which was clear: that any hepatitis infection, including NANB, was always considered to be an undesirable side effect of treatment, which should be avoided if possible. *Inter alia* the systemic efforts by the transfusion services to exclude donations from potentially infected donors and subsequent research in connection with viral inactivation attest to that fact.[13] Accordingly, while there

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tests are available for these agents, the possibility of using small pool concentrate or a wider use of cryoprecipitate should be considered for patients with mild coagulation defects requiring treatment to cover surgery or other major treatment' (FN9, p12)

[10] Indeed, given the variety of insults which could result in abnormal liver function tests (such as exposure to other toxins or immune responses), the use of the term NANB hepatitis did not entail commitment to a definite infectious aetiology or infection with a single virus.

[11] An infectious aetiology was suggested by chimpanzee studies and this was assumed until 1989 when the Chiron Corporation discovered the Hepatitis C Virus in 1989

[12] Professor Christopher Ludlam, Rule 9 statement dated 25th September 2020, para 191 [WITN3428001]

[13] Multiple studies during the 1970s stressed the importance of volunteer donors to reduce risk of post-transfusion hepatitis. On 24th January 1976 the Lancet published a letter from Prof. Cash regarding the World in Action programme where he stated: *"There is no doubt that the import into the United Kingdom of factor VIII concentrates derived from external sources, however well screened for hepatitis viruses represents an unequivocal pathway by which the level <u>of a potentially lethal virus</u> into the whole community is being deliberately increased. Although the absolute magnitude of this problem was exaggerated and over-dramatised by the television programme, nobody with direct or indirect responsibilities for this phenomenon would wish to*

existed wide scope for debate about how benign or otherwise the prognosis might be, that should not be conflated with a perception that NANB hepatitis could be regarded as in some way irrelevant, or immaterial side effect of treatment or transfusion.

~~17.~~ The emergence of medical literature contemplating the possibility that NANB hepatitis might be a chronic condition did not pass unobserved by haemophilia clinicians and others.[14] However, profound uncertainty as to long-term prognosis arose as an inevitable function of several key features including the very mild, or even asymptomatic, nature of the acute infection and the unusual latency period: cirrhosis typically develops more than 20 years post-infection, if ever at all.[15] Accordingly, as treatment with cryoprecipitate only became progressively available from the late 1960's (before widespread use of concentrate therapy started in the early 70s), there were very few patients who had developed clinically overt serious liver disease before the mid-1980s.[16] Cirrhosis may develop slowly and in a clinically inapparent fashion. The absence of clinical manifestations of the disease was another confounding factor: clinicians were not seeing patients with clinical symptoms of liver disease as a complication of transfusion. (For example, during Professor Hann's time at Great Ormond Street between 1988 and 2006, only 1 patient required treatment

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belittle the serious nature of the moral and practical dilemmas which face us all." Cash, 'Commercial and NHS factor VIII concentrates', The Lancet, 24 January 1976.

[14] For example in August 1978 the UKHCDO Hepatitis Working Party produced a report which discussed a pilot project to investigate incidence of chronic liver disease in Hemofil patients [PRSE0000780] This followed the publication of an article in the New England Journal of Medicine article on 22nd June 1978 which concluded that *"a large number of asymptomatic haemophilia patients which have received numerous transfusions must have histologic liver disease. In some, it must be severe."* Spero JA et al, 'Asymptomatic Structural Liver Disease in Haemophilia' (1978) 298 (25) The New England Journal of Medicine 1373 [PRSE0002523]

[15] Freeman AJ 'Estimated progression to cirrhosis in chronic HCV infection Hepatology' 2001;34:809 In a systematic review, at 20 years cirrhosis was seen to develop in 24% (CI 11-37) of patients with post transfusion HCV. Risk factors for progression were being male, being older at time of infection and alcohol consumption.

[16] The first UKHCDO NHS report on haemophilia treatment, 1969 – 1974, confirmed high premature mortality, especially from intracranial bleeding. There was no increase in fatal liver disease; and of the five patients who died of hepatitis four had received no treatment other than cryoprecipitate. Biggs R. 'Haemophilia treatment in the United Kingdom from 1969 to 1974'. Br J Haematol. 1977; 35: 487 – 504. In the second UKHCDO report, 1976-1980, during which concentrates and home treatment were used increasingly, average age of death was increasing, without increases in fatal liver disease. Rizza CR, Spooner RJD. 'Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976 – 80: report on behalf of the directors of haemophilia centres in the United Kingdom.' Br Med J. 1983; 286: 929 -33

for hepatitis C hepatopathy.[17]) Liver function tests undertaken on patients tended to show only very mild and apparently insignificant elevations of liver enzymes. Most conditions associated with very minor elevations of liver function tests are benign and non-progressive. The carrying out of liver function tests was one of the only forms of monitoring available to clinicians, other than biopsy, which was conducted only quite sparingly due to the attendant ethical and safety concerns (including risk of death[18]) and the fact that there was, in any event, no available treatment for the condition. Against the background where many patients' lives had been radically transformed by the benefits of concentrate treatment, there was little evidence in clinicians' day to day practices indicating towards the existence of a major problem. Professor Ludlam summed up the position, saying that in the period 1980 - 1982 "*we were very uncertain about its' seriousness, whether it was a serious problem or not, but <u>the general overall feeling was it's not terribly serious</u>.*"[19] (emphasis added)

18. If it is the case that there was a general overall feeling within the medical profession that Non-A Non-B hepatitis was not terribly serious, a question arises as to how that came to be. In the event, that view turned out not to be correct.[20] In our submission a combination of highly unusual and challenging factors go a long way towards explaining how that state of affairs arose. That such a view also existed beyond the specialism of haemophilia care finds some support from the evidence of SNBTS employees, who indicated that up until at least the early 1980s they did not consider that NANB hepatitis was a condition capable of causing long-term organ damage.[21] Even Dr McClelland, whom the Inquiry may find to be otherwise conspicuously far sighted and prescient in his contemplation of emerging viral risks, believed up until

[17] Transcript 08/12 20 p49. The evidence presented by the IBI statistics group for the period 1992-2000 indicates that there were fewer than 5 deaths per year from liver disease in UK men with haemophilia who were HIV negative but HCV positive. As such, the chance of such an observation being made in even large haemophilia centres was very small. See also the Glasgow Centre report on transaminases in GRI and Yorkhill. This was the largest UK survey, in 139 adults and children, of whom 58 (42%) had an elevated transaminase level. No patients had hepatomegaly, splenomegaly, or other evidence of chronic liver disease (results, line 1) Steven MM, Small M, Pettigrew A, et al. *Liver dysfunction in haemophilia.* Scott Med J. 1986; 31: 103-108

[18] Prof Christine Lee [Transcript, 20.10.2020 p15]

[19] [Transcript 1.12.20, p119]. Professor Ludlam stated that the perception of NANB changed in the mid 1980s [Transcript 1.12.20, pages 117 to 120] See also Professor Lowe, [Transcript 9.12.20 at p97 and 98.]

[20] At least in relation to a significant proportion of those infected with Non-A Non B hepatitis.

[21] See for example the evidence of Dr Gillon that upon joining SEBTS in 1983 [Transcript 19.01.2022, p81]

the early 1980s that NANB hepatitis was not a particularly serious condition.[22] This appeared to be a commonly held view amongst transfusionists.[23] Given the gradual manner in which understanding of NANB hepatitis evolved, it is likely that the rate of dissemination of knowledge would have varied significantly between different clinical groups and specialisms. In this regard, it seems reasonable to conclude that the level of knowledge amongst virologists, gastrointestinal physicians and specialist transfusionists would in general have been higher than amongst surgeons or anaesthetists administering transfusions as an incidental aspect of their clinical duties. For this reason, any consensus view likely derived primarily from the former specialisms, including the relatively small number of specialist haemophilia clinicians and transfusionists. Furthermore, for reasons discussed in this submission, that view is likely to have prevailed more widely within the medical profession.

19. It appears that like many others Dr McClelland was influenced in this belief by the important and authoritative medical textbook by Dame Sheila Sherlock *"Diseases of the Liver and Biliary System"*[24] The 6th edition (1981) said that NANB hepatitis accounted for 75% of post-transfusion hepatitis, and that it "*often progresses to a mild chronic hepatitis. The prognosis of this is, at the moment, uncertain, but probably benign.*"[25](emphasis added) The reasons giving rise to the uncertainty of prognosis are not explored in detail in the book. Nor is the converse scenario to which the "*probably* benign" prediction implicitly alludes discussed in any detail.[26] The language employed by Dame Sherlock, at least in the first part of the critical sentence, seems to be deliberately tentative in nature, explicitly acknowledging the uncertainty which then prevailed. However, the final words ("but probably benign") may have suggested to the reader that this is where the emphasis should lie,

[22] Dr Brian McClelland [Transcript 28.01.2022 p77 - 81]
[23] In this regard we note Dr James Smith's suggestion that in general fractionators were more concerned than clinicians (in his view, partly from an earlier awareness of product liability cases.) Rule 9 Statement of Dr James Smith, paras 29 – 36 [WITN3433001]
[24] Supra FN 23. Professor Sheila Sherlock, *Diseases of the Liver and Biliary System 6th ed) 1981 pp257* The 6th edition (1981) said that NANB accounted for 75% of post-transfusion hepatitis and that it "*often progresses to a mild chronic hepatitis"* and the "*long-term prognosis was uncertain but probably benign.*" 3
[25] P258.
[26] However it is also said that the clinical course of the disease was such that "cirrhosis can develop" p257 At this time Dame Sherlock was still of the opinion that NANB hepatitis might be more than one disease with more than one pathogen or aetiology. [p257 – 258]

potentially reinforcing the view amongst clinicians and transfusionists that NANB hepatitis was benign and non-progressive[27] On any view, what is said in the book could not be said to support any view that NANB hepatitis was well understood, as definitely an innocuous condition for all patients.

20. The report of the 1975 study by Mannucci et al[28] *'Asymptomatic Liver Disease in Haemophiliacs'* may be seen to begin to trace, if only in relatively faint outline, the initial emergence of a number of key themes of later discussion surrounding NANB hepatitis: the absence of overt illness, the unknown prognostic significance of abnormal liver function; an informed suspicion or anxiety that the longer-term prognosis might be other than benign in some patients; and the need for longer-term surveillance and follow up in order to gain a clearer picture. The authors stated that their data suggested that repeated contact with NANB hepatitis agent might cause chronic liver damage not associated with overt illness but: *'the clinical and prognostic significance of the observed abnormalities is unknown, and the lack of liver biopsies renders the task of clarifying them rather difficult. The great majority of patients were completely asymptomatic and free of physical signs of liver involvement…However, the evidence accumulated with the investigation of asymptomatic carriers of HBsAg <u>suggests that these humoral abnormalities are not entirely benign</u>, since they may be associated with structural changes of the liver similar to those occurring in patients with chronic hepatitis."* (emphasis added)

21. The latent nature of the condition meant that only by invasive and potentially risky investigation in the form of biopsy study could its long-term effects on the liver begin to be revealed, and later yet properly understood from studies undertaken over several years. In this regard, the results of the liver biopsy studies conducted by Professor Preston in Sheffield and published by The Lancet in September 1978 constituted preliminary evidence sufficient, at least, to raise the possibility of

[27] It might be said that the way in which the sentence was written created some ambiguity.

[28] Manucci et al, 'Asymptomatic Liver disease in Haemophiliacs', Journal of Clinical Pathology', 1975; 28:620 Manuc. The paper noted that a long-term prospective evaluation of any possible relationship between the observed abnormalities and the development of overt hepatic dysfunction was required. In the meantime. regular testing was recommended.

long-term liver damage, including cirrhosis, caused by NANB hepatitis acquired through factor concentrate treatment, in our submission.[29] In support of this conclusion, we note that that the Preston study did not stand entirely alone, at least from an international perspective.[30] For example, its publication was book-ended by the US studies by Lesesne et al in 1977[31] and by Koretz et al in 1980, both of which reported biopsy study results apparently pointing in a broadly similar direction to those of Preston.[32]

22. A question which arises for the Inquiry to consider is whether this study, in retrospect seen to be seminal, was given sufficient credence and attention at the time it was published. It is worth recalling Dr Boulton's evidence that the Preston results were received *"in some quarters, including myself, with some incredulity at first"*[33]. Dr Boulton frankly explained the reasons for this reaction as including *"some wishful thinking"* allied to a degree of scepticism as to the research methodology,[34]

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[29] *Percutaneous Liver Biopsy and Chronic Liver Disease in Haemophiliacs,* Preston et al, The Lancet, 16 September 1978 p592. Biopsies were carried out on 8 symptom-free haemophiliacs with abnormal liver function tests. The results were summarised as follows: "A wide spectrum of chronic liver disease was demonstrated, including chronic aggressive hepatitis and cirrhosis. The liver pathology bore no relationship to clinical history or to biochemical findings. Hepatitis -B virus markers were common, but evidence suggests that this is not the only factor contributing to the development of liver disease. The high incidence of chronic liver disease seems to be a recent development and is probably related to factor-concentrate replacement therapy." "…..In addition, non-A non-B hepatitis may well be an important factor and observations in four of our eight patients support this possibility" As regards one patient found to have cirrhosis it was said: "…We feel that the time interval and clinical pattern makes it unlikely that the cirrhosis was caused by the hepatitis-B infection, preferring to implicate some earlier non-hepatitis-B agent…This suggests that he probably acquired at least two separate hepatitis infections, although it is impossible to tell which was responsible for the liver lesion" (p594). It might be observed that the willingness of some within the profession to expose patients to biopsy is an indicator of ongoing concern that the perception of NANB as mild and benign was not in fact correct.

[30] In 1979 Iwarson & ors (Sweden) published details of progression of NANB hepatitis (Sweden) in 2 patients one of whom died of liver failure as a result of chronic liver disease**.** Iwarson S et al, 'Progression of Hepatitis Non-A Non-B to Chronic Active Hepatitis', Journal of Clinical Pathology Apr 1979, 32 (4) 351 – 355 [PRSE0002174]

[31] Lesense et al 'Liver Biopsy in Hemophilia A'. *Annals of Internal medicine,* 1977; 86: 703-707. The authors stated: *"It is our fear that liver disease may become a significant cause of morbidity and mortality in these patients as haemorrhagic complications are reduced with improved concentrate therapy. This report shows that patients with haemophilia A may develop significant chronic liver disease"* (p705)

[32] Koretz et al, '*The Long-Term Course of Non-A, Non-B Post-transfusion Hepatitis*', *Gastroenterology,* 1980; 79:893-8 (published 16 May 1980) Liver biopsy on 18 patients followed up over 2-5 years had revealed chronic persistent and chronic active hepatitis in all of them. Two had developed cirrhosis. A third patient not biopsied had symptoms of cirrhosis. Most had remained asymptomatic. The conclusion was that NANB hepatitis appeared benign in most instances but could progress to cirrhosis and liver failure over a number of years.

[33] [Transcript 04.02.2022 p53 – 54]

[34] Ibid. This scepticism seemed to arise chiefly from the possibility of other causes of cirrhosis including alcohol in middle aged men; and also ethical reservations as to the use of biopsy in haemophiliacs. Dr Boulton

"*which on reflection was completely unjustified.*" Dr Boulton thought *"there was a bit of self-denial among haemophilia doctors and I include myself in that*." At the same time, and in fairness to such as Dr Boulton, it would equally be fair to acknowledge that the Preston study had significant objective limitations: small numbers of patients studied; all from a single centre; and with a strong selection bias.[35] In addition, other studies such as those by Berman (1979), Manucci (1982) and Stevens (1983) were also being published, which did not find evidence of progressive liver disease.[36] However, it might be going too far to say that these served to negate the findings of the Preston study. If due allowance is made for the possible latency factor, it might be argued that such studies only showed that, at that time, the patients examined had not *yet* shown signs of serious sequelae. Be that as it may, it is also fair to say that they must certainly have contributed to a confused, uncertain and radically incomplete picture in relation to future prognosis.

23. In the event, such 'incredulity' as described by Dr Boulton did not appear to prevent the Preston study from becoming, at least, influential in informing mainstream discussion of the topic as time went on.[37] In April 1979 Dr Kernoff, a reference centre director with particular knowledge and expertise in hepatitis at the Royal Free Hospital, wrote to Dr Brian Colvin describing NANB hepatitis as *"a serious disease with long-term consequences."*[38] In his evidence Professor Ludlam described this as

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accepted that the latter factor ought not to have been considered relevant at least from the perspective of "a clear cut academic mind" [p53 – 54]

[35] Moreover, in today's terms, applying the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) framework for developing and presenting summaries of evidence, the Preston study would likely attract a "certainty rating" of "low" i.e. "The true effect might be markedly different from the estimated effect."

[36] See e.g.,: Berman, 'The Chronic Sequelae of Non-A, Non-B Hepatitis', *Annals of Internal Medicine,* 1979; 91:1-6. The conclusions of this study included a finding that although it could be clinically severe, acute NANB hepatitis after transfusion was usually an anicteric, mildly symptomatic disease and probably went undetected in most patients; and, Manucci PM, Colombo M, Rizzetto M. "Nonprogressive course of non-A, non-B chronic hepatitis in multitransfused hemophiliacs". *Blood* 1982; 60: 655-8. A prospective study was undertaken in 10 haemophiliacs with non-A, non-B chronic hepatitis followed up for more than 6 years. The study, published in 1982, demonstrated no case of progression towards cirrhosis or hepatocellular carcinoma.

[37] In July 1981 it was cited by the British Medical Journal as evidence in support of the stark but prescient warning: *"Surveys in haemophiliacs have shown changes in the liver architecture consistent with previous viral assault, including those of chronic persistent and chronic active hepatitis and cirrhosis. Indeed, in some cases early death from liver disease might prove to be the price paid by haemophiliacs for the improved quality of life afforded by the easy availability of clotting factor concentrates" (*Post-transfusion hepatitis', *British Medical Journal,* 4 July 1981

[38] [BART0002487]

"a very reasonable view" likely to have been informed by Professor Preston's study and his experience of working in the United States.[39] On the other hand, Professor Charles Hay said that that characterisation did not reflect his own understanding in the 1980s, because the long-term consequences were unknown.[40] When Professor Hann was asked in evidence whether he would have disagreed in the early 1980s with Dr Kernoff's characterisation of the disease, he responded: *"To a certain extent I would disagree because we didn't know – if you'd added the words "could be" or something like that, I would entirely agree with it."*[41] (emphasis added) It is submitted that Professor Hann's answer to counsel's question goes right to the nub of the issue. As Professor Hann explained, while it was by then known that that NANB hepatitis was likely to be contracted from the first dose of concentrate treatment; what was not known was the prevalence of persistent infection and liver damage: a great degree of uncertainty still prevailed.[42]

24. An inevitable difficulty which perhaps arises most acutely in the context of knowledge of risk, is whether and to what extent it is legitimate for the Inquiry to assume or infer from the publication of a particular article or study within the medical literature that its conclusions may be taken to reflect part of the body of knowledge of the medical profession (or relevant speciality) at that time. And if so, how quickly or otherwise the necessary process of dissemination might be expected to occur. Much may depend on where it was published, by whom the publication was read and the arrangements (if there were any) within individual hospitals or organisations to encourage medical staff to take notice of such reported developments. On a realistic view, many physicans treating patients with haemophilia with multiple other clinical responsibilities, particularly those working in smaller centres, would have relied heavily upon information being passed down via

[39] [Transcript 1.12.20 p127 - p128]
[40] [Transcript 04.11.2020 p39-40]
[41] [Transcript 08.12.20 p53-54]
[42] In his evidence, Professor Hann stated: *"What happened in the latter part of 1979 and 1980 was that hepatitis - non-A non-B Hepatitis had come much more into the forefront of publications, et cetera, but unfortunately, and it brings up a problem I think we struggled with and I…believe that I failed to a certain extent to communicate adequately, and that is the level of uncertainty associated with certain problems."* [Transcript 08.12.2020, p48-49] The degree of uncertainty at the time is acknowledged in the testimonies of a number of clinicians who gave evidence.

organisations such as UKHCDO and The Haemophilia Directors of Scotland and Northern Ireland. Similarly, doctors from other specialisms ordering transfusions might rely on such advice filtering down via the transfusion centres. In general, it seems unlikely that the event of publication and the process of dissemination would occur simultaneously, at least in the ordinary course of events.

25. Partly for this reason, the proceedings of the international symposium *"Unresolved Problems in Haemophilia"*[43] held in Glasgow in September 1980 may provide a helpful reference point for the Inquiry as to the state of knowledge within that clinical specialism at that time. The symposium was held in conjunction with the UKHCDO AGM. It featured presentations and discussions from respected figures in the field of hepatology, virology and haemophilia. Amongst other *"unresolved problems"*, the symposium had a significant focus on liver disease. The book subsequently published recorded not only the contents of the presentation but also discussion between doctors present at the symposium. Consideration of this publication may not present the same problems as others, as discussed above, at least to the extent that those Haemophilia Centre Directors present may reasonably be taken to have been aware of what was discussed. Moreover, insofar as attendees' individual contributions to those discussions are recorded in the book, that may reveal at least a partial snapshot of their thinking at that time in relation to the risk of NANB hepatitis. It is therefore worth dwelling briefly on some of the detail of what was said.

26. In his paper for the symposium Dr Craske of the Public Health Laboratory Service noted that *"most cases of non-A, non-B hepatitis are mild illnesses"* but that 50% of patients subject to biopsy study had histological evidence of chronic persistent hepatitis and other patients had shown evidence of chronic liver disease or cirrhosis. He then predicted that *"it seems likely that some patients will develop chronic liver*

[43] See in particular the book recording discussion at the proceedings *Unresolved problems in Haemophilia Proceedings of an international symposium held at the Royal College of Physicians and Surgeons*, Glasgow, September 1980. Charles D Forbes and Gordon D O Lowe (Eds) According to the foreword "a major sections of these proceedings…(was)…devoted to the investigation of liver disease in haemophilia." The symposium was held in conjunction with the UKHCDO Annual General Meeting. [RLIT0001242]

disease over the next 10 years."[44] In the Report of the Haemophilia Centre Directors' Hepatitis Working Party 1979[45]' which was presented at the UKHCDO AGM Glasgow on the day before the symposium it was stated that surveillance results suggested that: *"if transaminitis is related to viral hepatitis, the patients who become carriers and develop chronic hepatitis will only contract mild or symptomless acute hepatitis, and the most overtly jaundiced patients will fully recover."*

27. However, Dr Howard Thomas,[46] a consultant hepatologist at the Royal Free Hospital, London observed that 42% (5/12) of patients studied under biopsy were found to have chronic active hepatitis: *"Although the prognosis of this lesion following NANB hepatitis was unknown, a similar lesion associated with chronic hepatitis B virus infection is progressive and, in a proportion of patients, ultimately results in the development of cirrhosis and its attendant complications".*[47] That none of his patients had yet developed cirrhosis was of limited comfort: "*The lesion of chronic active hepatitis, is a progressive lesion, and one would, in a proportion of these patients expect an element of fibrosis, and ultimately cirrhosis".*[48] The fact that many of those affected were young patients; that the lesions could take 20 – 30 years to progress and that the proportion of patients infected was thought to be high (60—80%) led Dr Thomas to predict: *"It will be an enormous problem when it happens."*[49]

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[44] Of about 40 patients regularly treated with factor 8 concentrate biopsied in the UK approximately 50% had histological evidence of chronic persistent hepatitis and other patients had shown evidence of chronic liver disease or cirrhosis. Most of the patients in this group were children or young adults. Supra FN44, p11

[45] HCDO0000135_023

[46] Supra FN44 *Clinical, immunological and histological aspects of non-A, non-B hepatitis in haemophiliacs* H.C. Thomas, M. Bamber and P.B.A Kernoff

[47] Ibid, p32 *".The potentially serious nature of the disease, however, make close clinical and biochemical observation mandatory in order that the natural history may be fully documented."*

[48] Ibid p36 – "*None of our patients has had cirrhosis, but then, if we are to believe that this illness at the most has been going on since 1974 when the commercial concentrates were introduced, then this period is short in the course of the disease. There are some indications that these patients may have lesions which will turn to fibrosis or cirrhosis….they do have a chance of developing fibrosis or cirrhosis ultimately, and the complications that result from that. It is really now a question of how long it takes. Just because we have not seen it in this six year period, it does not mean that it will not happen. I think the thinking is that it takes ten or twenty years or even thirty years for these lesions to progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions."* See also the discussion at p49.

[49] Professor Lowe expressed the position succinctly: *"for a young person it is bad news. It may take years to happen but it is going to be bad news."* [Transcript 09.12.20; pp94-5]

28. In a similar vein, the contribution of Preston, Triger and Underwood also emphasised the risk of chronic active (aggressive) hepatitis in progressing to cirrhosis and argued that the research raised the possibility of non-A non-B viruses, rather than Hepatitis B, as aetiological agent in chronic hepatitis in haemophiliacs.[50] The report of the discussion between Dr Thomas and Dr Triger at the symposium reflected in graphic terms a strong degree of trepidation for the long-term prognosis of the children studied, notwithstanding the absence of obvious morbidity in patients at that time.[51] In his evidence, Professor Lowe highlighted, with approval, Dr Thomas's observations that: 1. the advantage accrued by volunteer donations is probably eliminated by having to use a large pool; 2. the risk of the large pool NHS concentrate and the commercial concentrate may therefore be similar; 3. where chronic liver disease was found it must be assumed that large pool NHS concentrate is equally involved; and 4. that chronic liver disease could also be acquired from infections resulting from cryoprecipitate and fresh frozen plasma.[52]

29. Taken together, the presentations and discussions at the symposium in 1980 may appear to indicate a view that NANB hepatitis was still assumed to be a mild condition for most patients at that time. The overall long-term prognosis of the disease was yet unknown. However, there was also considered to be, at least, a realistic possibility that some patients NANB hepatitis would develop chronic liver disease, which might progress to cirrhosis. Given the young age of many of the patients studied, and the possible progression of disease over many years, there were reasonable grounds to believe the disease would become a major problem in the future. On the face of it, there may be some difficulty in reconciling what was said at the symposium with other evidence which the Inquiry has heard to the effect that, until about 1985, there was a widely held view within the medical profession

[50] Supra FN44, p44 *Experience of Liver disease in Haemophilia* F.E. Preston, D.R. Triger and J.E Underwood
[51] Supra FN44, p5
[52] [Transcript 09.12.20 85-87]. Supra FN44, p37 *"The other thing I should perhaps like to say is that there is evidence that a small number of haemophiliacs who have come to post-mortem have evidence of having had chronic liver disease, probably contracted years back from long-term exposure, acquired in the years before commercial concentrate was even thought of, when plasma or cryoprecipitate was used. No one should take away the idea that commercial concentrate is the sole causative agent. We must assume that the large pool NHS concentrate is equally involved."*

that NANB hepatitis was a mild and non-progressive condition[53]. Certainly, discussions such as occurred at the Glasgow symposium in 1980 could not be said to reflect a firm belief in such a view on the part of those present; indeed, quite the reverse.

30. Yet all of this has to be considered against the wider background of clinicians' actual state of knowledge at the material times. It is suggested the evidence before the Inquiry paints a rather varied and inconsistent picture. For example, in his evidence, Professor Lowe[54] agreed that one of the key messages from the symposium in 1980 was that NANHB hepatitis was by then understood to be a *"bad disease"* [55] which was *"potentially going to be highly problematic for years to come."*[56] However, Dr Anna Pettigrew, then practising in haemophilia care at Yorkhill Hospital[57] in the same city as hosted the symposium, was unaware of NANB hepatitis as a concept until she attended a meeting at the Royal Free Hospital in 1984.[58] That conscientious junior doctors practising in haemophilia care such as Dr Pettigrew were not properly informed of the existence of NANB hepatitis, let alone developments such as discussed at the Glasgow symposium, might appear to indicate a deficiency in the systems for providing junior doctors with medical and clinical information about developments in haemophilia care. Indeed, Dr Pettigrew testified that there was no such system in existence at Yorkhill at that time.[59]

31. It does not appear that the Glasgow example necessarily stood alone in this regard. In her evidence, Professor Christine Lee recalled that her colleagues at the haematology department at St George's Hospital, London, expressed complete ignorance of the condition when in 1982 she left to take up her post researching NANB hepatitis at the Royal Free: *"amongst my colleagues, there was almost a*

[53] See i.e.: Dr Frank Boulton [Transcript, 04.02.2022 p52]; Professor Charles Hay [Transcript,04.11.2020 p35 – 52]; Rule 9 statement of Professor Lowe at section 30.5 to 30.6.7. [WITN3496013_0120] There was also other evidence indicating a "range of views".
[54] Prof Lowe did not attend the symposium. [Transcript, 9.12.20 p77 – 78]
[55] [Transcript 09.12.20 p82; p90]
[56] [Transcript 09.12.20, p82]
[57] Dr Pettigrew transferred from Glasgow Royal Infirmary to Yorkhill Hospital in May 1980.
[58] Dr Pettigrew [Transcript 07.12.20 p51 – 52]
[59] Dr Pettigrew [Transcript, 07.12.20, p54]

universal thing: what is that? Why are you doing that?"[60] It goes without saying that, to the extent that some clinicians were unaware of the existence of the condition, they cannot have been in a position to form a view one way or another as to the likely severity of the disease. The Inquiry may find such evidence to indicate towards a conclusion that, for whatever reasons, when it came to knowledge of NANB hepatitis the reality 'on the ground' did not reflect the contents of the published literature prior to 1985. The Boards would accept it follows that such a conclusion may be taken to infer shortcomings in the systems in place for continuing professional education within the NHS in Scotland at that time.

Conclusions and Findings

~~32.~~ In the Boards' submission, it is fair to say that during the period from the late-1970s until the mid-1980s the long-term prognosis for NANB hepatitis was objectively highly uncertain. The commonly held view within the medical profession that it was a benign or mild condition was influenced by a variety of factors, including the absence of clinical evidence of the disease in patients, which only later came to be properly understood as more a function of its lengthy latency than any cause for reassurance.

33. The situation became significantly clearer in 1985[61] when the second, longitudinal, study from Sheffield demonstrated a range of pathology including histology associated with more severe and progressive liver disease, with publication of its results heralding a change in perspective on progressive liver disease in

[60] Professor Christine Lee [Transcript 20.10.2020 p89-90]

[61] By this time the important Fletcher paper of 1983 had been published suggesting almost uniform transmission of NANB by concentrates. Fletcher ML, Trowell JM, Craske J, Pavier K, Rizza CR. Non-A non-B hepatitis after transfusion of factor VIII in infrequently treated patients. Br Med J. 1983; 287; 1754-57.
See also: the evidence of Professor Christopher Ludlam, [Transcript 01.12.2020, p118]. See also Manucci, 'Aids, hepatitis and hemophilia in the 1980s: memoirs from an insider', *Journal of Thrombosis and Haemostasis,* 1: 2065-2069: "*Hence, it was only in the mid 1970s that it became clear that hepatitis was frequent in hemophiliacs and it was only in the mid 1980s that it was shown to be progressive and severe in approximately one-sixth of patients. Beforehand, the view at that time held by me and, as far as I am aware, the great majority of hemophilia treaters was that the problem of hepatitis was a tolerable one, because the benefits of concentrates seemed to outweigh risks."(2066)*

haemophilia.[62] These findings were supported by two subsequent reports from the USA[63] and Germany.[64]

34. Upon consideration of the evidence led at the Inquiry it does appear that, at least as a broad generality, the emerging evidence in the late 1970s and early 1980s pointing towards possible long-term risks from NANB hepatitis may not have been afforded sufficient weight within the medical profession and transfusion services community. As a result of this, the potential severity of the disease may have been underestimated.

35. It seems possible that the view of NANB hepatitis as a mild condition may have been maintained, at least in part, by the way in which the language used to describe the disease tended to err on the side of emphasising a more optimistic interpretation of the uncertain prognosis. For example, it is interesting to speculate whether Professor Sherlock's description of the long-term prognosis as "*uncertain, but probably benign"* would have provoked a different response had she instead written "*uncertain, but possibly not always benign.*" In a similar vein, insofar as there has been evidence of a widely held view that the NANB hepatitis was a mild or benign condition in *the majority* of patients, that way of formulating the position seems to raise similar difficulties. If the natural corollary of such a statement is that for a minority of patients the disease might be serious and progressive, then a statement to the effect that most patients would be fine runs the risk of eliding or obscuring the nature of the emerging risk: a risk to even a minority of patients is still a risk. With respect, it is submitted the conclusion of Lord Penrose that: "There was no generally accepted view prior to 1985 that NANB hepatitis had other than a *generall*y benign

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[62] Hay, C.R. et al, '*Progressive liver disease in haemophilia: an understated problem?*' Lancet, 1985 1(8444): p1495-8. Following an 8 year prospective study conducted in Sheffield, histological signs of cirrhosis were found in 9 of 79 haemophiliacs (12%) with chronic non-A, non-B infection.

[63] Aledort, L.M. et al, '*A study of liver biopsies and liver disease among haemophiliacs*' Blood, 1985 66(2): p367-72. A large retrospective study of liver biopsies from haemophilia centres worldwide provided histological evidence of cirrhosis in 15% of cases. Professor Ludlam stated that it was only following the studies (Hay et al, Aledort, and Schimpf) that it became "clear" that NANB was progressive [Transcript 1.12.20, page 118].

[64] Schimpf, K, *Liver disease in haemophilia.* Lancet, 1986 1 (98476): p 323. A retrospective biopsy study published in 1986 found that cirrhosis developed in 13% of multi-transfused German haemophiliacs during a follow up of 13 years.

prognosis"[65] may appear to reflect a similar misplacement of emphasis. A complete analysis would surely also require consideration to be given to the other side of the coin, namely the possibility of long-term risks to patients falling outwith this generality.

36. To employ Dr James Smith's memorable analogy, the predictions of "Cassandras" such as Dr Preston – which turned out to be correct - may not initially have been given due regard at least in hindsight.[66] If the Inquiry finds that to be so, then the reasons *why* this situation arose may be more difficult to definitively identify. As Dr McClelland put it, no doubt upon considerable reflection, *"viewed in retrospect it seems difficult to understand why NANB post transfusion hepatitis… was believed to be a relatively small problem in the UK."*[67] Dr McClelland reflected that "*a lot of it was about the weight of expert opinion and prevailing belief and, because of those two factors, a reluctance perhaps to take a fresh look at the evidence."*[68] The Inquiry may consider that this summary resonates with, and encapsulates, the substantial body of other evidence bearing upon this important question.

37. During the Inquiry hearings counsel posed the question (slightly paraphrased) why, in the absence of clear and convincing evidence one way or the other, it should be assumed, or "positively" believed, that the condition was mild and non-progressive.[69] It seems to us that is a fair question standing that there was, at least by 1980, a body of emerging evidence, including biopsy studies, raising the possibility that the

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[65] Penrose Report para 16.70, emphasis added. Lord Penrose describes 1985 as the "turning point" when "information began to emerge that would lead to changing views" (16.70, emphasis added). The question for the Inquiry may be whether information began to emerge before 1985 that should have led to changing views.

[66] Rule 9 Statement of Dr James Smith, para 38 *"As I recall Cassandra was ultimately correct in her predictions but received scant thanks for it. Our Cassandras faced much opposition but their fate was less harsh."* [WITN3433001]

[67] Rule 9 Statement of Dr Brian McClelland, para 292 [WITN6666001]; [Transcript 28.01.2022 p80]

[68] [Transcript 28.01.2022 p80 – 81]. Professor Ludlam's position in evidence was: *"I was well aware of the Sheffield study of 1978 showing a range of liver pathologies and I was aware of the other Papers by Mannucci and from Manchester questioning the progressiveness of it, but by mid-1980s with the study from Sheffield, the one from Lou Aledort and the one from Klaus Shimff in Heidelberg it was clear it was progressive.."* [Transcript 01.12.2020,p 118] (emphasis added)

[69] See, for example, during evidence of Professor Ludlam [Transcript 01.12.2020,p120) and Professor Lowe [Transcript 09.12.2020, p97 and 98]

long-term prognosis of theis disease might *not* be mild and non-progressive, at least in some patients.

38. In our submission there is evidence before the Inquiry from which it could conclude that:- 1. the risks associated with hepatitis transmission in blood products were potentially initially underestimated in the late 1970s and early 1980s; 2. any generally held view of NANB hepatitis as a benign or mild condition did not give due regard to emerging evidence in the late 1970s and early 1980s pointing in the opposite direction; and 3. that NANB hepatitis carried a *possible* risk of serious liver disease in at least some patients ought to have been capable of being appreciated in the late 1970s and early 1980s, notwithstanding all of the uncertainties and relative absence of long-term data.

39. Finally, the Inquiry may find that clinicians working in these difficult circumstances would have benefited from greater use of clinical guidance to encourage more uniform dissemination of knowledge across the medical profession. The historical difficulties encountered by clinicians in keeping abreast of emerging knowledge of NANB hepatitis may serve to underscore the value of guidelines published by the Scottish Intercollegiate Guidelines Network (SIGN) in Scotland from 1995 (including management of Hepatitis C, from 2007), which are widely used in NHS Scotland. Likewise, those published by the National Institute for Clinical Excellence (NICE) from 2000 for the rest of the UK.

CHAPTER 3: KNOWLEDGE OF RISK – HIV/AIDS

Introduction

40. According to the World Health Organisation, an estimated 40.1 million people have died world-wide as a result of infection with the HIV virus since the beginning of the epidemic.[70] In the particular context of this Inquiry, its expert group on statistics

[70] https://www.who.int/data/gho/data/themes/hiv-aids

conclude that around 1,250 people with bleeding disorders were infected with HIV in the UK prior to 1991, of whom around three quarters have since died.[71] Such bare statistics serve to indicate, but can scarcely begin to describe, the sheer enormity of the disasters to which they relate. The harrowing evidence heard by the Inquiry from and about patients infected with HIV by blood and blood products has shone a light on the incalculable scale of suffering and loss which these figures connote. It may be difficult, from that perspective and in 2022, for anyone to contemplate with complete detachment from hindsight issues relating to the state of knowledge of clinicians who were practising in a world where this unprecedented human catastrophe had yet to unfold. However, for the same reasons explained above (at para 10) the Boards consider that these are foundational issues for the Chair to determine upon in this Inquiry. The methodical and forensic examination of these issues undertaken in evidence by the Inquiry has been revealing of how, amidst great confusion and uncertainty, the existence of a risk of AIDS to recipients of blood and blood products nevertheless came to be appreciated within the medical profession. With hindsight, and given what transpired, it is clear that the gravity of the emerging risk was severely underestimated. Difficult questions arise as to the reasons why that was so.

41. The focus of this submission is therefore directed towards how and when NHS clinicians in Scotland came to appreciate that HIV could be transmitted by blood; and how their appreciation and perception of the attendant risk to patients first developed. The Inquiry's findings in this regard will undoubtedly serve to inform its analysis of the response by NHS organisations and individual clinicians to the emergence of the risk of AIDS. However, having regard to some of the evidence given to the Inquiry, it is important to emphasise once more that in the Boards' view issues of *knowledge* of risk are logically anterior to, but should not be conflated with, questions in relation to NHS organisations' *response* to the risk, including those

[71] *Expert Report to the Infected Blood Inquiry: Statistics*, p1. The group also concluded that at least 79 and possibly up to around 100 people were infected with HIV through blood transfusions in the UK between 1970 and 1991, around 85% of whom have subsequently died. 60 were likely to have been infected in Scotland (p.13)

relating to whether greater modification of haemophilia treatment policies would have been justified. These are addressed separately at Chapter 5 below.

Discussion

42. It is submitted that following the identification of AIDS in 1981, the international medical and scientific community faced a unique challenge in seeking to understand and address a disease of unknown aetiology which was known to be rapidly progressive and fatal in some, but had a much longer incubation and mode of presentation in others. Information and evidence in relation to the possible cause and nature of this phenomenon emerged apace over the next few years, in a piecemeal and sometimes bewildering manner. Clarity was only achieved, and major divergence of scientific opinion resolved, after the HIV virus was first identified by Montagnier et al in May 1983 and confirmed as the cause of AIDS by Gallo et al in April 1984.

43. Despite the gathering body of evidence demonstrating a risk to haemophiliacs from the condition, until early 1984, the UK Government persisted in communicating to the public a position that there was *"no conclusive proof"* of the transmission of the agent causing AIDS through blood products.[72] Whether or not that formulation may have been technically accurate, it delivered a message of false reassurance which singularly failed to convey a true or complete description of the developing state of knowledge within the medical profession and scientific community during that immensely difficult period. The emerging reality of the situation, at least for some clinicians in Scotland (and the rest of the UK), was far more troubling, as we submit for reasons set out below.

44. The emergence of a risk to haemophilia patients was preceded by increasing volume of earlier reports through 1981 and the first half of 1982, of an increasing number of cases, often in gay men, of what came to be referred to as AIDS. In late 1981,

[72] In contrast, the leaflet issued in September 1983 for distribution to blood donors included in a Q & A section the following: *"Can AIDS be transmitted by transfusion of blood and blood products? Almost certainly yes…"*

Professor Forbes at Glasgow, had his attention drawn to a case by Dr Oskar Ratnoff of Cleveland, Ohio concerning a haemophilia patient with *"a funny immune problem"* who became ill and died.[73] At that stage, as Dr Mark Winter explained in evidence: *"there was no suggestion at all it was anything to do with blood or anything transmissible."* [74] However, this position was soon to change. Professor Lowe gave evidence that he himself became aware of AIDS cases in haemophiliacs in 1982 when told about it by Professor Forbes. By that stage, Professor Forbes had already become sufficiently interested by the early data to initiate a study of immune abnormalities in patients with severe haemophilia.[75] The relative alacrity with which these investigations were commenced by Professor Forbes may be seen to indicate an early appreciation of at least a potential or theoretical risk to patients in Scotland.

45. However, the recurring problem of sub-optimal dissemination of knowledge within the medical profession at that time undoubtedly hindered the haemophilia clinicians in keeping up to date with developments in relation to AIDS. The Inquiry has examined in detail the role of the UKHCDO in keeping its members within the haemophilia specialism up to date.[76] However, it appears that the consequences of professional demarcation between different specialisms also operated to restrict the circulation of information to an extent which may, from a current perspective, be difficult to understand. A stark example of this was provided in Professor Hann's account of the *Second International Symposium on Infections in the Immunocompromised Hos*t held in Stirling in June 1982. According to Professor Hann, this was *"the best, by far, conference of its nature in the world, and it was attended by many microbiologists and infectious disease doctors."*[77] There was an *"extremely frightening"* presentation on AIDS[78] which described the appearance of an *"alarming epidemic"* in certain cities in the United States. AIDS was reported to be a *"devastating"* illness with a high mortality rate associated with irreversible

[73] Penrose Inquiry Final Report, Chapter 9.22
[74] Dr Mark Winter, [Transcript 01.10.20 p74]
[75] Professor Lowe, [Transcript 10.12.20, p4]
[76] For example, it appears that the first published advice from UKHCDO in relation to AIDS was produced in June 1983.
[77] Professor Ian Hann, [Transcript 08.12.20, p66]
[78] Professor Ian Hann, [Transcript 08.12.20, p61]. [PRSE0002220]

immunodeficiency.[79] Persons with haemophilia were included in the list of persons who might be affected. According to Professor Hann *"it was a very, very shocked meeting, indeed, and it's impossible to exaggerate that:"* the news came as a *"bombshell."*[80] Professor Hann left the conference thinking that this new disease was caused by a new viral agent and it might possibly be relevant to patients with haemophilia.

46. However, the haematologists in attendance were all doctors with an interest in leukaemia. No haemophilia clinicians were present. While a book of the meeting was produced,[81] it does not appear that the information from the meeting was disseminated to any haemophilia clinicians in Scotland.[82] Given the magnitude of what was discussed, and the location of the conference, this must be regarded as an extraordinary lost opportunity, at least from a Scottish perspective.[83] The absence of a multi-disciplinary approach such as found in modern practice today might go some way to explain this situation. However, it may be this example forms part of a wider theme of problems in effecting the uniform dissemination of rapidly developing knowledge and events. The consequences of this may be seen in the striking variability in the levels of knowledge exhibited by clinicians. The Inquiry will have noted, for example, the striking contrast between Professor Hann's early grasp of the potential enormity of the situation, and the position of his predecessor at Yorkhill, Dr Michael Willoughby, who departed from Yorkhill at the end of 1982.[84]

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[79] Professor Ian Hann, [Transcript 08.12.20, p63]

[80] Professor Hann, [Transcript 08.212.20 p64]

[81] Professor Hann, [Transcript 08.12.20 p66]. Professor Hann said: "*unless you bought that book or disseminated that book, you wouldn't know about it.*"

[82] Penrose Inquiry Report, Chapter 9.40. At that time Professor Hann was working at the Royal Free Hospital in London.

[83] Professor Ian Hann, rule r9 statement, para 37: "*Most non-American delegates were stunned to hear of the ravages of a new disease which had come out of a clear blue sky.*"

[84] See Dr Pettigrew [Transcript 07.12.20 ,p69] According to the Penrose Inquiry Final Report Dr Willoughby left his post at the "end of 1982" [21.293]. See Chapter 5 for a more detailed discussion in relation to the knowledge and actions of Dr Willoughby

Developing knowledge of AIDS: July 1982 – January 1983

47. In our submission, the key period during which an early appreciation of a risk to haemophiliacs from AIDS first developed was between July 1982, and January 1983. Professor Ludlam was able to discuss what transpired during this period in some detail. It is submitted this evidence is helpful to the Inquiry in determining the significance of various events in informing haemophilia clinicians in Scotland at that time. Professor Ludlam explained that he first became aware of cases of AIDS in haemophiliacs following the publication of the MMWR report of 3 cases in July 1982.[85] It appears clear that by September of 1982 the matter had come to the attention of reference centre directors, who tasked Dr John Craske of the Public Health Laboratory Service to investigate and report. On 11 November 1982 Dr Craske wrote to Professor Ludlam saying that 5 haemophiliacs had been identified with the syndrome in the United States, of whom 2 had died, without any other risk factors being present. A striking feature of the letter is its description of a working hypothesis in the United States that the disease had been transmitted to the haemophiliacs via factor concentrates containing infected plasma donations.[86] Enclosed with Dr Craske's letter was his report to the MRC Hepatitis Vaccine Working Group describing three theories considered by the CDC in relation to aetiology. Two of these theories (the effect of drugs such as amyl nitrate, and the immuno-suppressive effect of cytomegalovirus infection) appeared to have been effectively discounted as cause of AIDS in patients with haemophilia. The remaining theory, as summarised in the letter, was that the syndrome's association with sexual promiscuity, intravenous drug use and possibly the transfusion of commercial blood

[85] Professor Ludlam, [Transcript 02.12.20 p3]. Professor Ludlam explained the MMWR was not on his reading list and was a rather specialist journal for those interested in public health and infectious diseases. He estimated that it came to his attention between August and October 1982. The reporting of these cases to Dr Evatt at the CDC was described by Dr Winter in his evidence as *"an absolutely critical moment"* [Transcript 01.10.20 p75]

[86] Professor Ludlam [Transcript, 02.12.20 p4-5] [HCDO0000273_079]. Dr Craske wrote: "*The hypothesis being used to explain the acquisition of these cases …is that one or two patients in the incubation period of the disease donated plasma which has since been used to prepare Factor VIII or Factor IX concentrates All the haemophiliacs who have the disease have had severe coagulation defect requiring regular treatment with Factor VIII. The likelihood is, therefore, that other cases will be identified amongst severe haemophilia, though probably at low prevalence.*" From information subsequently provided to us, we understand that Dr Craske's letter was more likely than not sent to all Haemophilia Directors. We would suggest that the Inquiry may wish to check this for itself.

concentrates, together with evidence of clustering and a prodromal phase suggested an infectious agent with similar epidemiology to that of Hepatitis B. Significantly, the report noted that a feature of the condition was a delay between the initial infection and the occurrence of symptoms and diagnosis.[87]

48. It is important that the nature of this emerging information should be considered within the context of what Professor Ludlam described as *"a lot of uncertainty at this time…and puzzlement"*[88] about the cause of AIDS. The possibility that it might be a virus was acknowledged. However there were other theories too. One was that blood products themselves had altered the immune status of recipients (the 'antigen overload' theory). There was some evidence to demonstrate that the immune status of HIV negative haemophiliacs was also suppressed in a similar pattern. It was also suggested there might be 2 parallel aetiologies for AIDS appearing in homosexual men and people with haemophilia. The diverse and disparate nature of the competing possibilities speaks powerfully to the difficulties encountered by clinicians in forming any kind of clear view of matters at this stage. Equally, however, it appears that medical opinion was by then beginning to head down what turned out to be the right track: Professor Ludlam's summary of the position as at late 1982 was as follows: *"I think at this time there was much uncertainty but a viral aetiology was perhaps the most likely."*[89]

49. It is fair to acknowledge a range of views amongst haemophilia clinicians at this time. Dr Winter's view, even at that early stage was less circumspect:[90]*"Any clinician looking at this data would have to believe that AIDS was a transmissible disorder and that it could be transmitted by blood and blood products. It was the <u>only</u> clinical interpretation of the data which was available"*[91] (emphasis added) Consistent with that interpretation, the evidence of SNBTS witnesses indicated that by the end of

[87] [HCDO0000557]
[88] Professor Christopher Ludlam, [Transcript 02.12.20 p9]
[89] Professor Christopher Ludlam, [Transcript 02.12.20 p9]
[90] In evidence Dr Winter said: *"So in this period, say, from July'82 to December '82, by the end of that period, as a haemophilia doctor, you would have to look at that data and say…This is something which is in the blood. This must be a virus or something like that…"* [Transcript, 01.10.20 p75]
[91] Dr Mark Winter [Transcript, 01.10.20 p75-76], citing his evidence to the Penrose Inquiry

1982 they were in no real doubt that AIDS could be transmitted by blood and blood products, notwithstanding the multiple other uncertainties about the disease.[92]

50. If the perception of the condition described by Professor Ludlam was, perhaps justifiably, a more tentative one, then events in early 1983 appeared to fortify his view that haemophiliacs were now becoming at risk. At that time he became aware of reports of more transfusion-related cases, including a 20-month infant in California.[93] On 13 January 1983, the New England Journal of Medicine published an article by Dr Jane Desforge, which opened with the ominous sentence: *"The fact that haemophiliacs are at risk for AIDS is becoming clear."* Professor Ludlam agreed with this opinion.[94] On 19 January 1983 Dr Craske updated a meeting of the UKHCDO Hepatitis Working Party on information received from the CDC in Atlanta reporting 10 further cases of AIDS in haemophilia A patients, with none of the other predisposing causes such as heroin addiction, homosexuality and treatment with immunosuppressive drugs. It was considered possible that factor 8 or other blood products administered to the patients might be implicated. The CDC AIDS Task Force were working on the hypothesis that an infective agent was involved, possibly a virus specific for human T cells. Accordingly, these new cases were drawn to the attention of the Hepatitis Working Party because they supported the most likely theory of there being an infectious agent involved and an association between blood and blood products and transmission of the agent responsible for causing AIDS.[95]

51. On 24 January 1983 there was a meeting between representatives of Immuno and various Haemophilia Centre Directors, including Professor Ludlam, at the Excelsior

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[92] In his oral evidence Frank Boulton said (words to the effect of) *"…I am confident by December 1982 we were of the opinion, in the Edinburgh and South East Transfusion Centre medical community that the most likely explanation of the increasing number of haemophiliacs – in early 1983 there were some in Britain as well - would have been due to an infectious particle with an epidemiology resembling that of hepatitis B, although probably a very different kind of particle."* [Transcript 04.02.2022, p113]

[93] The infant from San Francisco had received multiple transfusions which had included platelets from a male found to have subsequently developed AIDS.

[94] The article, which Professor Ludlam became aware of in early 1983, went on to say, *"preventing the complications of treatment may have to take precedence over preventing the complications of haemophilia itself."* Professor Ludlam, [Transcript 01.12.20 p10,11] [PRSE0002410]

[95] Professor Christopher Ludlam, [Transcript, 02.12.20 p16] (Professor Ludlam was a member of the Working Party at that time.)

Hotel at Heathrow Airport. Amongst other topics, AIDS was discussed and Dr Craske gave an informal update. According to Dr Boulton's notes from the meeting, Dr Craske reported that by this stage 800 people had been reported as suffering from AIDS. There was 45% mortality. There were 10 cases in haemophiliacs in the US. 5 had died. The youngest was aged 7. The patients had in common a history of prolonged treatment with Factor 8. There appeared to be no suggestion by Dr Craske, speaking of course from a virological perspective, that the cause in haemophiliac patients or transfused patients was anything other than the receipt of blood or blood products. An article in the Lancet published on 29 January 1983 stated: *"Transmission of an infectious agent in blood products seems likely."*[96] Professor Ludlam stated that by the end of January 1983 *"I think it's fair to say that people with haemophilia appeared to be acquiring AIDS as a result of their treatment with clotting factor concentrates."*[97] It was also the case that in discussions around that time an infective aetiology was considered to be the most likely cause.[98] Professor Hann's evidence was in similar vein, also emphasising the *"frightening"* mortality rate which was by then already apparent.[99] The Boards consider that such conclusions were reasonable, based on the evidence which was by then already available.

Nature and gravity of the emerging risk

52. By January 1983 the likelihood that AIDS was being transmitted to haemophiliacs in the United States via blood products had become apparent to clinicians in Scotland, such as Professors Ludlam and Hann. A separate question is the extent to which the troubling news arriving from across the Atlantic was, or ought to have, translated into an appreciation of a grave and immediate risk to haemophiliacs and blood transfusion recipients in Scotland, and the rest of the UK.[100] The fact that substantial

[96] The Lancet, 29 January 1983 "*Acquired immunodeficiency-like syndrome in two haemophiliacs"*
[97] Professor Ludlam, [Transcript 02.12.20 p28]
[98] Professor Ludlam, [Transcript 02.12.20 p28] [RLIT0000201]
[99] Professor Hann, [Transcript 08.12.20 p72] Professor Hann agreed that by the end of 1983 it had become clear that it was likely haemophiliacs were being infected though use of blood products.
[100] Dr Winter's evidence was that *"however many alarm bells a human being has, they should have been ringing at this stage."* [Transcript, 01.10.20 p80]

quantities of factor concentrates produced in the USA were then being imported into the United Kingdom must clearly have been sufficient to raise that possibility in the mind of haemophilia clinicians involved in the prescription of such products. However, it was not until May 1983 when the diagnosis of AIDS in a patient from Cardiff was made public, that the geographically distant spectre of the disease in America first began to be acknowledged as having turned into a reality for haemophiliacs in the UK. This was followed by news that a patient from Bristol had died of AIDS in August 1983.[101] In Scotland, studies to monitor immune abnormalities in haemophiliac patients were commenced by both Professor Forbes at Glasgow, in 1982, and Professor Ludlam at Edinburgh, in early 1983. The introduction of such surveillance connoted a concern about how haemophiliacs in Scotland might possibly be affected by the developing AIDS situation, whatever the true cause of that condition might ultimately be found to be.[102]

53. On the assumption that AIDS was indeed caused by a transmissible agent, the progress by then achieved in Scotland towards achieving self-sufficiency would have been a relevant factor in the assessment of risk. By that time, the haemophilia centres (with the notable exception of Yorkhill Hospital prior to 1983)[103] were in a position to offer most patients treatment with NHS concentrate and cryoprecipitate manufactured from donations collected from volunteers in Scotland, rather than commercial concentrates produced in America. Professor Ludlam's enquiries with the infectious disease unit at Ruchill Hospital and elsewhere found there had been no reported cases of AIDS within the Scottish population. He therefore assessed that the risk of Edinburgh patients becoming infected with a putative virus was low because of the absence of AIDS cases in the general population in Scotland (and therefore also the donor population) and the efforts of SNBTS to encourage individuals in 'at risk' groups to refrain from blood donation.[104] This encouraged his view that the

[101] Dr Craske provided an update to the UKHCDO in this regard on 10.09.1983 *Haemophilia Centre AIDS Investigation -Surveillance of AIDS Cases in Patients with Blood Coagulation Disorders*
[102] Professor Ludlam, [Rule 9 statement para 329] [WITN3428001]; [Transcript 04.12.20 p75 – 77]. Professor Ludlam said in evidence that he fully expected the results to be normal.
[103] Upon taking up his appointment at Yorkhill in January 1983 Professor Hann reversed his predecessor's policy of using commercial concentrates in preference to SNBTS products.
[104] Professor Ludlam [Rule 9 Statement, para 211] [WITN3428001];

Scottish blood supply was *"relatively or reasonably… safe."* As he explained in evidence, *"on that basis, I thought the risk was low but not zero."*[105]

54. It does appear to be the case that Professor Ludlam's belief in the relative safety of the Scottish blood supply was shared, not only by other haemophilia clinicians, but also by SNBTS transfusionists. In his evidence Dr Brian McClelland said: *"There was certainly a widely held belief…that blood from indigenous voluntary donors is the safest you can get. We were optimistic that the frequency with which we would find evidence of an AIDS' virus in our donors' blood would prove very low because there was very little of the disease around at that point. We were some years behind the US, and that actually proved to be the case…certainly it came as a terrible shock to discover that, actually, our donor's blood had transmitted HIV to those patients."*[106] Dr Frank Boulton said that until November 1984 when the infection of patients by SNBTS factor 8 was discovered, there was a hope (*"I don't think it was a complacent hope"*) that blood donated in Scotland from carefully selected group of donors would not be contaminated with HIV: *"the fact that that …unfortunately proved to be misguided by this contamination was indeed a shattering blow."*[107]

55. A question arises whether such a relatively optimistic assessment was warranted at that time, or alternatively, may be seen in retrospect to signify a degree of over-confidence or complacency in relation to the safety of the Scottish blood supply.

56. An important aspect of the context in which this question arises is the level of access to emerging information which clinicians enjoyed during this period. Such would inform their evaluation of the emerging risk and their own response to it. There is evidence before the Inquiry to indicate that NHS organisations and their clinicians were hampered by a lack of timely and accurate information on the scale of the epidemic. One telling early example of this came in September 1983 when Dr Craske expressed concern to Professor Bloom that he had not heard about the Bristol case

[105] Professor Ludlam, [Transcript 02.12.20 p31-32] UKHCDO guidance from May 1983 was to continue to use NHS products as previously – see discussion of treatment polices at Chapter 5 of this Submission below.
[106] Dr Brian McClelland, [Transcript 27.01.2022 p126 – 127]
[107] Dr Frank Boulton, [Transcript 04.02.2022 p9 -10]

until after the patient's death.[108] More systematically, (as Penrose found)[109], adoption of the more restrictive CDC test for diagnosis of AIDS[110] and the limitations of a voluntary system of reporting combined to lead to significant under-reporting of cases of AIDS in the UK. In the result, up until mid-1984 there were only 24 reports of cases of AIDS in the UK of whom 2 were haemophilia patients and 1 had died.[111] Even allowing for what was then known about the delay between infection and symptoms, these low numbers must inevitably have impacted upon understanding of the developing epidemic until late 1984 when testing for anti-HTLV-III became available. On any view, it cannot have assisted clinicians in grasping the extent of the risk to patients or the likely scale of the epidemic amongst haemophilia patients.[112]

57. The same point applies in relation to information from government. For example, it appears the Reference Centre directors were not made aware of the Council of Europe recommendations to governments in June 1983 anent avoidance of coagulation factor products prepared from large plasma pools; and provision of information to haemophiliacs of the potential hazards of haemotherapy.[113] The opportunity to reflect on the significance of such recommendations for their own practices and treatment policies was thereby lost. Such was not an isolated example: Professor Ludlam was likewise not made aware of the advice from Dr Spence Galbraith's letter to Dr Field at the Department of Health dated 9 May 1983 entitled *"Action on Aids"*, recommending temporary withdrawal from use of blood products made from blood donated in the USA after 1978.[114]

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[108] Minutes of a Haemophilia Centre Reference Directors Meeting 19th September 1983 indicated the lack of a clear system for notifying the Communicable Disease Surveillance Centre of cases of AIDS. [HCDO0000413]

[109] Penrose Inquiry Final Report, para 10.161: *"As a result, the extent of the AIDS epidemic in recipients of blood, blood components and blood products in the UK generally has only become apparent following extensive retrospective analysis."*

[110] Which required identification of intractable AIDS-defining disease without a requirement to report significant evidence of impaired cell-mediated immunity.

[111] See Penrose Inquiry Final Report chapter 10.1

[112] This issue arguably also underscored the need for rules governing disclosure requirements to enable accurate monitoring of the position at a national level.

[113] Professor Ludlam, [Transcript 02.12.20 p42]. Professor Ludlam indicated that had he received the Council of Europe Document he might have taken steps to explain the risk of AIDS to his patients. [Transcript 02.12.20 p67]

[114] Professor Ludlam, [Transcript, 02.12.20 p46]. Professor Ludlam said it would have been 'very helpful' for the Reference Centre Directors to have seen this.

58. Assessment of the level of risk to haemophiliacs from AIDS was also affected by an incomplete understanding of the disease. As Professor Hann explained, there was a difference between realising that HIV was linked to blood products and also appreciating that AIDS was going to be a big issue. The natural history of the disease varied in different infected groups and its true pathogenesis was unknown. The symptoms of AIDS were presenting differently in haemophilia patients (who did not develop classical symptoms of AIDS such as Kaposi's sarcoma). For these reasons, the prospect of AIDS becoming a significant issue for haemophilia patients in the UK only began to be more clearly appreciated in the second half of 1983, following the isolation of the virus by the Montagnier' group in May 1983. [115]

59. For the forgoing reasons, the Boards submit that the risk to patients in Scotland from AIDS must have been extremely difficult for clinicians to gauge prospectively. Standing the difficulties, it may be difficult to fairly conclude that the assessments made by the clinicians and transfusionists, on the basis of extremely limited information, were unreasonable in all the circumstances. However, it would also be fair to observe that risk factors for AIDS, such as homosexual behaviour and intravenous drug use, were obviously known to exist within the general population of Scotland at that time. Having regard, for example, to the limitations of donor selection policies and the absence of any screening test, it would arguably have been naïve to assume that the disease would not enter the Scottish donor population. However, as Dr McClelland frankly explained: *"I think there was a deep seated reluctance to accept that there was any kind of link between our lovely blood donors and "those unpleasant habits.""*[116] Insofar as such an attitude ran counter to experience and logic, it may be argued that the assessment of the level of risk was too optimistic. To that extent, it appears likely that progress towards self-sufficiency in Scotland may have helped to generate a degree of over-confidence in the safety of the Scottish blood supply. As subsequent tragic events proved, such high levels of confidence were ultimately misplaced. Whether, in hindsight, the likelihood that members of the local donor population (and then the blood supply) would ultimately

[115] Professor Hann, [Transcript 08.12.20 p75 – 76]
[116] Dr Brian McClelland, [Transcript 27.01.2022]

become infected with AIDS is something which could have been more clearly appreciated in advance of those events is a matter for the Inquiry to determine. For their part, the Boards accept that such a conclusion would be open to the Inquiry to reach, on the basis of the evidence.

Significance of alternative theories

60. Finally, the Boards wish to say something about the significance of alternative theories about AIDS for the assessment of risk. As discussed above, the theory that AIDS was caused by a transmissible agent rapidly came to be acknowledged as the most likely explanation of its aetiology. However, at the same time there was continuing reluctance in some quarters to accept that the condition was likely to be caused by a blood borne transmissible agent, in the absence of the exacting requirements of Koch's postulates being fulfilled.[117] Alternative hypotheses, in particular the "antigen overload" theory whereby immunological defects were caused by blood products alone also gained a certain amount of currency amongst haemophilia clinicians, including Professor Forbes and Professor Ludlam.[118] In his evidence, Dr Boulton described his perception that "*there was what we thought, even then (May 1983), was a sense of wishful thinking among the haemophilia-treating community that this awful condition was not due to an infection but might go away because it was not very common yet at all in the UK.*" [119]

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[117] As Penrose found: *"Koch's postulates were an impossible test at the time. The demand for proof to that standard demonstrates the resistance among highly respected US clinicians to the infectious agent theory but leaves open the question whether that resistance was based on scientific grounds or reflected wider concerns about the implications for haemophilia therapy if the theory was given credibility."* [Penrose Inquiry Final Report chapter 11.35]

[118] See i.e.: Ludlam et al, *'Disordered immune regulation in haemophiliacs not exposed to commercial Factor VIII'* The Lancet, 28 May 1983. The letter referred to the ongoing study of haemophilia patients in south east Scotland. By this stage in Professor Ludlam's continuing research programme, 23 patients who had received exclusively SNBTS Factor VIII in the past five years, most of whom had never received commercial concentrate, had been studied. In the majority of these patients, the T_4/T_8 ratios were reduced. The letter stated: "*Since there are no known cases of AIDS in our blood donor population it seems likely that the immunosuppression observed in haemophiliacs, as reflected by reduced T lymphocyte helper/suppressor ratios, results from infusion of foreign protein or a ubiquitous virus rather than a specific AIDS virus in factor VIII concentrates*"

[119] Dr Boulton said he thought that Christopher Ludlam accepted it "intellectually" but that it was unthinkable emotionally. [Transcript 04.02.2022, p119] In this regard we note the conclusion of the Penrose Inquiry that *"The resistance of the haemophilia clinicians appears to have reflected their wish to continue to use factor concentrates of proven efficacy in treating their patients. The pharmaceutical industry had commercial interests to protect. Human nature rather than the strict application of scientific theory probably contributed to the persisting differences of opinion."* Penrose Inquiry Final Report, para 11.41

61. A complete analysis of the merits of these competing theories lies beyond the scope of this submission. However, the Boards consider it important to acknowledge that the divergence of opinion about aetiology of this new condition did not in itself amount to any good reason to discount the risk to haemophiliacs. Insofar as the "antigen overload" theory held that administration of high levels of factor concentrates could damage patients' immune system in a comparable way to homosexual men with AIDS, then serious illness and death in haemophilia patients would plainly have been a foreseeable consequence. Secondly, the Boards agree with the conclusion of the Penrose Inquiry that: *"…the possibility of antigen overload as a causative factor could not exclude the concurrent possibility of infection transmitted in blood and blood products, with a fatal prognosis in some cases. The two aetiologies postulated were not mutually exclusive. The positive risk could not exclude the increasing probability that haemophilia patients might also develop AIDS due to viral transmission. At best it was an additive risk. At worst it was an aggravating feature that could increase the threat to the patient exposed to an infective agent."*[120]

62. Accordingly, in our submission, the existence of alternative theories in relation to the cause of AIDS did not provide any grounds for comfort. Indeed if anything, quite the reverse.

Findings & Conclusions

63. Having regard to the above, it is submitted that the following ten conclusions may be drawn on matters relevant to the state of knowledge of haemophilia clinicians, as at the end of January 1983:

    i. The cause of AIDS had not yet been established.

    ii. The likely prevalence of the disease was unknown.

    iii. The natural history of the disease was little understood.

    iv. No cases of AIDS in haemophiliacs had yet been reported in the UK.

[120] Penrose Inquiry Final Report, para 11.133. Professor Ludlam's evidence to this Inquiry was to similar effect [Transcript 04.12.20 p85 – 86]

v. However, haemophiliacs in the United States appeared to be acquiring AIDS as a result of their treatment with blood products.

vi. The fact that haemophiliacs were at risk of AIDS was becoming clear.

vii. An infectious aetiology was being discussed within relevant specialisms as the most likely cause.

viii. It was known that AIDS was associated with a high mortality rate.

ix. It was known there could be a significant lapse of time before the onset of symptoms; and therefore:

x. The fact that numbers of cases were then comparatively low would not necessarily be a reliable guide as to how many might be infected.

64. By January 1983, it was widely recognised that AIDS was probably transmitted by blood and blood products. The subsequent question to which this gives rise is how the nature and gravity of the risk to haemophiliacs and blood transfusion recipients in Scotland was assessed by clinicians. In this regard the Boards submit as follows:-

65. The risk to patients in Scotland arising from AIDS was extremely difficult for clinicians to gauge prospectively. NHS organisations and their clinicians were hampered by a lack of accurate and timely information on the scale of the epidemic and other matters relevant to their assessment of the nature of the risk to patients. Assessment of the level of risk to haemophiliacs from AIDS was also affected by an incomplete understanding of the disease, including the relationship between HIV and AIDS, the natural history of the disease, its symptoms and true pathogenesis.

66. At that time clinicians in Scotland realised that Scottish haemophilia patients were potentially at risk of developing AIDS as a result of their treatment with blood products.

67. Professor Forbes and Professor Ludlam took early and proactive steps to investigate the risk by commencing studies at their respective centres to monitor immune abnormalities in haemophilia patients.

68. The level of risk to patients from AIDS was generally assessed as low, assuming an infective aetiology. The reasons for such an assessment included the fact that Scotland was largely self-sufficient in blood products for haemophilia treatment; low reliance upon concentrates imported from the USA; the absence of any AIDS cases in the general population in Scotland; and the efforts of SNBTS to encourage individuals in 'at risk' groups to refrain from blood donation. Standing the difficulties, it cannot be said that such an assessment was unreasonable in all the circumstances.

69. The discovery in late 1984 that 17 patients at Edinburgh had been infected with HIV by SNBTS concentrate proved that the risk to haemophiliacs in Scotland had been underestimated. It appears likely that recent good progress towards self-sufficiency in Scotland, allied to a strong commitment to the principle of voluntary donation, may have contributed to an attitude of over-confidence in the safety of the Scottish blood supply amongst both clinicians and transfusionists at that time.

CHAPTER 4: CONSENT

Introduction

70. The evidence heard by this Inquiry serves as a valuable reminder to those working within the NHS today of the importance of the principles of informed consent; and of the harm that can result from failures in adherence to those. It holds lessons of continuing importance for the NHS in Scotland today.

71. We begin this chapter of our submission by highlighting some of the fundamental tenets of informed consent which the Boards consider important to state within this forum.

72. The general rule governing a doctor's duty to seek consent from patients to their medical treatment was well-expressed by the Medical Ethics expert group in their report to the Inquiry as follows*: "adult patients with requisite mental capacity should*

not be subjected to medical intervention unless they have given valid and informed consent." [121] Although relevant today, as ever, this concept is not a new one. The Medical Defence Union echoed the same essential point in their 1971 publication 'Consent to Treatment'*: "No amount of professional skill can justify the substitution of the will of the surgeon for that of his patient.*[122]

73. The main rationale underlying this rule is respect for a patient's autonomy. As explained in the expert group's report: *"The philosophical basis for informed consent is the principle of patient autonomy – by knowingly considering, and then accepting rather than rejecting a proposed course of action based on adequate information, a patient expresses their autonomy and their responsibility for the decision, while also accepting the expertise of the clinician."*[123] It is important to add that consent is more than a patient simply agreeing or refusing what is proposed. Consent should be voluntary and informed, without any form of coercion or control by others. In order for consent to be informed, the patient requires sufficient information and understanding to allow autonomous choice. In general, the clinicians recognised that it was important for patients to appreciate the risks and benefits of treatment and it was the responsibility of the doctor to provide adequate information in that regard.[124]

74. The long-term damage wrought by the breach of patients' autonomy to which failure to seek informed consent amounts has been well demonstrated by troubling evidence which the Inquiry has heard in this regard. The Boards recognise that where patients contracted serious diseases in consequence of NHS treatment, their immense suffering will have been further compounded and exacerbated where the treatment causing those diseases was administered without informed consent being given. Not least of the harm thus caused is the potentially irrevocable loss of trust, an essential ingredient in the relationship between patient and doctor. Insofar as the

[121] *Expert Report to the Infected Blood Inquiry: Medical Ethics* P12. MDUN0000061
[122] *Expert Report to the Infected Blood Inquiry: Medical Ethics* P23. Guidance for clinicians around the issue of consent has, however, evolved during the time period in question with BMA and latterly GMC Guidance. See discussion at paras 11 -13 below.
[123] Ibid, p12
[124] Professor Ludlam, [Transcript 01.12.20 p132 – 133]; Professor Lowe [Transcript 09.12.2020 p108]

Inquiry may identify past failings in relation to informed consent, the Boards consider it vital that the necessary lessons are learned. The fact that significant improvements have occurred in relation to guidance and clinical practice in the interim does not diminish the value of those lessons, or justify any degree of complacency on the part of the NHS in Scotland today.

75. For these reasons, the Boards consider that the issues arising in relation to consent are amongst the most important for the Inquiry to determine upon. As the Inquiry has heard, the application of modern standards to the actions of earlier generations of doctors is not without difficulty. In their report, the Medical Ethics Expert Group note that: *"Changes in law, professional guidance and practice, according to sociopolitical and cultural conditions, raise a difficult question about how to judge historical acts in the face of progress."*[125] While this observation may be capable of quite general application, the question it raises is singularly acute in the context and circumstances of this particular Inquiry.

76. Whether these issues should be examined from a perspective of moral relativism[126] or, alternatively one of moral realism or objectivism is not simply an academic philosophical discussion, but a real question for the Inquiry to consider in its assessment of the evidence.[127] In this regard, the Boards would agree with the Expert Group that, in principle, acknowledging that ethical and professional standards have changed over time would not preclude the application of enduring fundamental moral principles in considering whether past behaviour was questionable or wrong, even where such conduct may have proceeded on the basis of unchallenged or standard practice within the medical profession at the material time.[128] As Professor

[125] Supra FN124, p6
[126] The terms "moral relativism" and "moral objectivism or realism" are explained in the Report (p.6).
[127] Professor Farsides [Transcript 26.01.2021, p7-78]
[128] As Professor Kerridge explained: "*That's not to say that history and context are irrelevant. It's not a binary. ..there are ideas or principles or ethical norms that are incredibly stable across time. These are things we think are important, and they are core to our existence as human beings. But by the same token, it's the context in which we live, the historical norms at the time, the power structures that exist, the circumstances of our own life at the time, they undoubtedly interact and determine how these things play out. And in medicine, as in many spheres of life, we can see examples of practices and behaviours that at one particular point were deemed acceptable but, subsequently, with further thinking sometimes – and it's just with further thinking it*

Savelescu put it in his evidence, *"ethics is demanding…I mean, we may be as criticisable as people in the past. So I think it's important to recognise that, you know, we can all fail and can be failing now without us knowing or acknowledging it."*[129]

77. At the same time, in our submission any meaningful assessment of matters requires to acknowledge the practical reality that, then as now, individual clinicians will usually have sought to govern their clinical practice in accordance with the prevailing professional standards and practices, ethos and culture. If, as is generally acknowledged, a more paternalistic culture and attitude[130] prevailed within the medical profession in the 1970s and 1980s, it would perhaps be surprising if such was not also found to be reflected, at least to some extent, in the practices of many individual clinicians at that time. The fact that individual clinicians may be seen to have fallen short if judged according to contemporary standards should not be taken to infer that they were less committed to their vocation or dedicated to the welfare of their patients than their successors in the profession today. Any fair assessment would require to have due regard to these factors, in our submission.

78. In the law governing modern consent practice, the decision of the UK Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 now provides the touchstone. In *Montgomery* the Supreme Court reaffirmed the fundamental principle that *"an adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken."*[131] The Court recognised a duty of care on doctors: *"to take reasonable care to ensure that the patient is aware of material risks involved in any recommended treatment and of any reasonable alternative or variant treatments."*[132] For present purposes is worth

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becomes clear that those are just not acceptable and were never actually acceptable." [Transcript, 26.01.22 p80-81]

[129] Ibid

[130] Beauchamp and Childress define paternalism as: *"the intentional overriding of one person's preference or actions by another person where the person who overrides justifies this action by appeal to the goal of preventing or mitigating harm to the person whose preferences or actions are overridden."* Medical Ethics expert group report, p16

[131] Para [87], per Lords Kerr and Reed

[132] Ibid

emphasising the perhaps obvious point that, thus expressed, the nature of the legal duty is essentially two-fold:

1. to advise the patient of the material risks[133] of treatment[134]; and
2. to advise the patient of any reasonable alternative or variant treatments.

It has been commented that the decision in *Montgomery* has served to bring the legal position into better alignment with the content of professional guidance which has been in place since as early as 1998.[135]

79. While as a matter of legal theory *Montgomery* simply states what the law has always been, it is relevant to notice that in the 1970s and 1980s the *Hunter v Hanley*[136] test in Scotland (and the *Bolam*[137] test in England & Wales) were used to determine the legal standard for informed consent. Whereas *Montgomery* recognises a duty of care to warn of material risks, the earlier decisions test a doctor's conduct against the question of whether it would be supported by a responsible body of clinicians. It is plainly arguable that this approach reflected a misplaced emphasis on the doctor's opinion, rather than what the patient wanted to know from their own perspective. It is suggested that this particular feature of the medico-legal landscape which prevailed during the 1970s and 80s may be relevant to the Inquiry's examination of the underlying reasons for such deficiencies in consent practice as may be identified from the evidence.

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[133] The test of materiality is defined as follows: *"…whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."* Para [87]

[134] *"The first step is determining whether, as a matter of contemporary knowledge, there was a risk. The second step is determining whether the relevant clinician (here the registrar) knew or ought to have known of that risk. Whereas the materiality of the risk is something which the court may ultimately have to determine, the existence of the risk and whether the relevant clinician ought to have known about it are exclusively medical matters and therefore require to be established by medical evidence*." LT v Lothian Health Board [2019] CSIH 20 at [42].

[135] In his evidence Professor Cave said: *"The law on this matter now reflects guidance that has been in place certainly since 1998 in requiring disclosure of risks and benefits and alternatives that a reasonable patient would want to know or that that actual patient would want to know if they should reasonably be aware of that fact. The GMC has interpreted that, in its latest guidance, as requiring any risk of serious harm to be disclosed."* [Transcript, 26.01.2021 p197]

[136] Hunter v Hanley 1955 SC. 200

[137] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582, as affirmed in Sidaway v Bethlehem Royal Hospital Governors and others [1985] AC 871

80. However, the limited remedy for non-disclosure which the law of negligence formerly provided[138] should not, in our submission, be allowed to obscure the fact that by the 1970s the duty to warn of important risks was well recognised within mainstream medical ethics. In 1968, Sir Roger Ormrod wrote in the British Medical Journal that *"The patient will be entitled to demand a bona fide statement in broad terms of the risk to life or future health or of pain and discomfort involved in the contemplated procedure or to a frank admission that in the given circumstances these cannot be assessed with any accuracy."*[139] In a similar vein, the Medical Defence Union's 1971 edition of its pamphlet *Consent to Treatment* stated that: *"If the operation contemplated carries special risks which are probably unknown to the patient he should, as a general rule, be informed of these risks."*[140] A decade or so later, the 1980 BMA Handbook of Medical Ethics stated *"Consent is valid when freely given if the patient understands the nature and consequences of what is proposed."*[141]

81. The evidence provided by the Expert Group and the thorough review of historical guidance in counsel to the Inquiry's presentation[142] may indicate that the relevant clinical guidance from the 1970s and 1980s tended to place less emphasis upon advice about alternative forms of treatment. As the Expert Groups report narrates, the guidance issued by the British Medical Association in 1980 put the onus on the doctor to give an explanation adequate for the patient to understand 'the nature and consequences what is proposed.' However, the doctor's duty was expressed as

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[138] See ie: the Medical Defence Union document *Consent for Examination and Treatment* " current in 1953: "*To obtain consent it is necessary for the practitioner to explain carefully to the person in non-technical language the need for an examination to arrive at a diagnosis or decide on the line of treatment. The character and the likely results of the treatment should be outlined to the patient in such terms that he can appreciate fully what is proposed and what may ensue. A practitioner, aware of the uncertainties of treatment, should avoid sweeping promises; and should not minimise the risks that may be inherent in the procedure he proposes.*" (emphasis added) [Transcript 26.01.2021 p125] [MOJU0000001_014]

[139] Medical ethics *BMJ* 1968 19(2) 7-10, emphasis added. It is relevant to note that in the writings of experts at the time, it is apparent that most of the discussion of issues around consent reference surgical procedures and not drug (or product) prescribing.

[140] As observed by Counsel to the Inquiry in the *Presentation on Ethical and Clinical Guidance for Clinicians and Other Healthcare Practitioners "a purpose of the medical defence societies is to help protect and prevent a doctor from being sued in the course of their practice. As such, their advice and guidance is clinican centred with a view to protecting the doctor, rather than being patient focused*." (Para 54)

[141] [BMAL0000087]

[142] *Presentation on Ethical and Clinical Guidance for Clinicians and Other Healthcare Practitioners*

requiring him to decide which treatment option was preferable and to furnish the patient with information sufficient that they could *accept or refuse it.*[143]

82. A distinct shift in emphasis may be seen in later guidance. For example *'A guide to Consent to Examination , Investigation, Treatment or Operation'*, produced by the NHS in Scotland in 1992, provided that a patient was entitled to receive sufficient information in a way he could understand about any proposed procedure, the possible alternatives, and any substantial risks so he could make a balanced judgment.'[144] In 1998 the GMC produced its first specific guidance on consent to treatment.[145] It set out a patient's right to information about their condition, prognosis, treatment options and risks, and made clear that information should be tailored to the patient's needs and priorities. It said that information required to make an informed decision should not be withheld unless it would cause serious harm. It is submitted that the evidence heard at the Inquiry only serves to emphasise the necessity of such specific profession-wide guidance being available.

Approach to the Evidence

83. A key issue for the Inquiry to determine is whether or to what extent patients were given adequate and sufficient information in relation to the risks of blood and blood products, such as to enable them to give or withhold informed consent to treatment.

84. The Inquiry has obtained a substantial body of evidence from patients and their relatives providing their individual recollection of their experiences in this regard. The Boards do not propose to make submissions in relation to any individual cases. Instead, we attempt to identify some of the key themes emerging from the evidence as a whole, which seem upon reflection to be of particular importance from their perspective.

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[143] See also, in the context of consent to research: the ABPI *report in Good Clinical Research Practice from July 1986* which empathised the need to inform the patient about reasonable alternative therapies. *Presentation on Ethical and Clinical Guidance for Clinicians and Other Healthcare Practitioners*, para 82

[144] *Presentation on Ethical and Clinical Guidance for Clinicians and Other Healthcare Practitioners,* para 82

[145] *Presentation on Ethical and Clinical Guidance for Clinicians and Other Healthcare Practitioners,* para 86

85. It may be worth pausing to note that much of the evidence in this area relates to patients' recollections of conversations with their doctors, and also the doctors' recollection in relation to their own practices. How should the Inquiry approach the task of evaluating this evidence? As a generality, it might normally be suggested that a degree of circumspection should be exercised in assessing the reliability of evidence based on witnesses' memories of specific conversations with their doctors which occurred over 40 years ago. That human memory, particularly in relation to events many years ago, is notoriously fallible will be well understood by this Inquiry.[146] In many cases, where events are disputed, such medical records are as available may not really serve to advance matters. As a result, it may often be difficult to conclude with the requisite degree of confidence that a particular recollection spoken to in evidence by a witness is entirely accurate.

86. However, the Boards intend to eschew any overly cautious or legalistic approach for the purposes of what is necessarily a thematic examination of the evidence, in our submission.[147] Taking a high-level view of the evidence, it is clear that one of the dominant overarching themes of many patients' testimony was a strong perception that their treatment was given without adequate explanation of the risks which, in many cases, subsequently actually went on to materialise. Equally, consideration of the evidence given by the clinicians tends to confirm that such perceptions were, in important respects, justified. To that extent, we submit that, at least upon a broad and realistic view of the body of evidence as a whole, there may be a significant extent to which the evidence of the patients and the clinicians appears to be pointing

[146] See, for example, the comments of Leggatt J (as he then was) in *Gestmin SGPS S.A. v Credit Suisse & Ors [2013] EWHC 3560* paras 15 -22

[147] Plainly to the extent that specific allegations against individual clinicians are concerned, if it is necessary to determine the matter the Inquiry will require to have regard to all relevant evidence, including the witness statements.

in the same general direction.[148] Upon this approach to their analysis of the evidence, the Boards submit as follows:-

FINDINGS & CONCLUSIONS

Consent to Treatment: NANB hepatitis

87. For the reasons set out above at Chapter 2 above, the risks of NANB hepatitis (in addition to Hepatitis B) were such that patients were entitled to be advised of these prior to embarking upon treatment with blood products. Clearly the nature and extent of the information that doctors were in a position to provide will have varied over time. The Inquiry's conclusions in relation to what information ought to have been provided and the relative obligations upon the doctors will depend upon on its findings as to the state of knowledge within the profession at the material times. However, were the Inquiry to find, consistent with the Boards' submission, that in the late 1970s and early 1980s the *possible* risk of serious liver disease in at least some patients ought to have been appreciated, notwithstanding all of the uncertainties and relative absence of long-term data, that would give rise to the question of whether this information should have been communicated to patients at the time.

88. In accordance with modern professional guidelines, it appears to the Boards that such information ought, in principle, to have been communicated to patients.[149] However, considering the same question against the prevailing standards of the time as to what constituted a disclosable risk may not be entirely without difficulty. As Professor Cave explained during the evidence of the Ethics Group: *"…there's a fairly*

[148] Albeit we note Professor Ludlam's position in evidence that "*it is possible that patients may not recollect exactly what they were told, particularly with the passage of many years.*" He refuted the evidence to the Inquiry from his patients who said that they were not informed of the risks of NANB hepatitis, saying that *"if I was involved in their treatment, I hope I would have explained ….the risks to them."* [Transcript, 01.12.20 p147-148]. However, it may not be entirely clear from his evidence specifically what the patients were told as to the nature and severity of these risks. [Transcript, 01.12.20 p142]

[149] See for example, the General Medical Council (2020*) "Guidance on professional standards and ethics for doctors: Decision Making and consent"* which states in terms (para 26) *"If you are uncertain about the diagnosis, or the clinical effect a particular treatment might have, or if the available evidence of benefits and harms of an option is unclear, you should explain this to the patient."* See also Medical Ethics Expert Group Report at the top of page 56

complex debate around what happens when a risk is unknown or can't be readily quantifiable, and previous guidelines have focused perhaps on known risks. But the GMC's (latest) iteration certainly incorporates the possibility of unknown risks as well. So it seems then that there's an ethical duty to balance benefits and unknown risks and to be transparent about these unknown risks in order to allow the patient to make a choice, an autonomous choice"[150] (emphasis added)

89. However, while the long-term risks associated with NANB hepatitis may have been impossible to quantify in the late 1970s and early 1980s, the possibility that at least some patients might go on to develop serious liver disease was capable of being appreciated.[151] It seems to the Boards that this could reasonably have formed part of

[150] [Transcript, 26.01.2021 p197]

[151] The legal (as distinct from professional or ethical) duty of disclosure on the part of individual medical practitioners raises potentially difficult questions in our submission. As stated in the Medical Ethics Expert Group Report, *Montgomery* is concerned with known risks. In relation to "unknown risks" that should be known, the Report states the medical profession is left with the task of "*assessing whether a particular clinician knew enough about an emerging risk given what was, or is, known more generally at the time*" (page 55). In short, it has to be established that the risk in question was known, or ought to have been known, to the medical professional in question, and this is measured by reference to the standards of the profession. Furthermore if, on expert evidence, the risk was not known there is no need for the judge to consider materiality (*Medical Negligence* by Michael Jones, 6th edition at 7-044). In assessing whether a risk is "known", there requires to be a sufficient understanding of the existence of the risk within the relevant branch of the profession – comments made by experts in one case of the following type, *"[chronic post-surgical pain} was not common knowledge among gynaecologists at that time*" and "*there was no clear evidence of the specific risk in March 2008*" might indicate a relatively high threshold in that regard (*Duce v Worcesershire NHS Trust* [2018] P.I.Q.R. P 18 (2018),at [42], [43], [44]). Professor Dillon discusses the state of knowledge in 1981 in relation to NANB describing the (incorrect) general understanding of the condition on the part of practitioners at that time, and the backdrop of ongoing medical research which was not widely known and also subject to validation (Rule 9 Statement of Professor Dillon dated 16.12.2021 re the criticisms of W0181 at Q7) Specifically, a causal link between transfusion associated hepatitis and cirrhosis had as yet not been established – Professor Dillon states "*there was expert literature starting to appear at this time that suggested transfusion associated hepatitis might cause cirrhosis in the long-term in a small proportion of patients, this was not widely known and was for some years the subject of further research, before becoming established medical fact, among experts in around 1986…*". Based on the foregoing, it might be argued that the risk of cirrhosis associated with NANB did not become "known" in the relevant sense until it became "*established medical fact among experts*", at the earliest. From that point, it might possibly be said that there was the necessary sufficient understanding of the existence of the risk, there being "*clear evidence*" of the risk (as opposed to evidence of the possibility of the risk). However, any assessment may also turn on when other important features or aspects of the risk, including its magnitude, became commonly known (magnitude being expressly referred to as a potential factor of relevance in the determination of materiality of *such* risks. (*Montgomery* at [89]; *Duce* at [33] and [35]). On the evidence of Professor Dillon, the point at which this risk became "known" on this analysis may not have been until some point after 1986. However, as is hopefully clear from this document, irrespective of the strictly legal position (which is not straightforward in our view), the Boards maintain that the right course was that honest and candid conversations took place with patients about risks, including such "unknown" and unquantifiable risks, consistent with current professional guidance and Medical Ethics Group Report. We note that the analysis in this footnote may also be of relevance in relation to aspects of consent/ HIV/AIDS issue discussed below. (See generally, the Rule 9 Statement of Professor Dillon dated 16/12/2021 re the criticisms of W0181; *Duce v Worcestershire NHS Trust* [2018] P.I.Q.R. P 18 (2018), [11], [15], [25], [27], [33],

any discussion relative to the risks of treatment, whilst recognising that it is likely that the uncertainty of prognosis would also require to be emphasised. At all events, any positive advice to the effect that the disease was definitely mild and benign could not be sustained on the basis of the evidence. The challenge posed in translating that state of affairs into an appropriate formulation of advice to patients was well explained by Professor Hann, who said *"there was a great deal of uncertainty which - it was our job, if you like, to transmit to patients without causing unnecessary anxiety. I don't mean that in a patronising or patriarchal way. It's damaging for families to be told very damaging information and to be hung the sword of Damocles above them for many years"* [152]

90. Potentially complex questions as to precisely what form optimal advice on the risks should have taken, and at different points in time. However, from the Boards' perspective, there are a number of more elementary issues which upon reflection give rise to concern and merit highlighting here, as follows:-

91. Firstly, there is evidence that some patients in Scotland were not told of the risk of NANB hepatitis to any extent at all prior to commencing treatment with blood products, or undergoing a blood transfusion. [153] In certain instances, this may have reflected the fact that the treating clinicians were themselves unaware of the risk.[154] The absence of discussion of risks will certainly have applied to those prescribing blood transfusion, in relation to which formal consent to blood transfusion was only developed later. A substantial body of evidence to that effect from patients who acquired infections through that means is available to the Inquiry.

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[35], [42] to [44]*; LT v Lothian Health Board* [2019] CSIH 20 at [31], [32], [40] to [42]; Medical Ethics Expert Group Report, pages 53, 55 to 56; *Medical Negligence* by Michael Jones, 6th edition at 7-043 to 7-044)

[152] Professor Hann [Transcript 08.12.20 p52-53; 59]

[153] Of course, this was by no means universal. For example, in Professor Ludlam's own practice he *"very explicitly"* discussed the issue of 'hepatitis" when providing patients with their *"haemophilia card"* which stated "*Please give this patient if possible NHS Factor 8 if they come in for treatment or cryoprecipitate"* and not to use commercial products. Professor Ludlam [Transcript 01.12.20 p135-136] See also Professor Ludlam rule 9 Statement para 212. [WITN3428001_0082]

[154] Dr Pettigrew [Transcript, 07.12.20 p42,56] Dr Pettigrew did not provide any information about NANB hepatitis prior to 1984 because she was herself unaware of the existence of the disease.

92. Secondly, the evidence suggests that some patients with bleeding disorders were warned of the risk of "hepatitis" or "jaundice" generally, but not specifically NANB hepatitis - as distinct, for example from Hepatitis B.[155] Explaining this distinction, at least in general terms, would appear to be a prerequisite for a full discussion of the risks relating to those respective conditions.[156]

93. Thirdly, the evidence highlights the difference between informing a patient of the existence of a risk of hepatitis, and actually explaining the *nature* of those risks, as then understood, to the patient.[157] Even where patients were warned of the risk of NANB hepatitis, it was not always apparent to what extent the specific risks, such as the possibility of progressive liver disease, were discussed.[158]

94. Fourthly, and in similar vein, it was not always apparent to what extent patients were given information about the possible risk of chronic and severe liver disease.[159] In some cases, the risk relating to chronic liver disease may appear to have been implicit in advice provided, for example in relation to abnormal liver function tests, rather than expressly stated.[160]

95. Fifthly, the evidence indicates that on occasion important information was sometimes provided as an incidental aspect of a patient's routine treatment, rather than as part of a self-contained discussion of the risks prior to commencement of treatment.An obvious difficulty with such an approach is that, by that time, the risk

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[155] Professor Ludlam [Transcript, 01.12.20 p135-136]; 141; Dr Lowe [Transcript, 09.12.20 p74-75]

[156] Prior to the identification of hepatitis C, the terminology itself was also unclear reflecting both potentially infectious and non-infectious causes.

[157] Dr Lowe, [Transcript 09.12.20 p109-116] For example, Professor Lowe explained that at Glasgow Royal Infirmary the 1970s there were *"big signs on the wall saying "hepatitis" that nobody could miss."*

[158] Professor Ludlam explained that his predecessor Dr Davies asked patients to sign a consent form saying *"I understand that such materials may carry the risk of hepatitis."* However it did not say anything about the seriousness of the condition. [Transcript 01.12.20 p139]. As to his own practice subsequently, Professor Ludlam could not recall what he said to patients about the severity of the risk, but did recall advising them to moderate alcohol intake to avoid exacerbating damage to the liver. Professor Ludlam, [Transcript, 01.12.20 p142 – 143]

[159] Professor Ludlam [Transcript, 01.12.20 p141-142]. However it was not necessarily clear to what extent patients were given information about the seriousness of hepatitis or the possibility of chronic liver disease

[160] Professor Ludlam gave evidence that reminding patients of the risks of viral infection was part of his "*routine arrangement"* where Hepatitis B and liver function tests with significant abnormalities were discussed. [Professor Ludlam rule 9 Statement [para 212a]] Such would appear to be an example of good practice, provided of course that there had also been an appropriate discussion of the risks prior to treatment commencing.

may already have materialised.[161] It appears that practice in this regard may have been variable. On the other hand, for example, at Yorkhill Hospital Professor Hann made it his policy to meet families of previously untreated patients with Dr Pettigrew and Sister Murphy, explain the nature of the treatments and the risks, and to advise that in the first instance they would be given cryoprecipitate. Parents were also given relevant literature to take home.[162]

96. Sixthly, on some occasions doctors proceeded on the basis of an assumption, which may have been incorrect, that patients had previously been advised of risks of treatment by their previous clinician.[163]

97. Seventhly, the question of whether or not a patient would in any event have elected to consent to treatment if properly advised of the risks and benefits is irrelevant to the question of whether there was a duty to provide such advice in the first place. The decision to give or withhold consent to treatment was for the patient to make.

Consent to Treatment: HIV & AIDS

98. In relation to developing knowledge of the risk of AIDS, the Boards have submitted *inter alia* that: 1. in January 1983 it was widely recognised that AIDS was probably transmitted by blood and blood products; 2. the risk to patients in Scotland arising from AIDS was extremely difficult for clinicians to gauge prospectively; 3. NHS organisations and their clinicians were hampered by a lack of accurate and timely information on the scale of the epidemic and other matters relevant to their assessment of the nature of the risk to patients; 4. assessment of the level of risk to

[161] Professor Ludlam explained that all patients regularly receiving NHS concentrates understood that they had acquired hepatitis from concentrate (The Minutes of a UKHCDO Hepatitis Working Party from September 1983 stated that the Fletcher study had shown there was a 100% chance of contracting NANB hepatitis whether the product came from NHS Factor 8 or commercial sources.) Professor Ludlam, [Transcript 01.12.20 p151 – 153] [HCDO0000270_031]

[162] Prof Hann, [Transcript 08.12.20 p43 – 44]

[163] Professor Hann [Transcript 08.12.20 p52 – 53; p59] *"…it was information that I hoped and assumed, incorrectly, had been transmitted over the years… prior to my coming there. I did not spend enough time, having made that assumption, reinforcing information with the legacy patients…I made an assumption that knowledge was better than it was, that information had been provided that hadn't been provided.";* see also Professor Ludlam [Transcript 01.12.20 pp145-146]

haemophiliacs from AIDS was also affected by an incomplete understanding of the disease, including the relationship between HIV and AIDS, the natural history of the disease, its symptoms and true pathogenesis; 5. at that time clinicians in Scotland realised that Scottish haemophilia patients were potentially at risk of developing AIDS as a result of their treatment with blood products; 6. Professor Forbes and Professor Ludlam took early and proactive steps to investigate the risk by commencing studies at their respective centres to monitor immune abnormalities in haemophilia patients; and 7. the level of risk to patients from AIDS was generally assessed as low, assuming an infective aetiology.

99. If the Boards' submissions were to be reflected in the Inquiry's findings, either in full or in relevant part, a question would arise as to whether - and if so when - haemophilia patients ought first to have been warned of a possible risk of AIDS, to the extent that it was then known. Standing our submission that clinicians in Scotland came to realise by 1983 that Scottish haemophilia patients were potentially at risk of developing AIDS as a result of their treatment with blood products, an application of the relevant principles leads us to the conclusion that patients were entitled to be so advised from that date onwards.

100. In this regard, the Boards would respectfully disagree with any suggestion that the level of the risk was by then still too uncertain, or reasonably assumed to be so low, that patients should not be warned[164]. While these matters would undoubtedly have had a strong bearing on the content of any advice, what *was* known about the severity of ensuing symptoms and high mortality rate was sufficient to require disclosure to patients. In his evidence Professor Ludlam appeared to accept, in retrospect, that the risks of AIDS should have been explained to the patients.[165]

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[164] Professor Ludlam stated: *"It comes down to a matter of what is the level of risk. It's always been accepted that clotting factor concentrates may transmit viruses and other infective agents and there's a question as to what level it's appropriate and to whom to make that risk known."* [Transcript 02.12.20 p62]

[165] Professor Ludlam said that *"Looked at in retrospect and hearing what the patients are now saying and if we had received the Council of Europe Document, then maybe we should have explained this to patients."* [Transcript 02.12.290 p67] While it may be regarded as most regrettable that the Council of Europe recommendations were not more widely circulated throughout the medical profession, it is arguable that there was still sufficient information available from other sources to enable clinicians to warn patients of the possible risk of AIDS to haemophiliacs from factor concentrates. (See also: [Transcript 03.12.20 p72-73]) For completeness, Professor Ludlam's position was that he would have answered any questions raised by patients,

101. In light of the position adopted above, the Boards submit as follows:-.

102. Firstly, informing patients about the risk of AIDS prior to 1984 was an exceptionally difficult task for clinicians standing the rapid pace of developments and the high levels of confusion and uncertainty which prevailed at that time.

103. Secondly, the Inquiry has heard extensive evidence as to the confusion and uncertainty which prevailed in relation to AIDS in the early 1980s, which was exacerbated by the *"welter of unhelpful information in the media"* during this period, as described by Professor Hann. [166] In the Boards' submission, this state of affairs only served to underscore the importance of clinicians giving patients whatever relevant information they reasonably could about the emerging risks from the disease. In a similar vein, the dangers inherent in any assumption on the part of doctors that patients had become aware of the risks from other potential sources of information can also be clearly appreciated.[167]

104. Thirdly, during 1983 and 1984 many patients with bleeding disorders were given no information about the risk of AIDS unless they raised the issue themselves.[168] Agreeing with the evidence of Professor Ian Hann and Dr Anna Pettigrew, the Boards

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albeit he did not proactively raise the subject himself. [Transcript 02.12.2020 p59] Patients were also provided with literature containing information about AIDS published by the Haemophilia Society [PRSE0004704] [Transcript 02.12.2020 p59-62]]

[166] Professor Hann, [Transcript 08.12.20 p78] The evidence given by Professor Hann illustrated the limits of what *could* be said to patients and the difficulties in formulating good advice in the circumstances.

[167] Professor Ludlam said that one of the things he had learned over the years was the importance of not making assumptions, and to check out more carefully what a patient understands. [Transcript 04.12.20 p153-154.]

[168] Professor Ludlam candidly accepted that in 1983 and 1984 he took no proactive steps to advise patients of the risk of AIDS from factor concentrates unless they raised the issue themselves. [Transcript, 02.12.20 p59-60] However, we note that Dr Robert Carr, Senior Registrar in Haematology at Edinburgh Royal Infirmary, gave written evidence that: *"This 'expert' patient group were very aware and increasingly well informed about the developing 'AIDS' epidemic in the United States. They received information from the haemophilia society and it was discussed during their hospital visits. Discussion with patients about AIDS was part and parcel of their holistic care during this period. It was driven not by protocol but by good clinical practice."* [Rule 9 statement Q 67, p23] [WITN4677001_0022] In his evidence Professsor Ludlam confirmed that patients were also provided with literature containing information about AIDS published by the Haemophilia Society [PRSE0004704] [Transcript 02.12.2020 p59-62]]

consider that it would have been better if there had been a policy in all units to proactively inform patients of the risk of AIDS.[169]

105. Fourthly, the fact that not all patients were given information on the risks of AIDS may be seen to be anomalous in circumstances where, by June 1983 the Scottish Blood Transfusion Service was publishing leaflets warning donors in Edinburgh (not themselves at risk) that AIDS could *"almost certainly"* be transmitted by blood products.

106. Fifthly, such information would have been a necessary prerequisite to enable the patient to make an informed decision about whether to commence or continue with treatment.

107. Sixthly, such advice as was given to patients in relation to AIDS on occasion reflected an attitude of paternalism. To take one self-evident example, an advice sheet prepared for patients in Edinburgh and Glasgow said: *"remember that you must continue to treat yourself with the concentrates as the risks are much greater of bleeding than of contracting the rare disease of AIDS."*[170]

108. Seventhly, and on the other hand, there were clinicians who actively strove to avoid being regarded as *"the almighty doctor coming in and pontificating."*[171] From that perspective, keeping patients informed was a "process" which continued beyond the discussion that took place at the commencement of treatment. To that end, for example, Professor Hann set up parent groups, employed a social worker and set up

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[169] As Dr Pettigrew explained that while they didn't proactively advise patients or their parents about the risk of AIDS, most patients did discuss it as it was at the forefront of their minds at that time. She accepted it would have been better to have a policy of informing patients: *"It was a difficult and confusing time. Looking back we could have done it better."* Dr Pettigrew [Transcript,07.12.20 p63-64; p66; 100 -101] Professor Hann said "*It was a very difficult decision which we did not get…entirely right with regard to the process…as to how…best to contact people, how to see them, how best to get through to them all of the information we had."* [Transcript, 08.12.20 p81]

[170] *Advice sheet for adult patients and families, Acquired Immune Deficiency syndrome (AIDS)*The Glasgow version of the letter was changed from "*you must"* to *"you should"* [Professor Lowe Transcript 10.12.20 p46-47] PRSE0002785

[171] Professor Hann [Transcript 08.12.20 p79]

a clinic with an 'open door policy' and sought to promote an ethos of transparency and honesty at Yorkhill Hospital.[172]

109. Eighthly, it appears that many patients may not have been counselled in relation to alternative or variant treatments to concentrate therapy, such as cryoprecipitate. For example, it appears that prior to Professor Hann's arrival at Yorkhill, parents were not given any choice of alternatives to commercial concentrate, such as SNBTS concentrate or cryoprecipitate. Whereas there is evidence indicating that some patients may have expressed preference for commercial concentrates due to convenience factors, that clearly has to be considered in the context where they had not been advised of the risks in the first place.[173] Desmopressin (DDAVP), tranexamic acid or cryoprecipitate was offered in some hospitals to patients in certain defined circumstances, such as patients with mild haemophilia A, previously untreated patients and children[174] However, it is not apparent that other patients identified for treatment with factor concentrates were necessarily advised of the existence of any alternative treatment.[175] Some possible reasons for this are discussed below at Chapter 5.

Findings & Conclusions: Testing for Infections

110. It is submitted that, looked at overall, the evidence indicates that seeking patients' consent for testing for viruses may not have been universally regarded as a prerequisite by doctors during the 1970s and 1980s, albeit there may have been

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[172] Dr Pettigrew explained: *"…we operated a very open policy where we would try and be honest and open with parents and that open policy also operated from the point of view of the parents being free -- feeling free and able to call in and discuss, with particularly Sister Murphy and myself, anything that we were concerned about. So I think that over the period end of '83 and throughout '84 we would have had numerous discussions I'm sure with the majority of patients -- parents of patients with haemophilia who were on treatment, particularly home treatment, about AIDS and about our state of knowledge at the time."* Dr Pettigrew, Transcript [07.12.20 p61-64] See also: Professor Hann [Transcript 08.12.20 p80 – 81]

[173] Dr Pettigrew [Transcript, 07.12.20 p43]

[174] Professor Ludlam [Transcript 01.12.20 p74; 97-99; 154] Professor Lowe gave evidence to similar effect, that at Glasgow Royal Infirmary the policy under Directors McDonald, Prentice and Forbes for patients with mild haemophilia A (or mild von Willebrand disease) was to use cryoprecipitate, tranexamic acid (from 1972) or desmopressin (from 1978).

[175] Professor Ludlam [Transcript, 02.12.20 p 40]

significant variation in practice in this regard.[176] It also appears that in Scotland there was, initially, relatively little by way of formal guidance issued to doctors.[177] In January 1986, the WHO published *'Guidelines on AIDS in Europe'* which stated that the testing of heathy individuals for HTLV-III should only be done after informed consent had been obtained and that patients who tested positive should be provided with individual counselling and psychological support.[178] However, it appears that the issue remained a source of controversy within the medical profession until at least 1987.[179] Viewed from today's perspective that may appear surprising, considering the modern view that, in general, it is not ethical to test a person with capacity without their consent. [180]

111. In 1984, Professor Ludlam sent stored blood samples from Edinburgh Royal Infirmary to Dr Tedder for HIV testing without telling the patients and without their consent. Professor Ludlam explained that *"At that stage, it didn't seem a particular issue."*[181] Professor Lowe explained that at Glasgow the initial HIV tests were sent to Dr Gallo in the US by Dr Forbes without patient consent in 1984, but thereafter testing continued on an ongoing basis post-April 1985 with patients being informed as to what was going on.[182]

112. Later, the first generation Hepatitis C tests were carried out in 1990 using stored samples in Edinburgh, but Professor Ludlam thought he had written to his patients to explain what he was doing.[183] However the second generation tests were carried out in stored samples without patients' knowledge and consent and they only found out

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[176] As previously noted, the GMC guidance for testing was not published until 1988.

[177] The first such specific guidance narrated in Counsel to the Inquiry's presentation was a booklet from the Department of Health and Social Security addressed to 'All Doctors in England' entitled *'Information for Doctors Concerning the Introduction of the HTLV III Antibody Test'* which stressed the need for pre and post-test counselling for patients being tested for HIV (para 148)

[178] Ibid, Para 150

[179] Ibid, para 158 *"In July 1987 the BMA annual representatives passed a motion 'Testing for AIDS' which confirmed 'that testing for HIV antibodies should be at the discretion of the patient's doctor and should not necessarily require the consent of the patient."* See also the GMC guidance published in 1988.

[180] *Expert Report to the Infected Blood Inquiry: Medical Ethics* p63 citing the GMC Guidance on Consent published 2008.

[181] Professor Ludlam, [Transcript 02.12.20 pp67-68;03.12.20 p40]

[182] Professor Lowe [Transcript, 10.12.20 pp59-61]

[183] Professor Ludlam [Transcript 04.12.20 p51]

when told the result.[184] Professor Lowe explained that he was of the view that specific consent should be obtained for Hepatitis C testing[185] and that he did indeed seek informed consent from patients in his own practice prior to conducting the tests.[186]

113. Professor Hann accepted that the pre-test counselling at Yorkhill could have been better, although patients may have known that tests were going to be conducted in advance[187] Professor Hann explained that with better counselling, *"it would probably have come as less of a shock to the families because they would have been better informed about the potential outcomes….it really is a difficult situation, telling people about potentially terrible news when actually it might well not be relevant…the fact is…they would have been better informed, they would have been stimulated…to ask more questions and to be better informed."*[188] It is submitted that Professor Hann's evidence encapsulated in a nutshell both the inherent difficulty with, and necessity of, well-conducted pre-test counselling.

Findings & Conclusions: Consent to Research

114. The Declaration of Helsinki, first promulgated by the World Medical Association in 1964, stated *"consent must always be obtained from the individual subjects."* That has always been, and remains today, the fundamental principle governing clinical research. [189]

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[184] Professor Ludlam, [Transcript, 04.12.20 p53]

[185] The minutes of the meeting of the AIDS Group of Haemophilia Centre Directors on 12 February 1990 narrate that *"Dr Lowe thought there was a difference between testing LFTs and testing for Hepatitis C and he wondered whether the patient's consent to testing should be sought."* Professor Lowe pointed out he did raise this but did so because some people thought it was just another liver function test, but he was of the view it was more like a Hep B test and consent ought to be obtained Professor Lowe [Transcript 11.12.2020 p4]

[186] Professor Lowe [Transcript 11.12.2020 p11 - 12]

[187] Prof Hann, Transcript [Transcript, 08.12.20 p84; 155-156]

[188] Professor Hann, Transcript [Transcript, 08.12.20 p20; 155 -156]

[189] See Professor Ludlam [Transcript 04.12.20 p64] The rationale, as explained by the medical ethics experts: *"As with any consent, people need to know what the alternatives are to participation and what the risks and benefits of participation and non-participation are and what their probabilities are. So they need to be able to understand what will happen to them or what is likely to happen to them or what could happen to them, both*

115. However, those engaged in the vital work of clinical research during the 1980s did not have the benefit of today's formalised research governance framework.[190] The evidence led at the Inquiry illustrated some of the particular difficulties that may have arisen in identifying the distinction between *'research'* as distinct from *'audit'* or *'service evaluation'* and patient monitoring. As Professor Cave explained in evidence: *"I think the underlying point here is that the definition of research isn't uncontested. There's a grey area[191] between research and audit, between research and compassionate care, between research and compassionate use….there was this grey area between research and medical care that was potentially exacerbated by previous versions of Helsinki[192] and other guidelines. We have moved to a view now that where the aim is in part a research aim[193] that the patient should be aware of that fact and that really wasn't so clear in the guidance previously."*[194] The Inquiry may find this general observation to be of relevance to its assessment of the evidence in this area.

116. There is one other matter which the Boards require to specifically address. Particular concerns have been highlighted during evidence in relation to the "AIDS Study" carried out in Edinburgh by Professor Ludlam in 1983. The purpose of the study was to find out if lymphocyte (immune cells) abnormalities associated with the development of AIDS in healthy haemophiliac patients in the USA[195], were present in Edinburgh haemophiliacs. In his evidence Professor Ludlam maintained that the AIDS study fell within the definition of patient monitoring rather than research[196], whilst acknowledging that the findings were published in the Lancet in May 1983 and

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in terms of the risks and benefits, both of taking part and not taking part." Professor Savalescu, [Transcript 27.01.2021,p63-64]

[190] See ie: the concluding comments of Professor Robert Carr (r9 statement pp29-30)

[191] Professor Farsides said that there was a "fuzzy boundary" between research and service evaluation or audit. (p107))

[192] The 1975 version of the Helsinki Declaration said: *"In the field of biochemical research a fundamental distinction must be recognised 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."*

[193] Professor Savelscu offered the following rule of thumb: *"In general if you're thinking of publishing the results, it's usually considered to be research"* [Transcript, 27.01.2021 p119]

[194] Professor Cave [Transcript 27.01.2021 p110]

[195] Professor Ludlam, [Transcript 04.12.2020 p74-76]; Dr Robert Carr, rule 9 statement para 64,

[196] Professor Ludlam said: *"it was monitoring the patients because abnormalities had been shown in other patients with haemophilia that might be of significance, and I felt it was my obligation to conduct similar investigations on our patients."* [Transcript 04.12.20 p78]

June 1984[197]. Dr Robert Carr, who was responsible for collecting many of the blood samples and ensuring delivery to the laboratories, explained that he was given informed consent by patients prior to taking the blood samples.[198] As Dr Carr explained in his statement, the fact that he was using the word "AIDS", in large letters, to label the blood samples in the presence pf the patients, was evidence of the openness about why they were being taken.[199] It was also the case, however, that patients were not informed of the results.[200]

117. A number of patients treated by Professor Ludlam and involved in the AIDS study at Edinburgh (or their relatives) have raised concerns or expressed the belief that they were deliberately infected for the purpose of research.[201] In his evidence, Professor Ludlam said that he understood how the shortcut of writing "AIDS study" on a form might have been misinterpreted when subsequently seen by the patient. He expressed regret that, in part due to the way in which the GMC complaints procedure formerly operated, he had no opportunity to respond directly to a patient's "*very legitimate anxiety about what the AIDS Study was.*"[202]

118. The Boards consider it is important to emphasise that such grave allegations are entirely without objective evidential basis. Given that these allegations have been publicly ventilated during the Inquiry's oral hearings, it would be appropriate for the Inquiry to address the matter definitively.

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[197] Disordered immune regulation in haemophiliacs not exposed to VIII. Ludlam CA, Carr R, Veitch SE. Lancet May 23, 1983, p1226; Abnormalities of circulating lymphocyte subsets in haemophiliacs in an AIDS-free population. Carr R, Edmond E, Prescot RJ, Veitch SE, Peutherer JF, Steel CM. Lancet June 30, 1984, pp1431-1434

[198] Dr Carr explained that "*My practice was to write these forms (the AIDS Study' request form when with the patient, while explaining to them what the blood was used for, ie this specific investigation relating to AIDS and immunity. The label 'AIDS' was a shorthand for identifying the samples as needing specific processing when they reached the laboratory, invariably delivered by myself. The fact that I was using AIDS, in large letters, to label the blood samples is evidence of the openness about why they were being taken. Taking the blood samples myself, which could only be done with their consent, together with the explicit form, provided the opportunity for me to discuss the study with the patients and answer any questions they might have had.*" [Rule 9 statement, para 68]; see also Professor Ludlam [Transcript 04.12.2020 p80 -91] Professor Ludlam thought he "would have explained what we were doing" when he saw patients himself, but could not recall the detail.

[199] Ibid

[200] Professor Ludlam [Transcript 04.12.20 p77]

[201] See ie: [Transcript 04.07.2019, p43]

[202] Professor Ludlam [Transcript 04.12.2020, p96-99]

CHAPTER 5: RESPONSE TO RISKS OF VIRAL INFECTIONS

INTRODUCTION

119. This chapter of the submission considers certain aspects of the response to emerging viral risks by the NHS in Scotland more generally, and haemophilia clinicians in particular. This is an area in which the Inquiry's investigations have produced a substantial body of evidence across a wide range of different matters. This submission focusses on specific issues and themes arising from the evidence which are of particular concern or importance from the Boards' perspective, relating to policy and practice in the treatment of haemophilia and other bleeding disorders.

120. In this regard, the Boards submit as follows:-

FINDINGS AND CONCLUSIONS

Rationale for treatment of haemophilia with blood products

121. Questions arise for determination by the Inquiry in this area raising complex and difficult issues. The oral hearings have given extensive consideration to whether the response of the medical professions and individual clinicians reflected appropriate judgments and attitudes to the risks faced by patients. *Inter alia*, the application of the precautionary principle is clearly engaged as part of this discussion. Indeed, during the hearings this has been relied upon as a reference point for the Inquiry's analysis of what was done, or not done, at various times in response to the emerging viral risks.

122. As the evidence of the Medical Ethics Expert Group made clear, however, the application of the precautionary principle in the present context is not straightforward.[203] Whereas there may be situations in which adopting a particular

[203] The explanation given by Professor Kerridge on this topic bears repeating: *"So… (the precautionary principle…is an ethical principle. It's also an organisational principle in public health and epidemiology, which is where it has its genesis really. It's not a straightforward one and there's at least, sort of, seven formulations of the precautionary principle that I know. So it's the idea that if there's an identifiable risk, then we should take*

precaution in response to a risk is self-evidently the appropriate course of action, the choices facing clinicians in the present context were not always so straightforward. While the use of blood products as treatment was in itself done as a precaution to avoid the identifiable risks of haemophilia, the taking of such a precaution plainly brought risks of its own. As Professor Cash colourfully put it in his evidence to Penrose, this was a time when there were no therapeutic roses without thorns.[204] Accordingly, clinicians involved in haemophilia care found themselves constantly on the horns of a principled and practical dilemma, the nature of which evolved dynamically as knowledge of emerging viral risks emerged, as we discuss at Chapters 2 & 3 above. Applying another fundamental and related principle of medical ethics, that the best interests of the patients will be paramount, one could say, might require the exercise of invidious judgments in doctors' day to day practice.[205]

123. Many of these judgments involved the balancing of risks, made more difficult by the fact that not all of the risks were well understood. If the primary focus of questions during the clinicians' evidence may naturally have been upon the risks of the viral infections from blood products, it is plainly no less important to consider the extremely grave risks arising to patients arising from the conditions they were designed to treat. Such consideration is, of course, essential in arriving at a more informed understanding of why such treatments were introduced in the first place, and then persisted with as time went on. In our submission, the evidence shows overwhelmingly that the overriding motivation for clinicians in using blood products

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steps to avoid that risk, and if there's a risk of an adverse event happening in the future that we can take steps to avoid it. The problem there is that there might be questions about how foreseeable that risk is, how significant the risk is, what strategies are available to reduce that risk, and what's the cost of those strategies? So what we lose by introducing those strategies. So there may be a risk that's, you know, 1 in 3 million, 1 in 13 million, 1 in 15 million, 1 in 20 million of an infection related to the blood supply. We could get around that risk by, you know, expelling one half of potential blood donors or by introducing a new test looking for a particular infectious marker, and so forth. By doing those strategies, they may be affordable but, equally, they may bankrupt a health sector, it may strip a blood supply of its capacity to rescue people in dire circumstances. So there will have to be value assessments made about the risk, about its significance, its prevalence, its salience, about what can be done to avoid it, about what should be done to avoid it and about what is lost by taking steps to avoid that. There's been a range of examples relevant to this Inquiry, and subsequent to the HIV epidemic and the infection of people with hepatitis C and hepatitis B from blood, that have raised questions about the precautionary principles." [Transcript 26.02.2021 p91]

[204] Penrose Report para 21.124

[205] The "best interest" principle was discussed by the Medical Ethics Expert Group in their evidence. [Transcript, 26.01.2021, p140]

generally, and factor concentrates in particular, in treatment of bleeding disorders was a desire to ameliorate the worst ravages of the disease and improve the otherwise bleak quality of life and prognosis for patients.

124. As Professor Ludlam explained in evidence[206], in the 1970s and 1980s severe haemophilia was *"a dreadful condition."* It gave rise to *"great uncertainties in the patients' lives"* and *"the disability was huge."* Prior to advances in treatment with blood products, haemophilia was associated with high mortality. Patients' life expectancy was very significantly reduced.[207] Moreover, a retrospective study by Forbes & Prentice in Glasgow, published in 1976, indicated significantly that use of cryoprecipitate prior to 1974 had not reduced the high premature mortality in UK haemophiliacs, when intracranial haemorrhage remained the most common cause of death.[208] This was confirmed by a number of studies in the USA and UK.[209]

125. Without appropriate and effective treatment by blood products, the morbidity and disability caused by joint bleeds was also such as to cause a profound impact on

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[206] Whereas advances in prophylactic therapy have meant that since the 1990s children have grown up virtually free of bleeds, this was not the case previously. In this regard, Professor Ludlam's observation that *"I think the history of what haemophilia was like in the '70-s and '80s is almost lost – personal experience of what it was like in those days"* may have some force. Professor Ludlam, [Transcript 01.12.2020, p25]

[207] A Swedish study published in 1962 reported that between 1943 and 1957 the mean age at death of people in Sweden with severe haemophilia was 20 years: Ramgren,O.'(1962): *Haemophilia in Sweden.V.Medico-social aspects*. Acta Medica Scandinavica, 171: Suppl. 379, 37. As Professor Charles Hay explained in evidence: *"the introduction of cryo improved life expectancy enormously, because in the pre-treatment era, it was 10-15 years, and it increased to about 40. Actuarial methods published by Charlie Rizza et al suggested we'd nearly normalised life expectancy"* (following the establishment of concentrate treatment) [Transcript 04.11.2020, p61]. See also FN228 below.

[208] Forbes CD, Prentice CRM. Mortality in haemophilia – a United Kingdom survey. In: Fratantoni JC and Aronson DL, Eds. Unsolved Therapeutic Problems in Haemophilia. Washington D.C: U.S. Department of Health, education, and Welfare, 1976, pp 15-22. See also: Professor Lowe Rule 9 Statement, para 8.5.2.8 together with the papers referred to in footnotes 18 – 20; and Professor Hann [Transcript 9.12.20, p28]

[209] See ie:

Lewis JH, Spero JA, Hastra U. *Deaths in hemophiliacs*. In: Fratantoni JC, Aronson DL, eds. Unsolved therapeutic problems in hemophilia. Washington, USA: US Department of Health, Education and Welfare, 1976, 29-33 RLIT0000364

Aledort LM. The cause of death in haemophiliacs. In: Fratantoni JC, Aronson DL, eds. *Unsolved therapeutic problems in hemophilia*. Washington, USA: US Department of Health, Education and Welfare, 1976, 9-14. RLIT0000365

Biggs R. *Haemophilia treatment in the United Kingdom from 1969 to 1974*. Br J Haematol. 1977; 35 (): 487-504.DHSC0000303

Rizza CR, Spooner RJD. *Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80: report on behalf of the directors of haemophilia centres in the United Kingdom*. Br Med J. 1983; 286(): 929-933. CBLA0001687

patients' health and quality of life. Such bleeds could be extremely painful, lasting for up to ten days if untreated and requiring opiates for relief[210] and involving lengthy hospital visits.[211] Professor Ludlam explained that bleeds into muscles and joints led to the destruction of tissue such that patients became very disabled, causing severe restrictions in mobility and overall functional capacity.[212] The Inquiry has before it a substantial body of evidence demonstrating the tragic consequences of undertreated haemophilia, both in terms of radically diminished quality of life and premature death in patients.

126. These were the very significant harmful outcomes which treatment with blood products was designed to forestall. Viewed from today's perspective, it might be considered highly anomalous that a form of therapeutic treatment should be given to patients which was universally infective for a virus such as NANB hepatitis.[213] However, clinicians during that period faced the difficulty that there was no alternative treatment for severe haemophilia that was free from such risks, prior to the development of heat treatment techniques in the mid-1980s. Given the morbidity and mortality associated with the condition, any theoretical alternative of simply leaving haemophilia to go untreated was, in truth, no option at all for patients. Such was the invidious predicament in which both patients and their doctors found themselves during that time. If the forgoing observations amount to no more than a statement of the obvious, they nevertheless form an essential foundation for the Inquiry's deliberations about "what happened and why", with

[210] Professor Ludlam, [Transcript 01.12.2020, p26]

[211] "*Children needed to be at school, not coming up for treatment for bleeds.*" Professor Ludlam, [Transcript 01.12.2020, p42]

[212] Professor Ludlam explained that: *"an appreciable number of patients that I came to look after were very, very disabled. The knees would have perhaps five degrees/ tend degrees of movement. They would be bent and people would have to walk with bent knees. The calf muscles would have been destroyed from bleeds following fibrosis following bleeds…So these individuals ended up trying to walk on their toes with bent knees, and their arms were disabled because of bleeding into the elbows was common, led to the destruction of the elbow joint. That became an appreciable problem when patients couldn't get their hands to their mouths to feed themselves."* Professor Ludlam, [Transcript 01.12.2020, p26]

[213] However, it is recognised that management of other life-threatening conditions, such as childhood cancers, can also be associated with significant late effects in survivors, requiring the risks of such adverse effects to be balanced against the immediate advantages of treatment. See ie: Erdmann et al, *childhood cancer: Survival, treatment and modalities, late effects and improvements over time* Cancer Epidemiology, Volume 71, Part B, 2021.

regard to the infection of NHS patients with blood products given as treatment for bleeding disorders.

Haemophilia treatment policies prior to 1983

127. Before concentrates, cryoprecipitate was used in treatment of haemophilia A in Scotland, on an out-patient basis from the late 1960s.[214] By combining the cryoprecipitate from around 15 individual donations of plasma, it was possible to achieve an increase in factor 8 levels sufficient to stop haemorrhage. As Professor Ludlam explained in his witness statement, *"Cryoprecipitate transformed the treatment of patients with haemophilia A and allowed most bleeds (in non-inhibitor patients) to be treated effectively"*[215] It proved, to that extent, a viable treatment for the disease.

128. The development of factor concentrate treatment in the early-1970s gave rise to the opportunity for patients to be treated with a therapy that was far better suited than cryoprecipitate for administration at home. A major advantage of home treatment was that it could be given immediately upon occurrence of a bleed, without often lengthy and sometimes traumatic attendance at hospital.[216] In evidence, Dr Winter explained how the introduction of Factor 8 concentrates *"instantly and immediately revolutionised the quality of life for people with haemophilia"*[217] by normalising their

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[214] Penrose Inquiry Final Report, para 20.24

[215] Professor Ludlam rule 9 statement, para 100. See also paragraph 103 which sets out his view about the disadvantages of cryoprecipitate.

[216] In his evidence to Penrose Dr Winter explained *"…..it was a very harrowing experience. I have never, in all my years of haemophilia, ever heard a patient say, 'I went to casualty with a bleed and everything went well'. It never does, for pretty obvious reasons. These departments are very busy. The doctors know nothing about the condition, and haemophilia is rare. So not only was cryoprecipitate not a very good medical treatment, for the patients it was a pretty dreadful experience having to go to hospital to have the treatment. So that was why, when one spoke to patients or you went to residential Haemophilia Society weekends, there was a very strong, very strongly expressed view from the patients of, 'We want concentrate, not cryoprecipitate and we want it to be British concentrate, not American'* Penrose Inquiry Final Report, para 21.84

[217] Dr Mark Winter [Transcript 01.10.2020, p11-12; 39 – 40] Dr Winter spoke of how: *"There's this revolution. The patients are all saying to you, my life is totally, utterly changed. This is wonderful. We've always called this the golden interval, a little two-year gap, about 1974 to about 1976, where suddenly, after years of darkness, disability, pain, inability to work properly, have to go to a special boarding school, suddenly there's the land of milk and honey, home therapy concentrates, everything is wonderful, people are feeling really good, their joints are good, started to do sports again."*

ability to participate in the sort of every-day activities, which others would simply take for granted but which had previously been denied to them by their condition.

129. By contrast, the evidence indicates that cryoprecipitate was generally, though not universally,[218] considered to be unsuitable for home treatment. Amongst other disadvantages, cryoprecipitate was extremely difficult and laborious to reconstitute and required to be stored in a deep freeze. It was much less clinically effective than factor 8 concentrate, having less factor 8 in it than concentrate, notwithstanding the higher volume.[219] The actual number of units of factor 8 in each bag of cryoprecipitate was variable and it had bad immediate side-effects. In evidence Professor Ludlam explained that the main rationale for not using cryoprecipitate for home treatment was the risk of allergic reactions which were *"very common and unpleasant"*.[220] The variable dosage was also a problem: *"when you get cryoprecipitate, you really have very little idea of how much, exactly how much, Factor VIII there is in it"*[221] By contrast, using factor concentrates allowed for greater confidence that the necessary factor 8 levels would be achieved. Dr Mark Winter summarised the position thus: *"…whilst it was the first treatment ever, in 2000 years, for people with haemophilia, it undoubtedly saved lives, it was a very primitive…treatment…It was so unsophisticated in every regard compared with concentrate, which was everything cryo wasn't."*[222]

130. Moreover, the early research data (Rizza 1983) indicated that the introduction of concentrate therapy had led to an increase in median life expectancy to near normal levels. The study noted there had been a *"noticeable improvement in the management of haemophilia since factor VIIII became widely available and bleeding*

[218] As understood, cryoprecipitate was used for home treatment at a very few hospitals, including the Royal Free Hospital, Great Ormond Street Hospital and Birmingham Children's Hospital.
[219] Dr Mark Winter, rule 9 statement, para 35.4, [Transcript 01.10.2020, p86-101]
[220] Professor Ludlam [Transcript 1.12.2020, p74 - 75]
[221] Professor Ludlam explained that "*by the time the patient reached hospital…cryoprecipitate would usually stop the bleeding. One of the other problems…is you didn't actually know how much Factor VIII there was in the cryoprecipitate. The normal plasma levels of Factor VIII in the blood donors varies between 50% of normal and 150% of normal. So the amount of Factor VIII in the cryoprecipitate of each individual donation could vary that much, in other words, a threefold difference.*" Professor Ludlam [Transcript 1.12.2020, p76]
[222] Dr Mark Winter, [Transcript, 01.10.2020, p89]

to death from trivial injury – so common in the past – is now rarely seen."[223] It is likely that this reflected the greater efficacy of concentrate treatment and the considerable advantage conferred by home treatment in reducing potential delays in the administration of effective treatment.

131. The superior efficacy and ease of use of concentrates allied to the obvious benefits experienced by patients were factors which reasonably encouraged an increasing preference for such treatment, as an alternative to cryoprecipitate for patients in Scotland. For example, Professor Ludlam's predecessor at Edinburgh Royal Infirmary, Dr Howard Davies, had used cryoprecipitate as his treatment of choice for haemophilia A, apparently for reasons related to viral safety.[224] Upon taking up appointment in 1980, Professor Ludlam moved away from cryoprecipitate to a system based on PFC Factor 8 concentrates;[225] and brought about a substantial increase the number of patients on home treatment.[226] His rationale in doing so was simple: *"I moved away from cryoprecipitate because I wanted to give patients the benefit of treatment at home, because I thought that was very advantageous."*[227] However, Professor Ludlam continued Dr Davies' policy of preferring locally sourced

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[223] Rizza CR, Spooner RJD. *Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80: report on behalf of the directors of haemophilia centres in the United Kingdom*. Br Med J. 1983; 286(): 929-933. CBLA0001687
This study and the papers cited above (FN214) highlighted improvements in life expectancy with treatment developments over time. While the Aledort study of 1976 also showed premature deaths from bleeding (in particular intra-cranial haemorrhage) continuing into the early 1970s, it was not until the cohort studied by Rizza (1976 – 1980) that median life expectancy was seen to approach near normal levels, albeit these results were to be interpreted with caution due to the small numbers.

[224] According to Penrose, Dr Davies *"tended to avoid large pool concentrates preferring, where possible, to use cryoprecipitate in the belief that large pools of donations were more likely to contain transmissible viruses whatever their source."* Penrose Report Chapter 12.20. In evidence, however, Professor Ludlam said that he did not recall Dr Davies having reservations about the use of concentrates from large pools of donors. Professor Ludlam, [Transcript 01.12.2020 p69] Penrose also noted that the pattern of demonstrated use did not fit with Dr Davies having followed a policy of only using cryoprecipitate since significant amounts of PFC factor VIII were prescribed by Dr Davies (Penrose Final Report 21.271 to 21.272)

[225] As explained in evidence, Professor Ludlam agreed this was one of the reasons, if not the principal reason, for the 'strenuous efforts' in the part of SNBTS in the early 1980s to increase factor concentrate production requiring donor blood to be redirected from cryoprecipitate production to concentrate manufacture. [Written statement, paragraph 93 and [Transcript 01.12.2020, p78]

[226] This necessitated an increase in the purchase of commercial concentrates, albeit in large quantities only in 1981, and in relation to specific patients for specific reasons. Professor Ludlam [Transcript 1.12.2020, p70 - 71]

[227] Professor Ludlam [Transcript 01.12.2020 p69]

blood products, based on the belief that material derived from Scottish donors was safer.[228]

132. As noted above, the propensity for blood and blood products to transmit hepatitis was known even since prior to the introduction of cryoprecipitate as a therapeutic in haemophilia. It was well recognised by most haemophilia directors in Scotland that treatment with blood products carried risks from viruses, and required a discriminating approach to prescription. For example, Professor Ludlam's general approach for patients with mild haemophilia was to avoid using blood products "*as much as possible.*" If DDAVP was suitable that would be used, which failing cryoprecipitate or concentrates, the latter being reserved for severe bleeding episodes or major surgery in order to have confidence in achieving high enough factor 8 levels.[229] However, it also the case that the home treatment policy was judged to be appropriate for some patients with mild haemophilia, as well as those in the moderate and severe categories.[230] Treatment for patients with moderate haemophilia included hospital treatment with cryoprecipitate but also home treatment with concentrate.[231] Professor Ludlam used cryoprecipitate when patients attended at hospital in order to preserve scarce supplies of concentrate for home treatment in the early 1980s.[232] This may suggest that for many patients it would be regarded as a viable form of treatment in principle, even if reasonably considered greatly inferior to concentrate treatment in a number of important respects.

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[228] As Penrose narrates: *"Professor Ludlam's predecessor as director of the Edinburgh Haemophilia Centre Dr Howard Davies made almost exclusive use of locally-produced therapeutic materials. Professor Ludlam stated that Dr Davies avoided the use of imported materials as a matter of policy, believing those derived from Scottish donors would be safer. Dr Davies' argument in preference of locally sourced materials, centred on the risks associated with hepatitis viruses but appears to have had a more general basis: both Professor Ludlam and Dr McClelland stated that Dr Davies was reluctant to potentially introduce novel viruses to the local population."* [Penrose report para 12.20; Professor Ludlam Transcript 1.12.2020, p67]

[229] Professor Ludlam [Transcript 1.12.2020, p97-99; 154]

[230] Professor Ludlam said: *"..I think, latterly, we might have had some mild patients but mild patients don't bleed very often. When they bleed they may bleed very badly but because people with mild haemophilia don't bleed very often, the patients are not well practiced at injecting themselves or making up the treatment. So, on the whole, patients with mild haemophilia aren't usually on home therapy."* Professor Ludlam [Transcript 1.12.2020, p76]

[231] Professor Ludlam [Transcript 1.12.2020, p97]

[232] Professor Ludlam said *"one of the ways in which we eke at (sic) the PFC allocation was if patients were in hospital we would treat them with cryoprecipitate, if they didn't react too badly or didn't get reactions at all."* Professor Ludlam, [Transcript, 01.12.20 pp78- 82] See also the letter from Dr Boulton to Professor Ludlam urging greater use of cryoprecipitate to alleviate the pressure on PFC's stocks of concentrates caused by the home therapy programme [PRSE0003044]

133. Prior to the emergence of AIDS in the latter half of 1982, hepatitis was understood to constitute the main viral risk from factor concentrates. As discussed above, avoiding blood products where possible, and where appropriate using SNBTS cryoprecipitate or concentrate, were identified as ways to minimise the risks. In that regard, NHS concentrates were widely regarded as safer than their commercial equivalents. Unfortunately, it became apparent that SNBTS factor concentrate and commercially produced imported concentrates were both universally infective for NANB hepatitis,[233] in the sense that 100% of patients were exposed to the virus upon first treatment with either.[234] Unlike large pool concentrates, each cryoprecipitate treatment did not involve exposure to several thousand individual blood donations. As such, it was unlikely to be infective upon first or occasional exposure. In that respect, cryoprecipitate carried a lower risk than concentrates. However, it was understood that in the longer term, frequent treatment with cryoprecipitate was also ultimately likely to result in infection with NANB hepatitis based on the prevalence of the disease within the donor population.[235]

134. Accordingly, it seems likely that any policy of large-scale cessation of concentrate treatment in favour of cryoprecipitate would ultimately have been largely futile as a measure to achieve any significant reduction in the incidence of NANB hepatitis in

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[233] Fletcher ML et al *Non-A, Non-B hepatitis after transfusion of factor VIII concentrate in infrequently treated patients* Br Med J 1983;287:1754-57

[234] As Professor Lowe explained, *"I think the literature looking back over the late '70s, up until about 1985 was, yes, there's a problem. Is it all due to commercial concentrate? No. if commercial concentrate never been used and it was NHS concentrate, would the problem still be of the same size? Yes. You could go further back and say, if concentrate was never invented and we'd carried on treating patients with plasma or cryoprecipitate, the result would have been the same."* Professor Lowe[[Transcript 09.12.2020 p86-87]

[235] Professor Lowe explained that "*very sadly, this goes back to that 1964 Scottish Home & Health Department message saying 1 in 200 people has a virus that will give you jaundice and, no matter what you get, plasma, cryoprecipitate, concentrate, NHS or commercial, you are going to get it at some time. So what decision do you make in 1980 about changing the treatment for the majority of patients who have got it because, by this time, we know from the studies, such as the Royal Free, that just about everybody, regardless of their treatment, has abnormal liver function tests.*" Professor Lowe, [Transcript 09.12.2020 p87-88] Scottish Hospital Memorandum No. 89/1964. [PRSE0000157] We note the memorandum contained the following instruction: "No transfusion should be undertaken unless the benefits outweigh the risk of hepatitis." (para 11) On the significant risk of hepatitis from pooled cryoprecipitate treatment see: Thomas HC, Bamber M, Kernoff PBA. *Clinical, immunological and histological aspects of non-A, non-B hepatitis in haemophiliacs. In: Forbes CD, Lowe GDO, eds. Unresolved problems in haemophilia. Lancaster: MTP Press 1982, 27-38.*

patients requiring regular treatment.[236]Professor Lowe explained that: *"I think, in terms of practical management, the dilemma for treaters is, yes, we know there's a problem but what's the alternative?"*[237]

135. For that reason, until heat-treated concentrates became available in the mid-1980s, exposure to NANB hepatitis was an inevitable consequence of regular treatment with pooled blood products. It is submitted that this state of affairs provides extremely important context for the Inquiry's consideration of questions relating to whether continuing reliance on concentrate treatment was justified, as at the various points in time. Moreover, as we submit elsewhere, prior to 1985 NANB hepatitis was commonly understood by doctors to be a benign or mild condition or, in any event, that the long-term prognosis of the disease was considerably uncertain. On the other hand, the benefits of concentrate treatment were immediate and tangible, both in terms of reducing the risks to health from haemophilia and enabling improvements patients' quality of life.

136. For the reasons explained by Professor Lowe in evidence, the benefits of factor concentrate at that time appeared to weigh in favour of continuing treatment: *"The question is clearly what should haemophilia treaters have done because this evidence is now emerging when most patients with severe haemophilia A have stayed alive, because mortality is now approaching that of a non-haemophiliac, unlike in the era of cryoprecipitate and plasma when half of patients died before they were 40".*[238] In addition, by this time the psychosocial benefits of concentrate treatment had

[236] An analysis carried out by SNBTS for the Penrose Inquiry based upon typical annual consumption of cryoprecipitate by patients with Haemophilia A in the South East of Scotland in 1974 (500 IU factor VIII/kg body weight/year), found that the probability of exposure to infection would have been 60% after 1 year of treatment and 85% after 2 years of treatment (assuming an incidence of 0.3% in the donor population); or 27% after 1 year; 46% at 2 years and 95% at 10 years (assuming a lower incidence of 0.1%) The assumed level of treatment did not encompass home therapy, nor did it include major reconstructive surgery, nor other elective or general surgical procedures, nor treatment of inhibitors with large amounts of Factor VIII [WITN6666007]

[237] Professor Lowe qualified this by saying that *"if you have mild patients try and get away for as long as you can with cryoprecipitate or plasma for the haemophilia B patients because, hopefully, it's only a matter of time before you can get viral inactivation of concentrates."* Professor Lowe, [Transcript 09.12.2020 p87-88]

[238] Professor Lowe, [Transcript 09.12.2020 p89]

become apparent: "*it was a life changing treatment and only concentrates could do that.*"[239]

137. While the treatment of mildly affected and previously untreated patients raises discrete issues, in the Boards' submission, there were reasonable grounds for clinicians' overall preference for factor concentrates over cryoprecipitate as treatment for patients requiring frequent treatment to combat bleeds. Against that background, on the basis of the evidence available in the early 1980s, it would have been reasonable to conclude that risks involved in cessation of concentrate treatment, including premature death, would not have been justified.[240] In other words, for clinicians to continue to prescribe factor concentrates was generally justified on the balance of risks, as then understood, and upon an appropriate application of the precautionary principle as described above.[241]

Royal Hospital for Sick Children at Yorkhill

138. The circumstances in which children received treatment, and acquired infections, at the Royal Hospital for Sick Children at Yorkhill prior to 1983 raise specific issues which merit separate consideration.

139. During the tenure of Dr Michael Willoughby, a programme of prophylactic home therapy was introduced for children with haemophilia.[242] The inception of the programme in 1979 saw a dramatic increase in the use of factor concentrates and a corresponding reduction in cryoprecipitate.[243] The rationale for Dr Willoughby's treatment policy was plainly well-intentioned. His objective was to maintain his patients' factor 8 at a sufficient level to prevent spontaneous hemarthrosis; and

[239] Professor Lowe, [Transcript 09.12.2020 p89] Markova I, Forbes CD, Rowlands A, Pettigrew A, Willoughby M. 'The haemophilia patient's self-perception of changes in health and lifestyle arising from self-treatment'. Int J Rehab Research. 1983; 6: 11-18.

[240] Professor Lowe, [Transcript 09.12.2020 p90]

[241] Different considerations would apply in relation to previously or infrequently treated patients, such as those with mild haemophilia and children.

[242] Not only patients with severe haemophilia were given home treatment, but also patients moderate haemophilia, of whom 2 developed AIDS. Dr Anna Pettigrew [Transcript 07.12.2020 p45]

[243] We note it was not the case that Dr Willoughby *only* used commercial concentrate. If a patient came into hospital he would try to use NHS product if available, and previously untreated patients, babies and von Willebrand patients might be treated with cryoprecipitate. Dr Anna Pettigrew [Transcript 07.12.2020 p33;38]

generally to avoid prevent dreadful crippling arthropathy, such as was within the direct experience of those involved in haemophilia care at that time.[244] According to Professor Hann, Dr Willoughby was *"before his time"* in instituting such a policy[245]. Whilst done with the aim of increasing quality of life and reducing mortality, one obvious consequence of the policy was to greatly increase the amount of concentrate given to patients, in comparison to reactive treatment as and when required upon occurrence of bleeds.

140. Allied to this, a notable and unfortunate feature of Dr Willoughby's treatment policy was a preference for commercially produced concentrates, such as those manufactured by Armour in the United States. Such an attitude may be seen as anomalous even at that time, at least within the NHS in Scotland, when leading haemophilia clinicians such as Dr Davies and Professor Ludlam at Edinburgh and Dr Forbes and Dr Prentice at Glasgow[246], took the opposite approach, based on a principled preference for SNBTS products sourced from local unremunerated donors. Since NHS concentrates were then widely understood to be relatively safe in comparison to commercial products, that approach was undoubtedly correct.[247] While commercial concentrates were also used in other haemophilia centres within Scotland at that time, for a variety of reasons and to varying degrees, it appears that it was only at Yorkhill where they were used as a matter of policy in preference to locally sourced material.

141. There is conflicting evidence before the Inquiry as to the precise reasons why Dr Willoughby came to rely so heavily upon commercial concentrates. Dr Pettigrew

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[244] Dr Anna Pettigrew [Transcript 07.12.2020 p35-37] Dr Willoughby told Dr Pettigrew that spontaneous hemarthrosis occurs in patients with 1% or less of factor 8 and that US studies indicated that this could be prevented by regular factor 8 treatment a few times a week. See also Dr Willoughby's second statement to Penrose, para 3.1 – 3.2 [PEN.019.1274] *"Our prime concern at that time was to treat the haemorrhagic events as expeditiously as possible, such as instituting therapy at home rather than having to travel, often some distance, to hospital. And in the prophylactic home program the aim was to prevent serious joint and muscle pathology, and to transform these children's quality of life, and that of the family."*

[245] Professor Hann, [Transcript 08.12.2020, p26] Indeed, prophylactic home treatment has subsequently become recognised as the standard of care for haemophilia treatment.

[246] Professor Lowe [Transcript 09.12.2020, p24; p29-38; p45-48] Professor Lowe said: *"We only used commercial concentrate for things like surgery and tried, whenever possible, to use the NHS factor concentrate."*

[247] However, it subsequently became apparent that NHS and commercial concentrates were similarly infective for NANB hepatitis. See FN240 above.

recalled Dr Willoughby telling her that SNBTS could not provide sufficient or reliable amounts for home therapy.[248] While she had noted the reference in Dr Willoughby's statement to Penrose to convenience factors such as ease of use,[249] she had previously been led to believe that the main reason was reliability of supply.[250] It was also the case, according to Dr Pettigrew, that '*he obviously felt that it was just a more convenient product to be used.*'[251] Professor Hann recalled discussing the matter briefly with Dr Willoughby who preferred commercial product essentially due to its purity, and to a limited extent its availability.[252] In fairness to Dr Willoughby, it appears that he was not alone amongst haemophilia directors in experiencing such difficulties with SNBTS concentrates, at least in the period 1979-1981.[253]

142. In the Boards submission and acknowledging the clinical judgment inherent in therapeutic product choices, it is not objectively apparent that any of these considerations, whether individually or collectively, were such as to justify a policy of reliance on commercial concentrates at a time when SNBTS product was being widely used for home treatment elsewhere in Scotland.

143. It has to be accepted that Dr Willoughby appears to have taken no meaningful steps to reduce or minimise the risk of haemophilia patients being infected with a virus from their treatment.[254] In his initial statement to Penrose, Dr Willoughby wrote: *"We had no idea that we were exposing these patients to serious viral diseases. I believe*

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[248] Penrose found that "*the shortage of PFC Factor VIII at the beginning of the 1980s described by Dr Foster were reflected in an increase in commercial purchases*." Penrose Inquiry Final Report, para 21.264

[249] Penrose Inquiry Final Report, para 21.293. In his initial statement to Penrose, Dr Willoughby wrote: *"We wanted to make things as easy as possible for the parents. So, for home therapy we used a commercial source of Factor VIII (Hemofil I believe)…It proved relatively expensive but we thought its advantages justified this."* These included being much easier to reconstitute with a dilutant and easier venous access by syringe [PEN.019.1266] See also his second statement to Penrose, para 1.2 [PEN.019.1274]

[250] Dr Anna Pettigrew [Transcript 07.12.2020 p27-30]

[251] It was said that the commercial product dissolved more quickly and was provided in packs along with all the other necessary equipment.

[252] Professor Ian Hann [Transcript 08.12.2020 p21]

[253] The Minutes of Meeting of SNBTS Directors and Haemophilia Directors, 30 January 1981 recorded: "*The data provided for 1979 and 1980 showed that a significant and apparently increasing quantity of commercially produced factor VIII was being used, and the reasons for this were discussed. It was stated by haemophilia directors that sometimes only a commercial product was available; there were also occasions when, for clinical reasons, a high purity product was required. Some haemophilia directors said that the slower solubility of the PFC intermediate VIII was a disadvantage, and also that some patients experienced more side effects than with the commercial products.*" [Penrose ref: SNB.001.5055]

[254] Dr Anna Pettigrew [Transcript 07.12.2020 p70)

that problem only started coming to light in around 1983, after I had left the UK."[255] In fairness to Dr Willoughby it is relevant to note that at the time he departed from his post at Yorkhill in 1982,[256] the possibility of a risk to haemophiliacs from AIDS was only beginning to emerge in reports from the United States. The long-term prognosis for NANB hepatitis remained objectively uncertain, and was still regarded as a benign condition by many within the medical profession.[257] Accordingly, as explained to the Penrose Inquiry, his *"risk assessment"* of the treatment policy was made at a time when he was unaware of the existence of HIV, and proceeded on the basis that both NHS and commercial concentrates were highly infective for NANB hepatitis, but which was understood to be a "less serious" condition than Hepatitis B.[258] According to Dr Pettigrew, Dr Willoughby was unaware of the risk of AIDS during the second half of 1982 and understood that transmission of hepatitis through commercial concentrates had been at least partly addressed by improved donor selection and screening.[259] It follows that it is unlikely junior staff at Yorkhill such as Dr Pettigrew would be in any better position as far as their own knowledge was concerned.[260]

144. Whatever the reasons, the consequences of this policy were catastrophic. Evidence given to the Penrose Inquiry indicated that 21 children were infected with HIV as a result of their treatment at Yorkhill. (All 21 children had Haemophilia A; 19 had severe haemophilia and 2 had moderate haemophilia.)[261]

145. In our submission, the policy of instituting prophylactic home therapy for children using almost exclusively imported commercial concentrates cannot be sustained. These products were then generally understood by clinicians and transfusionists in Scotland to be less safe than equivalent NHS products, which were derived from a better donor pool. Such a view was also reflected in the strategic pursuit of self-sufficiency for Scotland by SNBTS at that time. In her evidence, Dr Pettigrew

[255] [PEN.019.1266]
[256] According to the Penrose Inquiry Final Report Dr Willoughby left his post at Yorkhill at 'the end of 1982.' [para 21.293]
[257] For the reasons discussed at Chapter 2 above.
[258] [PEN.019.1274] para 3.2
[259] Dr Anna Pettigrew [Transcript 07.12.2020 p70)
[260] De Anna Pettigrew [Transcript, 07.12.2020; pp59-60; 69; 119 – 121]
[261] Dr Anna Pettigrew [Transcript 07.12.2020 p73] Penrose Inquiry Final report, para 3.284

expressed the view that whilst such treatment was given in good faith the severity of the potential risks involved were not appreciated, and in hindsight it would have been better if Dr Willoughby had not used commercial concentrates given the "*subsequent terrible consequences.*"[262]

146. In the Boards' submission, such conclusions would be open to the Inquiry to draw, even without the benefit of hindsight. It appears that the risks inherent in Dr Willoughby's treatment policy were capable of appreciation by other clinicians, even in 1983. The Inquiry may find it telling that upon taking up appointment in January 1983, Professor Ian Hann immediately reversed the policy of using commercial concentrates *"right from the word go."*[263] The expressly stated reason for the change was considerations of safety, in that NHS Factor 8 from voluntary unremunerated donors was thought to carry less viral risks.[264] In evidence, Professor Hann explained that the most significant concern in the early 1980s was Hepatitis B, and it was known that the type of donors used by the commercial companies in America were high risk. Notwithstanding the significant financial cost, the hospital's existing stocks of commercial factor 8 were sent for destruction.[265]

147. Moreover, it does not appear that Professor Hann experienced any significant impediment by way of limited supply when implementing his new policy. Professor Hann explained that when he took up appointment, he contacted his liaison at SNBTS, Dr Crawford, who was *"extremely helpful"* and said *"If anything, we'll give you priority."* Accordingly, *"right from the word go, and within days or weeks at the most, I stopped all use of Factor VIII concentrates from abroad."*[266] This account would appear to be somewhat incongruent with the reported perception of Dr Willoughby in this regard, at least as to the position by the end of 1982.

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[262] Dr Anna Pettigrew, [Transcript 07.12.2020 p112] Dr Pettigrew thought this may have been due to insufficient supplies, or apparently insufficient supplies, of SNBTS factor 8 at that time.

[263] *"…right from the word go, and within days or weeks at the most, I stopped all use of Factor VIII Concentrate form abroad."* Professor Ian Hann [Transcript 08.12.2020 p22] Dr Anna Pettigrew [Transcript 07.12.2020 p25 – 26; 35] NHS Factor IX Concentrate was used for haemophilia B patients.

[264] By contrast Dr Pettigrew could not recall Dr Willoughby ever discussing the relative safety of SNBTS and commercial products. Dr Anna Pettigrew [Transcript 07.12.20 p40]

[265] This was *"…quite a difficult decision in one way because it is costly stuff and all that, but that paled into insignificance as far as I was concerned."* Professor Hann, [Transcript 08.12.2020 p22]

[266] Professor Ian Hann [Transcript 08.12.2020 p22]

148. As noted above, the precise reasons for Dr Willoughby's bias towards commercial concentrates may be difficult to understand at this remove of time. However, it is possible that the reality of the circumstances in which Dr Willoughby was working at Yorkhill may go at least some way to explaining how such a state of affairs came to arise. Professor Hann explained in evidence that he had great respect for Dr Willoughby who was a *"real workaholic and tended to plough his own furrow as a lone practitioner."*[267] His department was seriously under-resourced. Junior and trainee staff were funded through his own charity fundraising efforts. He had multiple areas of responsibility of which haemophilia care was but one. Latterly in 1982, the department's functioning was seriously compromised by industrial action which eventually provoked Dr Willoughby's departure to Australia.[268]

149. It is against that background, for example, that Dr Willoughby's attendance to UKHCDO meetings in London *("very infrequently, if at all")*[269] where information of emerging viral risks might be acquired, has to be understood. Dr Willoughby and Professor Hann were responsible for multiple services which would be the job of 5 or 6 consultants today.[270] Between 1983 and 1985 less than 20% of Professor Hann's time was spent dealing with bleeding disorders:[271] *"we were essentially a bone marrow transplant centre with very limited resources."*[272] In such circumstances, the difficulties experienced by clinicians in keeping abreast of developing knowledge in one particular area such as haemophilia must have been considerable. It is submitted that it would be appropriate for the Inquiry's findings in relation to Yorkhill to reflect the reality of the extremely challenging circumstances in which Dr Willoughby was working at that time.

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[267] Professor Ian Hann [Transcript 08.12.2020, p112] Professor Hann recalled that when he arrived at Yorkhill in 1983 "*I found myself in the eye of a storm with not a lot of calm.*"

[268] The serious effect of the industrial action was demonstrated by an incident where laboratory staff refused to cross-match blood required for a new-born infant requiring urgent neonatal surgery. [PEN.019.1277]

[269] Professor Ian Hann [Transcript 08.12.2020 p18]

[270] In a similar vein, Professor Ludlam explained that managing the haemophilia service was only a small part of his workload, which also included supervising laboratory work; leukaemia treatment; and bone marrow transplants. Professor Ludlam, [Transcript 01.12.2020 p31-32]

[271] Professor Ian Hann [Transcript 08.12.2020 18]

[272] Professor Ian Hann, [Transcript 08.12.2020, p7-10;15; 18] Professor Hann commented that Scotland was relatively slow to develop into sub-specialist paediatric care.

Haemophilia treatment policies – response to the risk of AIDS

150. In our submission, the response to the emergence of the risks to AIDS in haemophiliacs in late 1982 raises different, and in some respects more difficult and anxious, questions. In particular, the Inquiry has rigorously examined the question of whether cryoprecipitate should have been used in preference to concentrates for treatment of haemophilia A,[273] even as an interim measure to forestall infections with HIV, after the risk first became apparent.

151. This is a question which does not, or at least should not, arise only through the retrospective lens of this Inquiry. For example, in January 1983, the New England Journal of Medicine published an article by Dr Jane Desforge entitled *AIDS and Preventative Treatment in Haemophilia.* The article suggesting reverting to cryoprecipitate in order to combat the risk of AIDS.[274] It does not appear that the article gained a great deal of traction amongst haemophilia clinicians in the UK, in part due to the fact that Dr Desforge, a staff writer at the journal, was not a well-known figure within the haemophilia specialism.[275] Subsequent events were to demonstrate that this suggestion was deserving of serious consideration and discussion on its own merits.

152. However, it is not apparent that the question received the full degree of consideration merited at the time. When asked whether he considered a much greater use of, or reversion to, cryoprecipitate in 1983 or 1984 Professor Ludlam replied *"I'm sure we must have done. I don't recall discussion, but there would have been some discussion…But there wasn't a decision made."*[276] However,

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[273] Cryoprecipitate could not be used as treatment for patients with haemophilia B. Prior to concentrate therapy becoming available the main treatment for those patients was Fresh Frozen Plasma.

[274] The article stated: *"The fact that haemophiliacs are at risk for AIDs is becoming clear…Preventing the complications of the present treatment may have to take precedence over preventing the complications of haemophilia itself."* Professor Ludlam [Transcript, 10.12.2020 p10-11]

[275] Professor Ludlam commented that *"Had it been written by a well-known name in haemophilia, an eminent haemophilia physician…. Then maybe it would have carried more traction*." He also argued that*: "to suggest then on the basis of the data available that it might be prudent to move towards cryoprecipitate seemed a little premature*." Professor Christopher Ludlam Transcript [02.12.20 p12-13]

[276] Professor Ludlam said *"I'm sure it was discussed, but we felt it was reasonable to go on with using cryoprecipitate in decreasing quantities and using local concentrates for treating the patients."* Professor Ludlam, [Transcript 02.12.2020, p32]

contemporaneous evidence of substantive discussions appears to be limited. Indeed, even when the suggestion was raised by distinguished transfusionists in Scotland, it did not appear to gain a great deal of traction with clinicians. For example, Dr Brian McClelland wrote a report[277] following his attendance at a WHO meeting on AIDS in New York in November 1983 where he proposed that: *"The use of single donor or small pool cryo for haemophilia therapy should be reassessed. In particular, the extent to which the requirements of good manufacturing practice limit the production of small pool freeze-dried cryoprecipitate should be re-examined and the costs of this product estimated in relation to intermediate factor 8 concentrate."* In his evidence Dr McClelland explained that he believed on simple epidemiological grounds that small pool material made from indigenous material (such as small pool freeze dried or single donor cryoprecipitate) would be safer in relation to HIV, [278] Elsewhere in his evidence, Dr McClelland pointed out that for technical reasons only donations from established donors could be used for the manufacture of cryoprecipitate, giving rise to a reasonable inference that the blood was safer.[279] In his written evidence, Dr Peter Foster recalled a meeting with haemophilia directors in February 1984 when Professor Cash offered to produce more cryoprecipitate in response to the risk of AIDS, but the offer was declined.[280] Perhaps significantly, that was the only instance of which Dr Foster was aware where express consideration was given to the possibility of reversion to cryoprecipitate in Scotland.[281]

153. It seems possible that a similar mindset prevailed amongst haemophilia clinicians across the UK more widely.[282] At the AGM of the UKHCDO on 17th October 1983, Dr

[277] Dr Brian McClelland [Transcript, 27.01.2022, p150 – 151] He thought it was likely to have been circulated to the Haemophilia Centre Directors [p154]

[278] Evidence of Brian McClelland, [Transcript 27.01.2022, p150 – 153]. See also his comments about Dr Howard Davies who was an advocate of cryoprecipitate on grounds of safety [page 80]

[279] In his evidence Dr McClelland explained that cryoprecipitate had to be made from donations known to be group A or group O, which would only be known if the donor had given blood before (and therefore been subject to a negative Hep B test and no reports of problems from recipients.) [Transcript, 27.01.2020 p49-50]

[280] However, that was not reflected in the minute of the meeting as strongly as he remembered it being said at the time: Peter Foster Rule 9 witness statement, p127

[281] Peter Foster Rule 9 witness statement p128. However, we note that in 1990 Professor Cash prepared a note for the purposes of the HIV litigation where he indicated that the proposition that it might be prudent to switch haemophilia patients from large pool fractionated products to cryoprecipitate was actively considered and rejected in 1983 and then again in 1984. [SBTS0000062_073] [SBTS0000062_072]

[282] For example, Dr Mark Winter responded to a question on this theme by saying, apropos of England,: *"if you're moving towards why didn't we use cryo on everybody, I've already told you, there was just no supply.*

Chisholm raised the issue of possible reversion to cryoprecipitate. The minutes indicate that Professor Bloom responded by saying that he felt there was no need for patients to stop using the commercial concentrates, because there was no proof that commercial concentrates were the cause of AIDS.[283] Certainly, the experience of the small number of centres which had used cryoprecipitate for home treatment, such as Dr Katherine Dormandy at the Royal Free Hospital in London, does not appear to have received extensive study or consideration as possible relevant comparators.[284] In evidence, Dr Mark Winter described the idea of returning to cryoprecipitate in response to the risk of AIDS as *"a non-starter."*[285]

154. From the evidence of the SNBTS witnesses, it appears that it might have been possible to increase production of cryoprecipitate by Regional Transfusion Centres as necessary without insuperable difficulty, had they been asked to. (Any repurposing of the PFC to produce cryoprecipitate on a large scale may have been more complicated, however).[286] Dr Brian McClelland gave evidence that it would have been possible to scale up production to manufacture large quantities of cryoprecipitate: *"if it had been…felt sufficiently important to allocate an appropriate amount of finance,*

Secondly,… there would have been massive antipathy from the patients, and there would have been great reluctance from the doctors…I don't ever recall any haemophilia doctor ever suggesting, in response at this critical moment, that we should switch all patients to cryoprecipitate." [Transcript 01.10.2020, p96]

[283] Professor Ludlam, [Transcript 03.12.2020 p86] PRSE0004440. The minutes record that the agreed view, reached after discussion, was that it was appropriate to continue with concentrate (both NHS and commercial) for home treatment. This supported the previous unanimous view of the haemophilia directors taken at the Reference Centre Directors Meeting on 27 January 1978 when Dr Dormandy requested the meeting's view on using cryoprecipitate for home treatment.

[284] Professor Ludlam said he was aware that a small number of centres had used cryoprecipitate for home treatment but he didn't know the details. He himself had no experience of home treatment. Professor Ludlam, [Transcript 01.12.2020 p77] Dr Pettigrew said she was surprised to hear evidence at the Inquiry about cryoprecipitate being used for home treatment at, for example, The Royal Free Hospital because she had always been led to believe that it was not suitable for home treatment for various reasons. Dr Anna Pettigrew [Transcript 07.12.2020,p37] in September 1976 Prof Cash published an article in the BMJ which provided that cryoprecipitate was suitable for home treatment. IBI Presentation on Prof. John Cash presentation [p39]

[285] Dr Mark Winter, [Transcript 01.10.2020, p90]

[286] Professor Ludlam understood that as the Blood Transfusion Service had turned their whole system over to producing as much Factor VIII as possible it would *"technically have been actually very difficult to have gone back"* Professor Ludlam, [Transcript 02.12.2020, p32] See also Peter Foster's concern (in relation to preparation of single donor cryoprecipitate at PFC following the 1980 inspection) that *"As the preparation of cryoprecipitate did not comply with the GMP standards to which PFC was required to operate, I do not believe that single donor cryoprecipitate could have been prepared at PFC unless the Government (SHHD) had over-ruled the standards required by the Medicines Inspectorate."* [Peter Foster Rule 9 statement, p127]. See also evidence about the reason SNBTS did not progress its freeze dried cryoprecipitate development contained in SNBTS minute of meeting dated 21.1.83 and referred to by Professor Lowe [Transcript, 10.12.20 pages 1 to 2]

it could have been done very quickly."[287] This evidence may tend to indicate that reversion to cryoprecipitate would have been technically feasible from the point of view of manufacture and supply.[288] There is also evidence indicating that SNBTS made clear to haemophilia centre directors that they were open to continuing to supply cryoprecipitate for haemophilia treatment – even in increasing quantities if so requested[289]

155. On the totality of the evidence, it would be open to the Inquiry to find that insufficient consideration was given within the NHS in Scotland, and perhaps across the UK more widely, to alteration of treatment strategy in response to the risk of AIDS. The possibility of significantly increasing the use of cryoprecipitate would have been one potential option to consider. However, it does not appear that, despite the emergence of the risk of AIDS, and an understanding that cryoprecipitate was safer in that regard, that the idea was ever seriously entertained.[290] What would have been the outcome had there been a more rigorous debate on the merits must thus remain a hypothetical question. There would have been an arguable position to be adopted

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[287] Dr Brian McClelland [Transcript 27.01.2022 p131 – 312] Dr McClelland added: "*We would have had enormous community support in doing that which would have made it go very quickly"* In his witness statement Dr McClelland said (at para 141): *"Expanding cryo production would have been dependent on receiving funding to obtain improved accommodation, additional equipment and additional staff. This did not happen until the function was moved to improved premises in the RIE Phase 1 Building. It had taken several years to achieve financial approval and complete the planning, construction, equipment and commissioning of this laboratory."* However , we note that in 1990 Professor Cash prepared a note for the purposes of the HIV litigation where he indicated that a substantial increase in cryoprecipitate production was actively considered and rejected in 1983 and then again in 1984, partly on the grounds of "operational impossibility" due to limited accommodation and facilities.. [SBTS0000062_073] [SBTS0000062_072]

[288] See however the comments of Dr Frank Boulton to the effect that it would not have been feasible for the UK clinical services in the 1980s to have cryoprecipitate substituted for f8 concentrates in any substantial quantities in order to maintain the level of clinical demand after the onset of HIV. It is not entirely clear to us whether he considered that it would not have been feasible for the blood services in Scotland to increase production to the necessary levels. [Dr Boulton Rule 9 Statement, Q66, paras 156 – 160]. As noted above [FN292]Professor Cash produced a paper on the possibility of increasing cryoprecipitate production stating that it would not be possible. It may also be relevant to the issue that, at the time, the Medical inspectors were critical of cryoprecipitate production arrangements in Edinburgh and wanted radical change merely to bring the arrangements up to expected standards.

[289]At a meeting of SNBTS haemophilia centre directors and haemophilia directors in 1981 Professor Cash emphasised the important part cryoprecipitate could play in haemophilia treatment and suggested considering whether it could be used in home therapy. However it appears the haemophilia centre directors were not in favour of this suggestion. I[BI Presentation on Prof. John Cash presentation p24.] As understood, during the first half of the 1980s SEBTS scientists were actively exploring modifications to the cryoprecipitate production method to improve the factor VIII yield, with at least some degree of success.

[290] When Dr Brian Colvin was asked about the possibility of reversion to cryoprecipitate for a much larger cohort of patients, in response to the AIDS crisis from January 1983 onwards he responded: *"…I don't think it ever actually occurred to me to do such a thing."* [Transcript 07.10.2020, p56]

both for and against, even if it seems likely that the current perception of a low risk to patients in Scotland would have weighed in favour of continued adherence to concentrates as the mainstay of therapy for severe haemophilia.[291]

156. Indeed, it appears that in 1984 the general policy in Scotland was to continue to *decrease* the use of cryoprecipitate in haemophilia A patients (other than children).[292] Whilst at first sight this might be though to be a somewhat surprising response to adopt in the face of the new danger of AIDS[293], such a policy is consistent with the prevailing view that the risk of AIDS to patients in Scotland was assumed to be low. When it was suggested that Professor Ludlam's loyalty to local concentrates led him to disregard the risks of viral transmission from the local pool, he replied that he appreciated there was a risk of AIDS but thought it was very low.[294] Professor Ludlam explained that he made no significant changes in his approach to treatment in 1983 and 1984 because he assumed that the SNBTS concentrate was *"relatively or reasonably…safe."*[295] As discussed above, the basis for this assessment based upon the absence of any reported cases of AIDS in Scotland allied to the policy of using SNBTS factor concentrate in preference to commercial products imported from the USA, where multiple cases of AIDS in haemophiliacs had been reported. When news emerged of the HIV infections in Edinburgh in October 1984, showing that the risk to Scottish patients had been underestimated, SNBTS responded with alacrity in producing a heat-treated concentrate which was safer from HIV than cryoprecipitate. These considerations may help to explain why, at least in Scotland, only limited consideration appears to have been given to the idea of stopping, or pausing,

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[291] The reasons for this view are discussed in detail at Chapter 3 above.

[292] Minutes of Meeting between SNBTS and Haemophilia Directors 2nd February 1984 [PRSE0001556], Professor Ludlam [Transcript 02.12.2020 p32 – 34] The Minutes stated: *"Members discussed the suggestion that the production of cryoprecipitate could now be reduced. Dr Ludlam said that cryoprecipitate was preferred in the treatment of children at present, because of the new danger of AIDS. Dr Hann concurred."* In evidence, Professor Hann explained that he understood the Minutes to mean that cryoprecipitate was the preferred treatment for mild and newly diagnosed children but not all children. When heat treatment was introduced for concentrates, cryoprecipitate came to be regarded as less safe. Professor Hann [Transcript 08.12.2020 p34-37]

[293] Professor Ludlam, [Transcript 02.12.2020 p31 – 33]

[294] Professor Ludlam, Transcript [04.12.2020 p124]

[295] Professor Ludlam explained that that he established no cases of AIDS had been reported in Scottish population: *"so I made the assumption that the likelihood of there being a transmissible agent was low in Scotland…on that basis, I thought that the risk was small but not zero."* Professor Ludlam, [Transcript 02.12.2020, p31 -32]

concentrate therapy in favour of cryoprecipitate, notwithstanding the emerging risk of AIDS.

157. The use of NHS blood products sourced from local donors had been identified and, to a substantial extent, implemented as the principal measure to reduce the risk of viral infection (initially in response to risk of hepatitis) at centres within Scotland by the time the threat from AIDS began to emerge. It is clear that the risk of AIDS from SNBTS products was also reasonably perceived as lower, in comparison to commercial concentrates from the USA. As Professor Ludlam observed, this policy was also consistent with the guidance issued by UKHCDO in June 1983, which suggested that NHS concentrates would be an acceptable form of therapy for patients with haemophilia.[296] It is regrettable that the UKHCDO was apparently unaware of the recommendations by the Council of Europe in 1983, which included to avoid, wherever possible, the use of coagulation factor products prepared from large plasma pools.[297]

158. In the Boards' submission, these considerations do not entirely suffice to explain why the relative risks of concentrate and cryoprecipitate treatment was apparently not the subject of more anxious scrutiny and discussion. For example, insofar as Professor Ludlam and Professor Hann were advocating the use of cryoprecipitate for children in 1984, that may infer that it was regarded as a safer form of treatment at that time[298]. The question arises, if such were the case, why further consideration was not given to greater use in adults as well, where the exposure to thousands of

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[296] On 13th May 1983 there was a special meeting of reference centre directors where the minutes recorded that: "*many directors have up until now reserved a supply of NHS concentrates for children and mildly affected haemophiliacs and it was considered that it would be circumspect to continue with that policy.*" However, it appears that at that time the UKHCDO did not regard its role as issuing advice or guidelines to membership, albeit that the activities of the Reference Centre Directors and information provided at the meetings would exert some influence on how haemophilia care was provided. Professor Ludlam explained that *"this was not an original function of the Reference Centre Directors. Giving advice and guidelines, if I can perhaps call them guidelines, was something that emerged in the 1990s."* Professor Ludlam [Transcript 03.12.2020 p61-62]

[297] Professor Ludlam, [Transcript 02.12.2020 p41- 45] [PRSE0000372] These recommendations included: 1. Take all necessary steps and measures with respect to AIDS and in particular to avoid, wherever possible the use of coagulation factor products prepared from large plasma pools; 2. To inform attending physicians and haemophiliacs of the potential health hazards if haemotherapy and possibilities of minimising those risks; and 3. To provide all blood donors in information re AIDS. As understood, the recommendations by the Council of Europe did not lead to other European countries stopping concentrate use.

[298] Supra FN297

donations was only magnified due to the greater dosage required.[299] However, beyond relying on the policy of using NHS concentrate which was already in place, there appear to have been no significant changes of approach in 1983 and 1984 in response to the risk from AIDS to adult haemophiliacs, which had by then come to be appreciated.[300] In his evidence, Professor Ludlam highlighted factors such as the greater dose of cryoprecipitate which adults would have required; that the infective risks of cryoprecipitate were in themselves not negligible; the destructive and diluting effect upon the HIV which occurs in the preparation of Factor concentrate, but ultimately accepted that: *"it could be argued that the risk…would be smaller with the use of cryoprecipitate."*[301]

159. Against that background, it would be open to the Inquiry to find that greater consideration should have been given to extending the use of cryoprecipitate for adult patients during 1983 and 1984, rather than reducing it as was in fact the policy. Apart from anything else, it is reasonable to suppose that this might have led to more extensive discussion with patients about the risks and benefits of alternative treatment options. One possible inference suggested in the evidence may be that their earlier experience of the benefits of concentrate treatment caused some haemophilia clinicians to develop a strong commitment to that form of therapy such that any change in course became difficult to countenance.[302]

Treatment of children

[299] Professor Ludlam, [Transcript 02.12.2020 p34-35] Professor Ludlam was asked whether in February 1984 he thought that NHS concentrates were safer or less safe than cryoprecipitate and replied that *"I find that a difficult question to answer because I thought it likely that the risk of infection…in the donor population was low"* [Transcript 02.12.2020 p38]

[300] Professor Ludlam, [Transcript 01.12.20,p30-32]

[301] Professor Ludlam [Transcript 02.12.2020 p38]

[302] In his evidence, Dr Frank Boulton said "*There was what we thought, even then, a sense of wishful thinking amongst the haemophilia-treating community that this awful condition was not due to an infection but might go away because it was not very common yet at all in the UK….I'm sure that intellectually Christopher (Ludlam) accepted the probability of infection but, emotionally, the implications of that were so vast, in terms of potential withdrawal of treatment for patients, that, in a sense it was almost unthinkable.*" [Transcript 04.02.2022 p117; 119-120]

160. Cryoprecipitate gave rise to particular problems when used in the treatment of children. In terms of Professor Hann's policy at Yorkhill Hospital in 1983, cryoprecipitate[303] was used in patients with von Willebrand's disease where DDAVP was not appropriate; in patients with mild or moderate haemophilia if the bleed was not serious; and in newly diagnosed patients.[304] The option of cryoprecipitate was discussed with patients receiving concentrates and a small number of families elected for treatment with cryoprecipitate.[305] However, the use of cryoprecipitate in children was very limited for a number of reasons. Firstly, as noted above, there was evidence indicating that use of cryoprecipitate prior to 1974 had not reduced the high premature mortality in UK haemophiliacs, during which period the commonest cause of death was intracranial haemorrhage.[306] One of the commonest causes giving rise to the need for treatment in children with haemophilia being head injuries meant that a treatment which was well tolerated with reliable dosage was required. Secondly, cryoprecipitate was not a safe treatment in children: the efficacy was extremely difficult to manage so as to achieve fast, reliable factor 8 levels without causing transfusion overload. Thirdly, somewhere between a third and a half of children had *"very frightening"* side effects. Accordingly, home therapy with cryoprecipitate was *"not an option"* in Professor Hann's view.

161. Notwithstanding, and in contrast to Dr Willoughby, Professor Hann's policy in relation to concentrate was to use it *"conservatively and only when necessary".* Standing the risk of AIDS, he felt it was reasonable to be more conservative with the use of concentrates, even for those on home treatment. On that basis he terminated prophylactic treatment after discussion with the families, unless they wished to

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[303] Professor Ian Hann [Transcript 08.12.2020 p27-30;] We note that Professor Ludlam even attempted to treat children with severe haemophilia with cryoprecipitate, but it was challenging with young children due to volume and viscosity: "*it's not easy to give cryoprecipitate to small children but if it seemed feasible that's what I would think of doing first.*" As children with severe haemophilia were likely to require relatively frequent treatment the benefits of using cryoprecipitate would diminish as far as hepatitis is concerned. Professor Ludlam [Transcript 01.12.2020 p101]

[304] Professor Ian Hann [Transcript 08.12.2020 p30; 109] See also Professor Gordon Lowe, Second rule 9 statement para 8.5.2.8, [WITN3496014-16]

[305] Professor Hann [Transcript 08.12.2020, p27]

[306] Forbes CD, Prentice CRM. Mortality in haemophilia – a United Kingdom survey. In: Fratantoni JC and Aronson DL, Eds. Unsolved Therapeutic Problems in Haemophilia. Washington D.C: U.S. Department of Health, education , and Welfare, 1976, pp 15-22

continue.[307] He also introduced a written policy of using cryoprecipitate for newly diagnosed previously untreated patients and younger children not on home therapy.[308] Thus, cryoprecipitate was offered where practicable due to safety considerations, notwithstanding the difficulties with venous access and the volume required to produce suitable effect.[309] The Boards endorse the steps described, as taken by Professor Hann.

Treatment policies 1985 – 1987

162. Upon learning of the HIV infections in Edinburgh patients at the end of October 1984, the Protein Fractionation Centre ("PFC") immediately changed its approach to viral inactivation by dry heating its existing stocks of concentrates. According to Dr Peter Foster's evidence, this decision was taken because dry heated concentrate could be introduced more quickly than a pasteurised product, despite the heating conditions being known to be ineffective against NANB hepatitis.[310] Once the strategy at PFC had been reappraised, matters proceeded apace. Clinical trials were underway by 29th November on product heated for 2 hours at 68 C. Because PFC had 12 months' supply in unheated stock which could then be heat-treated, they were able to fill the supply line immediately. Supplies of the new dry heat product were issued to the Regional Transfusion Centres on or around 19th December 1984. It appears that the PFC's initial dry heat treatment protocol was successful in inactivating HIV, standing the absence of reported infections subsequently. It is worth noting that the decision by SNBTS to issue the heat-treated product was not without risks of its own, at least as perceived at that time.[311]

[307] Professor Ian Hann [Transcript 08.12.2020 p24 – 26; p33 – 34; p139 - 142]
[308] Dr Anna Pettigrew [Transcript 07.12.20 p69-70]
[309] Dr Ian Pettigrew [Transcript 07.12.2020, p129-130]
[310] Dr Foster Rule 9 statement, page 69, para (iii)
[311] In summary (as understood) its effectiveness against HIV was not certain; damage to the clotting factor and other proteins remained a possibility; adverse effects of the heat treatment could not be excluded, including increased incidence inhibitor formation which would have been a disaster for any patients affected. Dr Perry gave evidence to Penrose that *'the risk/ benefit balance changed overnight. It was dramatic and it was quite clear, moving from a position where everyone was very nervous about introducing heat treatment to a position where the advantages clearly outweighed the risks'* [Penrose Inquiry Final Report para 23.178.]

163. The factor 8 product issued by PFC between 1985 and 1987 (NY) was a dry heated concentrate (at 68 degrees for 24 hours) which was effective in inactivating HIV but not NANB hepatitis. A product which was safe for NANB hepatitis as well as HIV (Z8) was not introduced to routine supply in Scotland until May 1987.[312] Meanwhile, in England, a new product called 8Y (dry heated at 80 degrees for 72 hours) was issued by the Blood Products Laboratory ("BPL") for general release to Regional Transfusion Centres in September 1985. In time, it became apparent that 8Y was safe for NANB hepatitis as well as HIV. The net result was that there was a period of several months between September 1985 and May 1987 when the main NHS factor 8 product in Scotland continued to transmit NANB hepatitis to patients whereas the English product did not.[313] For reasons discussed further below, the 8Y product was not widely available in Scotland. Haemophilia clinicians were thus faced with difficult treatment decisions during this period, bearing in mind that cryoprecipitate carried a reduced risk of hepatitis but was also not free from a risk of AIDS.[314]

164. The cohort most directly affected by this 'window period' was of course patients in Scotland with no previous exposure to concentrates, who had not yet been infected with NANB hepatitis. During this period, policies and protocols were developed at haemophilia centres to address the position of minimally treated or previously untreated patients presenting with a possible need for treatment. For example, at Glasgow Royal Infirmary, the policy was that a moderately severe or moderate haemophilia A or von Willebrand's sufferer with no or minimal previous treatment would likely be treated with cryoprecipitate, based on considerations of pool size. Patients with mild haemophilia would be given DDAVP if possible.[315] Professor

[312] When Z8 became available for clinical trial in December 1986 Prof Ludlam (supported by the other haemophilia centre directors) refused to undertake trials of the product unless satisfactory arrangements were in place for patients suffering damage as a consequence of infusion of the new product.

[313] It appears that during this period approximately 29 patients received NHS concentrate for the first time. On follow up, 6 tested positive for HCV, 9 were negative and the status of 14 patients was unknown. [Penrose Inquiry Final Report, para 22.3]

[314] Professor Lowe, [Transcript, 10.12.2020 p101]; Professor Ludlam said that he was influenced by the view of Professor Bloom, who considered by mid-1985 that it was probably imprudent to use cryoprecipitate and heat-treated concentrates were more appropriate. Professor Ludlam said: *"I think this reflects the evolving situation, which many of us found difficult to manage."* [Transcript, 04.12.20 p12]

[315] Professor Lowe, [Transcript, 10.12.2020 p101 - 102] Professor Lowe said: *"..and I think when push came to shove and I was asked at the Penrose Inquiry: well, if it was you and you have just been diagnosed, what would you have? And after much persuasion…I said I'd probably go for the cryoprecipitate."*

Ludlam gave evidence that during this period he explained the risks to patients in greater detail, including the changing picture and uncertainties, was well as the available treatment options.[316] Professor Ludlam explained that during this period HIV was the main priority, rather than NANB hepatitis, and that a mild haemophiliac or child might still require concentrate if they had a serious bleed [317]

165. The Boards very much regret that these efforts were insufficient to prevent the infection of a number of previously untreated patients during this period. It may be that the occurrence of such infections serves to underscore the importance of treatment guidelines such as are commonly in use today, and their effective dissemination amongst medical staff, including in particular junior doctors. For example, the Inquiry has considered the particularly regrettable circumstances in which an untreated patient with mild haemophilia was infected with NANB hepatitis as a result of prescription of SNBTS factor concentrate at Edinburgh Royal Infirmary in June 1986.[318] As a result of this incident, Professor Ludlam asked Dr McClelland to make enquiries with a view to procuring a supply of 8Y from BPL to be reserved for the treatment of such patients should they present at hospital in the future.[319]

166. At the time when Professor Ludlam made this request, the safety of the 8Y product had yet to be fully established. However, in January 1986 SNBTS had been kept abreast by BPL of encouraging indications that the 8Y product might well be, at least, less infective for HCV.[320] In evidence, however, Professor Ludlam wondered whether

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[316] Professor Ludlam, [Transcript 04.12.2020, p13]
[317] Professor Ludlam [Transcript 04.12.220 p12]

[318] Professor Ludlam [Transcript 04.12.2020 p16 -18] In a letter to Dr Perry Dr Boulton wrote: *"Christopher is a bit ruthful with his own staff because he feels that his patient should have received 8Y or an equivalent product"* In evidence, Dr Ludlam's said that his subsequent request to Dr McClelland asking if possible, to obtain BPL product (8Y) for treating previously untreated patients was triggered by this incident. [Transcript, 04.12.2020, p33]
[319] Professor Ludlam, [Transcript 04.12.2020 p32-33]
[320] In January 1986 Dr Perry wrote a report for the regular joint meetings of SNBTS directors and haemophilia doctors (held in March 83) which noted that BPL were now issuing 8Y to RTCs and *'preliminary clinical data indicates that this material was non-infective with respect to HTLV 3, NANB and Hepatitis* B'. At PFC on 17 March 1986 a meeting took place between PFC and BPL. The minutes recorded that *"Dr Smith outlined clinical trial results of the f8 product so far. While results cannot be considered conclusive at this stage, he indicated that no cases of virus infection have occurred (attributable to 8Y material) after 12 months experience of 8Y in virgin haemophiliacs."* [Transcript 18/03/2022, p93-94] However, it appears Professor Ludlam was not present

"…maybe it was inappropriate of me to have, if I can put it this way, jumped the gun and requested the VIIIY."[321] In the Boards' submission, there would be no basis for criticism of Professor Ludlam on those grounds. While there was not yet any certainty that the 8Y product was[322] hepatitis safe, there were by this stage, at the very least, valid grounds for optimism that it would prove so to be – in comparison to the Scottish product which was known to remain potentially infective for NANB hepatitis. In those circumstances, it was legitimate to seek to procure a supply of that product for Scottish patients. That was particularly so given that the anticipated release of the broadly equivalent PFC product, Z8, in the spring of 1986 had not yet materialised. Indeed, the Boards would regard it as unfortunate that Professor Ludlam appears not to have received the preliminary data provided to SNBTS prior to and during early 1986[323], which might have enabled his earlier consideration of the emerging disparity between 8Y and NY, and the potential implications for the treatment of previously untreated patients.

167. The circumstances in which a small supply of 8Y was acquired by SNBTS illustrates the extent of the administrative separation between the United Kingdom blood services which prevailed during that period.[324] On the face of it, this was regrettable. After Professor Ludlam made his request there followed a series of correspondence between Dr Perry and his counterparts at BPL, which ultimately resulted in an agreement to provide 50 vials of 8Y to SNBTS on the understanding that any patients using it would be entered into a clinical trial. It was not assumed that the request would be granted. In evidence, Professor Ludlam expressed surprise that BPL had

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at the meeting nor was the information in Dr Perry's report brought to his attention. Professor Ludlam [Transcript 04.12.2020 p20-21; 27-28]

[321] Professor Ludlam, [Transcript, 04.12.2020, p23] Professor Ludlam stated: *"Whether it was actually prudent of me to have requested it, I think is rather questionable. Here is a product under clinical trial. The first few patients appear to have been, if I can put it in this way, successfully treated, and I was jumping to the conclusion that maybe this was a good medicine."."* For a fuller account of Professor Ludlam's reasoning in relation to this matter see pages 23 and 24 of the transcript.

[322] The first clean batch pilot ran on 16 October 84. Dr James Smith stated: *"It should be borne in mind that development programme for a product such as 8Y normally takes 3 years …but because of HIV…this was compressed into a few months….One consequence as that huge extrapolations were made about the product on the basis of very limited clinical data. Clinical trials were organised with some haste…. in the event the product proved to be everything we hoped for"* [Transcript 18.03.2022, p54]

[323] Professor Ludlam [Transcript, 04.12.2020 p24 – 28]

[324] See the discussion between the Chair and Professor Ludlam in this regard. [Transcript 04.12.2020 p38 – 43]

agreed to provide even that limited quantity because *"I knew that VIIIY was in very short supply, and was treated like gold dust in England, and I thought they were unlikely to let us have any."*[325]

168. Finally, the Boards regret that other haemophilia directors in Scotland were not made aware that SNBTS held a supply of 8Y.[326] Self-evidently, such information would have been useful for those clinicians to know during that period.

CHAPTER 6: RESPONSE TO INFECTIONS

INTRODUCTION

169. The Inquiry has examined in detail the way in which NHS organisations responded to diagnosis of infections in patients when tests became available, firstly for HIV in 1984 and then for Hepatitis C in 1989. Appropriately, much of the focus has been upon the circumstances in which patients, or their parents, were first informed of their diagnoses. The Inquiry has also examined in detail issues such as the provision of pre-test and post-diagnosis counselling, as well as the quality of treatment given in relation to infections. Certain aspects of this evidence have given the Boards much to reflect upon, in relation to which they submit as follows:-

FINDINGS & CONCLUSIONS - HIV TESTING

170. After the HIV virus was first identified by Montagnier et al in May 1983 and confirmed as the cause of AIDS by Gallo et al in April 1984, scientific attention turned to the development of tests for the virus. When early tests became available from a limited number of providers in the UK and USA, clinicians in Scotland took steps to

[325] Professor Ludlam [Transcript 04.12.2020, p22]
[326] Professor Lowe [Transcript 10.12.2020, p104]; Penrose report para 22.70 – 22.75

arrange testing of blood samples from haemophilia patients in order to confirm their status. The unexpected news of positive test results amongst the patients gave rise to considerable shock and alarm on the part of clinicians and transfusionists alike. A number of extremely difficult questions for clinicians then arose, in relation to which there had been only very limited forward planning, preparation or detailed consideration. At least in part, this was a function of the rapidly evolving turn of events, incomplete understanding of the condition[327] and the unprecedented nature of the challenge with which clinicians at that time were presented.

171. In the Boards' submission, it is essential that any evaluation and assessment of the response by individual clinicians to the discovery of HIV infections amongst their patients should reflect and acknowledge the reality of the working conditions within the NHS in Scotland at that time. In particular, the Boards consider it is important to appreciate the fact that, in the absence of effective organisation at a national or local level, individual clinicians were to a great extent left to their own devices in deciding how to respond, and at a time of acute professional anxiety and distress. Moreover, there was little in the way of guidance and direction such as would be available today, to ensure an appropriate response. Then as now, the importance of NHS Boards' responsibility to ensure that their clinicians are provided with the requisite support to navigate such testing circumstances cannot be overstated. Indeed, the stark contrast with the co-ordinated national and local response during the COVID-19 pandemic, which played out in real time whilst the Inquiry was examining these very issues in its oral hearings, will not have been lost on any of those involved. The rapid dissemination of daily infection rates, hospitalisations and deaths to Health Boards and the general population, as well as the pro-active and effective role played by Public Health Scotland and the Chief Medical Officer in guiding the response of the Health Boards are given as but two examples.[328]

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[327] As Professor Ludlam said, *"What was so difficult was trying to cope with uncertainty. Was this actually a situation where 100% of those infected were going to get AIDS or only 1%? Trying to cope with that and explain to patients and ourselves that degree of uncertainty for a serious disorder was taxing."* [Transcript, 02.12.2020, p98]

[328] Albeit the Boards note that certain aspects of the response to the Covid 19 pandemic have attracted significant criticism and is now the subject of two Public Inquiries.

172. As a result of these factors, the response within the NHS in Scotland was deficient in a number of respects. In particular, the Boards are sorry that the process of informing patients in Scotland of positive test results for HTLV-III was too often characterised by unacceptable delay. The Boards acknowledge and regret that the suffering of those infected and their loved ones must only have been exacerbated by these failings.

HIV TESTING – EDINBURGH ROYAL INFIRMARY

173. In the autumn of 1984 Professor Ludlam sent blood from 50 – 70 stored samples to be tested by Dr Richard Tedder at Middlesex Hospital. This was done without patients' knowledge, and *a posteriori* without consent or any pre-test counselling having been given, all of which is regrettable.[329] It appears that of 22 patients infected with HIV as a result of treatment at the Edinburgh Centre, 17 were infected from single batch of SNBTS product and comprised 'the Edinburgh Cohort.'[330]

174. A question has arisen as to whether or not Professor Ludlam had developed a clinical suspicion by the time he sent the samples to Dr Tedder. This appears to have been prompted, at least in part by Dr Tedder's evidence to the Lindsay Tribunal, where he suggested that Professor Ludlam *"already had a clinical suspicion that something had occurred"* when he sent the samples.[331] However, in his evidence to this Inquiry Dr Tedder said that Professor Ludlam "*certainly didn't"* anticipate the infection of the Edinburgh cohort and that *"his aspiration was to show that his recipient panel was clean – clear of HIV infection."*[332] The latter understanding of the position was consistent with the evidence given by Professor Ludlam. It was, of course, the case that from early 1983 he had carried out monitoring of immune abnormalities in his

[329] Professor Ludlam [Transcript, 02.12.2020 p68]

[330] Professor Ludlam [Transcript, 02.12.2020 p30-32] It appears the original figures quoted in Penrose (23 and 18 respectively) did not take account of the fact that one patient who tested positive was treated at another haemophilia centre.

[331] Professor Ludlam, [Transcript 02.12.2020 p70] Dr Tedder recalled *"….going through this litany of positive, positive, positive. And Christopher Ludlam obviously getting more and more pensive and me feeling less and less kind, as this evolution of damage done to a cohort evolved. That was the very early testing when he had sent us cohorts of samples which he already had a clinical suspicion that something had occurred, and that was the beginning of evolution of knowledge of the Edinburgh cohort."* [LIND0000310]

[332] Dr Richard Tedder, [Transcript 13.10.2022, p79-81; p118 – 120] He said his previous evidence in this regard was *"probably wrong."*

patient group, an initiative which became known as the "AIDS Study." While abnormalities in the results caused him *"puzzlement and surprise and wonder"*, Professor Ludlam did not think these were related to "a putative AIDS virus or AIDS effect".[333] When he sent the samples to Dr Tedder he was *"pretty confident"* they would be negative, but as two or three patients had been given commercial concentrates, he decided to have everyone tested when he learnt that a test had become available.[334] In his evidence, Professor Ludlam was adamant that he had developed no clinical suspicion prior to sending samples for testing: he had *"no prior inkling that any of our patients had been infected."*

175. Professor Ludlam was able to give detailed evidence as to the precise sequence of events, which will allow the Inquiry to construct a more comprehensive chronology than would be possible in relation to events at other Haemophilia Centres, including Glasgow Royal Infirmary. It appears that on 26 October 1984 Professor Ludlam received the first results from Dr Tedder: six patients had developed the antibody to HTLV-III.[335] Professor Ludlam telephoned Dr Brian McClelland at home that night to inform him of the news.[336] On or around 30th October 1984, Professor Ludlam then sent further samples to Dr Tedder. On or around 2nd November further results were produced by Dr Tedder indicating there were positive tests in a total of 16 patients.[337] Professor Ludlam telephoned Dr McClelland again to advise of the news.

176. It was immediately appreciated by Professor Ludlam and others that patients who had tested positive could present a risk of transmitting the infection. On 7 November 1984 Professor Ludlam attended a meeting with other relevant specialists from Edinburgh Royal Infirmary where the situation was discussed. The summary of the

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[333] Professor Ludlam [Transcript 04.12.2020 p155-156]
[334] Professor Ludlam [Transcript, 02.12.2020 p70; 72-74]
[335] Professor Ludlam said: *"It was only when I got the results back, probably of the larger number, perhaps the second batch, and that I went through who the patients were, and I saw that one of them was the individual who had the operation in…March or April 1984, and had had a horrendous postoperative course. It was only when I saw that his result was positive that I began to wonder whether it was actually due to HIV, and because we had these stored samples, I could go back and see that he was negative before and he was positive afterwards, and then it began to make sense, although I don't think anyone had previously described anything like this in the literature.*" [Transcript 04.12.2020, p157]
[336] Professor Ludlam [Transcript, 02.12.2020 p69] [PRSE0000828]
[337] Professor Ludlam [Transcript, 02.12.2020 p80]

meeting recorded that: *"This new human retrovirus is now believed to be the aetiological agent of AIDS…it is important to appreciate that patients with antibody are infectious and can transmit the virus."*[338] Various precautions for medical and dental professionals to implement high-risk operative procedures were identified.[339] The incongruity of such infection control measures being adopted at a time when the patients concerned (and their families) were unaware that they had been infected ought to have been apparent to those present, even at that relatively early stage, and notwithstanding the confusing and uncertain state of affairs which prevailed.[340]

177. No steps were taken by Professor Ludlam or anyone else to inform the patients during the month of November, 1984. However, Professor Ludlam did take active steps to ensure that the information remained confidential, indicating his appreciation of its extremely sensitive nature[341] although the enormity of what had happened had yet to fully sink in.[342] On 29th November Professor Ludlam attended a meeting with SNBTS, which was convened to discuss the implications of the recent finding of HTLV-III antibodies in Scottish haemophiliacs. The account of the meeting in the minutes reported that *"Views were exchanged on the very difficult ethical questions which had arisen. These included whether patients' and patients' relatives should be informed and perhaps subjected to needless worry."*[343]

178. From today's perspective, the notion that the existence of a duty to inform a patient of a positive result from an HIV test should raise difficult ethical questions might seem difficult to understand. However, in relation to the events under consideration

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[338] Professor Ludlam [Transcript, 02.12.2020 p74 [LOTH0000097_007]

[339] Professor Ludlam explained: *"we were quite taken aback…and taking stock of the situation and, if you like, it was out the blue and we actually had to think about what the implications were"* [p77]

[340] In particular, interpretation of individual anti-HTLV III test results was not straightforward at that time.

[341] In a letter from Dr McClelland to Professor Cash on 15th November 1984 he wrote *"Dr Ludlam has specifically requested Dr Ludlam has specifically requested that the information relating to the batch associated with seroconversion be treated in confidence."* [PRSE0001828]

[342] On 16th November Professor Ludlam wrote: *"We hope at the clinical end of our service this is not going to cause too much disruption although it is going to be necessary to offer a reasonable explanation to some of the patients."* [LOTH0000097_007] Professor Ludlam said in evidence: *"I think the implications of it were so enormous, actually, that it took us a bit of time to – for it all to sink in and for us to think of the best way of responding. And, as you see, there were a series of meetings, and I was keen to gather as much wisdom and help and advice as I could so that I could help with the patients as I thought was best"* Professor Ludlam [Transcript 2.12.20 at 87]

[343] Professor Ludlam, [Transcript 02.12.2020, p84]

it appears that was indeed the position, and amongst very senior haemophilia clinicians. On around 30 November 1984, Professor Ludlam received a letter from Dr Craske of the Public Health Laboratory Service which posed the question *"Should the patient be told?"* His answer: *"Ideally, I think he should, but this will depend on many factors including the amount of anxiety concerning AIDS already present in the centre and the degree to which the patient is capable of understanding the situation."*[344] The issue was discussed at the meeting of the Haemophilia Centre Reference Directors on 10th December 1984, which Professor Ludlam attended. The minutes recorded that after a long discussion, in which differing views were expressed, it was agreed that individual clinicians would decide each case depending on the facts, but in general information would be provided if asked for.[345] Assuming the accuracy of the minutes, such ambiguous guidance cannot have been of any great assistance to any clinicians faced with a predicament such as Professor Ludlam's. It is submitted that the actions, or indeed inaction, of Professor Ludlam in this particular regard require to be considered against this background and context, including the lack of formal professional support and guidelines to assist in navigating such a difficult situation.

179. The event which acted as the immediate catalyst for engaging with the patients occurred when Professor Ludlam was *"door stepped"*[346] by a journalist from the Yorkshire Post on 11th December. The reporter had acquired information about "*the Edinburgh episode''* and intended to publish the story the following day.[347] However, it appears that Professor Ludlam was able to persuade him to delay running the story until 20th December. As Professor Ludlam judged it impossible to see all of the affected patients within that time-scale, the *"next best thing was to write to all the patients and say we were holding a meeting about AIDS and HTLV-III on the evening*

[344] Professor Ludlam, [Transcript 02.12.2020, p86] and HCDO0000273_058, page 4. In the appendix to the letter, Dr Craske, describes a protocol with two alternative strategies: first, informing the patient and family of the risks and secondly, restricted follow up. At the end he adds, "*In my view option (1) is the only one tenable on moral and ethical grounds*". There is possibly a tension between that and his comments in the body of the letter quoted above (HCDO0000273_058, page 5)

[345] DHSC0001181 at page 4

[346] Professor Ludlam, [Transcript 02.12.2020, p91]

[347] One inference may be that details of discussions of the subject at the UKHCDO meeting the day before, on 10th December, had been 'leaked' to the journalist. Professor Ludlam said of the meeting: *"It was a big meeting, we discussed it, it was important. It was q stressful meeting and I was keen to get other people's views"* p89

of the 19th – if they'd like to come we would tell them more."[348] In evidence, Professor Ludlam explained how it was these unusual circumstances which led him to organise a group meeting of patients from Edinburgh and elsewhere in Scotland in a lecture theatre in the Royal Infirmary, rather than invite the HIV positive patients to attend individually and receive the result in a confidential manner. At the meeting Professor Ludlam explained that tests had been carried out by Dr Tedder on stored samples and some of these had been reported as positive; and that preliminary results indicated there had been at least one batch of PFC concentrate that had caused infection in patients. The patients were then sent an information sheet inviting them to make an appointment to see Professor Ludlam which, he recalled, most of them did.[349]

180. On any view, for patients to be informed of the possibility that they were infected with HIV in such a public forum, before having been given their own individual result, was regrettable.[350] To say the least, being presented with information in this way must have resulted in considerable anxiety amongst patients in attendance, which articles appearing in the Scottish press following the publication of the story in the Yorkshire Post on 20th December would only have served to amplify and compound. Alternatively, there was an obvious risk that patients might develop a false sense of reassurance based upon the reasonable expectation that if they were amongst the numbers infected, they would already have been told.[351] Moreover, there was no way to ensure that all affected patients were in attendance at the meeting, an outcome made all the more likely by the fact that the letter inviting patients to the meeting failed to mention the fact of the positive results.

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[348] On 12th December 1984 Professor Ludlam wrote to patients to invite them to a meeting. The letters said that the purpose of the meeting was to *"discuss with patients some of the anxieties and issues that have been raised regarding AIDS."*

[349] A very small number of patients "*when asked if they would like to know the result were adamant that they did not wish to know."* As a result they only learned of their condition at the end of 1986 and in January 1987. [Transcript 03.12.2020,p19-20]

[350] Professor Ludlam, [Transcript 03.12.2020 p5] At the meeting, Professor Ludlam, Dr Forbes and Dr McClelland gave presentations setting out *"all that we knew at that time...We were very open about the situation, about the testing and particularly that we had results that we would be happy to share with the patients if they would like them."*

[351] Professor Ludlam [Transcript, 03.12.2020 p6]

181. The fact that the meeting was prompted by imminent newspaper publication serves to underscore the urgent imperative for the affected patients to have been informed earlier. That news of such alarming events as these would eventually enter the public domain, whether by means of investigative journalism or otherwise, must have been foreseeable given the nature of the information concerned. In these circumstances, the Boards regret the apparent lack of effective corporate oversight throughout this process, such as would have been a pre-requisite for ensuring an appropriate and timely response to events.[352]

182. By the time the group meeting took place at Edinburgh Royal Infirmary on 19th December 1984, Professor Ludlam had known of the results for almost two months without telling any of the patients. It was only then that the process of informing patients who had tested positive began. Given that patients were known to be infectious, and the disease was known to be sexually transmissible, the natural question would be to ask the reason for the delay. When asked this question in evidence, Professor Ludlam replied: *"I think the implications of it all were so enormous, actually, that it took us a bit of time - for it all to sink in and for us to think of the best way of responding….there were a series of meetings, and I was keen to gather as much wisdom and help and advice as I could so that I could help the patients as I thought was best"* [353] In response to a question from the Chair, Professor Ludlam agreed with the description that he was in the position of "*not quite knowing where to turn; just trying to work out, come to terms with the situation.*"[354] In the Boards' submission, it would be fair to conclude that Professor Ludlam's actions during this episode were principally motivated not by any lack of concern or indifference on his part but, on the contrary, a genuine determination to reach the correct decisions around management of the infected patients and their families. It is accepted, of course, that the consequent delay in informing patients had quite the opposite result.

[352] In the intervening period corporate governance and oversight within the health services have evolved and improved enormously in comparison to the arrangements in 1984.
[353] Professor Ludlam, [Transcript 02.12.2020, p87]
[354] Professor Ludlam, [Transcript 02.12.2020, p97]

183. The delay in informing infected patients of their test results can now be seen to have been an error of judgement. As Professor Ludlam acknowledged, it should not have happened[355] and he expressed regret for failing to act more promptly, saying: *"I wish I had been more proactive in encouraging patients to come up and find out about their HTLV-III results."*[356] The Boards deeply regret the delay and the inevitable suffering that will have caused to the patients and their families. In the Boards' submission, it is self-evident that decisions of this magnitude should not have been left to a single individual clinician to make and manage in relative isolation, without the necessary advice and support which both doctors and patients were entitled to expect from the Board as the employer and treatment provider. The Boards are sorry that Professor Ludlam was not better supported during this process.

HIV TESTING – GLASGOW ROYAL INFIRMARY

184. In around July 1984, some 77 stored blood samples from patients at Glasgow Royal Infirmary were sent to Dr Gallo in the United States for the purposes of HIV testing.[357] As with Edinburgh, this appears to have been done without the knowledge of the patients involved. In September or October 1984, results were received indicating that 12/77 patients (16%) had tested positive.[358] In around November 1984 an article was written for the Lancet by Forbes et al describing these results, which was published on 29th December.[359] At this stage, the patients concerned had yet to be

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[355] Professor Ludlam said: *"...it was a very difficult time and certainly I do see that, in retrospect, maybe we should have done things differently."* [Transcript 02.12.2020, p89]

[356] Professor Ludlam said: *"...if there hadn't been the Yorkshire Post and the need to have – or the way I had responded, by having the meeting in 19 December 1984, then the process of informing the patients would have rolled out in a much more reasonable and controlled way, and I think patients would have been better managed as a group."* [Transcript 04.12.20p152 – 153]

[357] Professor Lowe [Transcript, 10.12.2020 p10-11; 65-68]

[358] The Penrose Inquiry found that 12 patients contracted HIV infection while attending at the Glasgow Royal Infirmary Haemophilia Centre. Ten of the 12 patients had Haemophilia A (eight severe and to moderate) and two had haemophilia B. It appears that 3 of the patients were probably infected by an SNBTS product. Professor Lowe, [Transcript, 10.12.2020, p93]

[359] The Lancet, December 1984 *HTLV-III sero-positivity in European haemophiliacs exposed to Factor VIII concentrate imported from the USA*. The article stated: *"In Scotland 11 (18%) of 62 haemophilia A patients and 1 (7%) of 15 haemophilia B patients were HTLV-III positive. All but 2 of the seropositive subjects were known to have received commercial factor concentrate in the period 1979 -84."* Professor Lowe [Transcript, 10.12.2020 p10-15] [PRSE0001630]

told of the results.[360] A draft letter to patients dated 8 January 1985 was written under the names of Dr Lowe and Dr Forbes, which drew attention to the risk of AIDS and advised *inter alia* that 10% had positive antibody tests, enclosing an invitation to an appointment. However, on the evidence it is not entirely clear whether this letter was actually sent to patients at that time.[361] A revised draft of the letter was written in April, in the same month as confirmatory testing was carried out.[362] In his evidence, Professor Lowe said it was possible the January letter may not have been sent out until the redrafted version was produced in April following a discussion at the UKHCDO Working Party on 11 April. However, the Inquiry may find Professor Lowe's evidence to have been inconsistent on this point. He later stated that he was "pretty sure" that letter which was drafted in January was also sent in January.[363]

185. The absence of detailed evidence from Dr Forbes makes it difficult to construct such a comprehensive timeline as Professor Ludlam was able to provide in relation to events in Edinburgh. Unfortunately, however, the available evidence in relation to Glasgow Royal Infirmary, as set out in the preceding chronology, shows a delay of, at the very least, 3 months, between Dr Forbes receiving news of the seropositive tests for antibody in 16% of his patients and the first of those patients being told.[364] On any view, there was clearly a lengthy delay, indeed even more so than that which occurred at Edinburgh. On the evidence, it appears there was no good reason why the letter that was written in January 1985 could not have been sent out when the results were first received in September or October 1984.[365] In the Boards' view, it is difficult to overstate the importance of patients being promptly advised of their

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[360] Professor Lowe said in evidence: *"Dr Forbes, I think, was in a very difficult situation…he had reservations about whether the tests were accurate or not, and he did want authoritative tests."* However, Professor Lowe accepted that as a matter of principle that the proper course would have been to tell patients about their results, before placing any information about those results in the public domain. He thought Dr Forbes was "*balancing the need to publish the information in the public interest"* and that *"things were moving very fast…and Dr Forbes was quite conflicted as to publishing the information and his duties to the patient."* [Transcript 10.12.2020 p26-29] PRSE0000859

[361] Professor Lowe [Transcript 10.12.2020 p40 – 41; 67 – 68; 71] Rule 9 statement paras 41.5 – 41.6 [WITN3496013_0090]

[362] Professor Lowe [Transcript 10.12.2020 p38]

[363] [Transcript 10.12.2020 p33; 40 -41; 67; 71] Rule 9 statement paras 41.5 – 41.6.

[364] In light of that, Professor Lowe's description of Dr Forbes's letter as *"very prompt"* cannot be sustained. [Transcript 10.12.2020 p70; 81-82]

[365] Professor Lowe could not think of any [Transcript 10.12.2020 p88]

diagnosis in these circumstances. According to Professor Lowe, there were significant concerns about the reliability of the antibody test. Dr Forbes was anxious to be able to offer patients a validated test.[366] However, standing the obvious urgency, a possible risk of a false negative or positive test result would not provide justification for a delay in giving such information until a confirmatory test became available from Dr Follett's Regional Virus Laboratory in April 1985.[367] Nor would waiting for a proper system for counselling and treatment of infected patients, important though such would be. In this case, there was, in addition, clearly an additional risk to consider, namely that publication in the Lancet would result in patients discovering about the possibility of infection through the media.

186. For all these reasons, the delay in informing patients at Glasgow Royal Infirmary of their diagnosis undoubtedly amounted to an error of judgment. The Boards deeply regret these delays, and the additional suffering caused to patients and their families as a result. They are also sorry that Dr Forbes and his colleagues were not better supported during this process. In this regard, the observations made above [at paras 181 and 183] in relation to the lack of the requisite corporate oversight and clinical governance in Edinburgh are accepted to apply with equal force in relation to the emerging situation in Glasgow.

187. An issue arises as to whether publishing the results of tests before these had been communicated to the patients who had tested positive might be justifiable, on the basis of a doctor's duty towards public health taking precedence over his duty to the patient. Having regard to Professor Lowe's evidence on this issue in particular, the Boards wish to state that they do not agree with his position on this matter.[368] Insofar

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[366] Professor Lowe [Transcript 10.12.2020 p25-26; 35 – 36; 79 - 81] In his rule 9 statement, Professor Lowe cited an article written by Dr Follett (Virology of HIV Testing. Scottish Medical Journal, 1987, 32,113) in 1987 which stated: *"An HIV-1 positive test result has such traumatic consequences for the patient that the most sensitive and specific confirmatory test should be used. No positive result should be notified to a clinician before the result has been confirmed and a patient must not be informed of a positive finding based solely on an ELISA test result."* However, in October 1984 when the initial results were received, no such confirmatory test was yet available to Dr Forbes [para 75.2, WITN3496013_0120. Transcript 10.12.20 at 87]

[367] Professor Lowe recalled that there was one 'query' positive result, which was confirmed as negative on subsequent confirmatory testing [Transcript 10.12.2020, p88 – 89]

[368] Professor Lowe said: *"I think the first obligation of testing a sample of stored serum samples in patients with haemophilia, or any other group that is an at-risk population, to establish the extent of a new infection and take*

as infected patients were all potentially capable of infecting others with the disease, the interests of both the patients and of public health would be best served by providing prompt diagnosis and advice, such as to enable patients to regulate their conduct so as to avoid further spread of the infection. The Boards do not view the obligations owed to the patient and their public health duties in these circumstances as being mutually exclusive.

HIV TESTING – ROYAL HOSPITAL FOR SICK CHILDREN AT YORKHILL

188. Professor Hann at Yorkhill Hospital operated a proactive policy, whereby parents were informed at their next clinic attendance (whether spontaneous or planned) after a positive test result was received from Dr Follett.[369] According to Dr Pettigrew, this would usually be within four weeks of their receiving the test result[370] In Professor Hann's view, it was *"not appropriate"* to convey such information by letter, particularly since parents *"were already all very worried indeed."* In addition, it was necessary to advise on universal precautions and information in relation to symptoms.[371] The governing principle for counselling the families was to tell them the truth, at least to the extent that was then known.[372] The evidence of Dr Anna Pettigrew brought home what a distressing experience these discussions were, both for the doctors and, most of all, the parents.[373] As noted above, evidence given to the Penrose Inquiry indicated that a total of 21 children were infected with HIV as a result of their treatment at Yorkhill.

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appropriate action to turn off the tap, to stop any further patients being infected is a priority." [Transcript 10.12.2020, p76 to 81]

[369] It appears the process of telling parents probably began in May 1985, Dr Anna Pettigrew [Transcript 07.12.2020, p77] Professor Hann [Transcript 08.12.2020 p86]

[370] Dr Anna Pettigrew [Transcript 07.12.2020 p76] Professor Hann said, *"we would make sure that this was done within a six-week maximum period and preferably before."* [Transcript 08.12.2020 p88]

[371] Professor Hann said *"...I remember it quite well because it was a very difficult decision. To be honest with you, neither of us knew the best way to do this."* [Transcript 08.12.2020 p87-88]

[372] Professor Hann said: *"Throughout my career I looked after hundreds of children with leukaemia…and we always had one mantra, which was really, first of all, whatever you tell them has to be the truth, not necessarily the whole unvarnished truth, if it's just frightening, but it really has to be given in that way."* [Transcript 08.12.2020, p93]

[373] Dr Pettigrew said: *"It was a very, very distressing experience , because we knew these mothers, we knew these children, and it was a very distressing experience to have to explain to the parents that this had happened to their child. It was an awful time, a far worse time for those parents but it was an awful time for all of us who were involved in their care...I knew that some of these children had died and it was just an awful, awful, awful tragedy."*[Transcript 08.12.2020, p88-89]

189. The fact that a confirmatory test had not yet been carried out was not allowed to delay the process of informing patients. At the appointment, parents were typically advised that their child had been infected with the HTLV-III virus, albeit that a confirmatory test was required. It was also explained that it was not yet known how many patients who tested positive would go onto develop AIDS.[374]

190. However, Professor Hann was quite self-critical in relation to the lack of arrangements for pre-test counselling.[375] He wished he had he explained to patients the process for testing the samples in more detail in advance. He considered that doing so would have given an opportunity for open discussion of a whole series of questions which were not adequately dealt with at the time, such as the implications of positive and negative results. He acknowledged that the circumstances made this particularly difficult for both the doctors and patients.[376] He considered that with better pre-test counselling *"it would probably have come as less of a shock to families because they would have been better informed about potential outcomes."* The insights gained from this experience were at the forefront of his mind when conducting Hepatitis C testing at Great Ormond Street Hospital in 1990. In that respect, Professor Hann's evidence perhaps exemplified the effect of the emergence of HIV in encouraging a greater recognition within the medical profession of the importance of pre-test counselling.

191. Professor Hann also regretted there were occasions when only one parent was informed, typically the boy's mother, as a consequence of the procedure for advising of the test results. As he explained, this was *"far from ideal...as probably I should have realised. There was at least one case…where this caused unnecessary*

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[374] Dr Anna Pettigrew [Transcript 07.12.2020 p76]

[375] Professor Hann said *"I greatly regret that I didn't spend more time – or at last realised there was gap at the time"* [Transcript 08.12.2020, p155]

[376] Professor Hann said: *"it really is a difficult situation, telling people about potential terrible news when actually it might well not be relevant. It's not an easy thing to do, to deal with uncertainty which goes from one pole to another: life changing. To just carry on…there were no complaints at the time and I'm amazed. I suppose they were just so dependent on us that they would not complain. And that's a matter of event greater regret. But the fact is, you know, they would have been better informed, they would have been stimulated, if you like, to ask more questions and to be better informed."* [Transcript 08.12.2020,p155 – 156]

suffering." Professor Hann said that *"On a balance, I think in retrospect it would have been better to bring them up to clinic visits over a period of a couple of weeks."*[377]

192. For the reasons explained by Professor Hann, the children were not informed of their diagnosis directly by him due to the potential trauma involved.[378] In order to ensure that appropriate counselling facilities were available for children he recruited a social worker and nurses with expertise in counselling. He also arranged external referrals for psychological treatment to a child psychologist and a psychiatrist.[379] Such an approach reflected Professor Hann's strong and instinctive preference for an ethos based on teamwork rather than that of the 'consultant king.'[380] In that, amongst other respects, his approach to clinical care was seen to be notably forward-thinking, in the Boards' submission.

193. In common with other haemophilia clinicians in Scotland, Professor Hann was particularly sensitive to issues of stigma and prejudice arising in consequence of an HIV diagnosis.[381] As he explained to Penrose, *"We fought constant battles on behalf of our patients to prevent them being treated as lepers."* Consistent with evidence given elsewhere at the Inquiry, it was clear that such attitudes were to be found within the NHS, as was the position in wider society more generally. Hospital policies were promulgated which both reflected and encouraged these, such as blanket procedures for reverse barrier nursing of haemophiliacs.[382] Perhaps unsurprisingly in light thereof, portering staff at the hospital refused to assist children with AIDS.[383] Laboratory work gave rise to particular difficulties. Moreover, the problem did not

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[377] Professor Hann, [Transcript 08.12.2020 p89-90] Dr Pettigrew gave evidence to similar effect [Transcript, 07.12.20 p85-86]

[378] Professor Hann said: *"with regard to imparting information which could be extremely frightening, especially to very young children, even as a …full y trained paediatrician, this is not something that one should ever take on lightly. It requires specific training, specific counselling training."* [Transcript 08.12.2020 p97 - 98]

[379] Professor Hann, [Transcript 08.12.2020, p93 – 94] Professor Hann acknowledged that the psychology departments to which referrals were made were in themselves under-resourced.

[380] *"I really must emphasise, there was no question of me being the senior person there. I was responsible but we worked as a team."* Professor Hann [Transcript 08.12.2020, p93]

[381] Professor Hann, [Transcript 08.12.2020, p101 – 104]

[382] *"There was a hospital policy… I can't remember if it ever happened, when any child had haemophilia, no matter what was wrong with them, had to be reverse barrier nursed, which means they got their food on paper trays."*

[383] Professor Hann recalled: *"I ended up one easter putting children into radiology myself because nobody would take them."*

appear to be confined to junior members of staff, exemplified by Professor Hann's recollection of *"a terrible run in with a deputy chief medical officer who was a public health doctor who wanted the list of our patients so that he could disseminate them to all dental surgeries so that they didn't get infected by our patients."*

194. This echoed the stigma and prejudice faced by haemophiliacs at a time when alarmist media coverage and government information campaigns were generating widespread fear and hysteria within society more generally. Professor Hann's evidence on this melancholy and disturbing theme echoed that of many of the infected and affected.[384] As he explained, *"a number of bad things happened…they may seem trivial but they are incredibly important to the families. And I could list them forever…extreme difficulty in travel. They couldn't get travel insurance. When they grew up, of course, they couldn't get mortgages…they couldn't get through customs because they had needles, et cetera, and were defined in that way. Within the society in general…They were ostracised in schools. Some children had to be taken out or change schools. It was extremely difficult."*

195. Efforts were made to combat the stigma, and the attitudes described were far from universal. For example, Dr Pettigrew gave evidence that "*the sister who ran the ward would not have tolerated any distinction between the patients."*[385] However it was revealing of the level of concern on the part of the doctors that the HIV test results were initially deliberately omitted from patent records on account of the stigma associated with AIDS, the *"hysteria"* evident amongst hospital employees and concerns that this highly sensitive and confidential information would be distributed out with the hospital.[386] In an effort to assist in addressing the particular problems in schools, Sister Murphy and Dr Pettigrew visited schools to provide information in relation to haemophilia and address the stigma associated with HIV.[387]

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[384] Professor Hann, [Transcript 08.12.2020, p101 – 104]
[385] Dr Anna Pettigrew [Transcript 07.12.2020,p98]
[386] Dr Anna Pettigrew [Transcript 07.12.2020, p88]
[387] "*They also educated the schools in relation to measures to be taken to prevent transmission of hepatitis.*" Dr Anna Pettigrew [Transcript 07.12.2020, p118-119]

196. Overall, however, the effect of stigma in compounding the already immense suffering experienced by families as a result of the infections cannot be overstated. In the poignant words of Dr Pettigrew: *"To my mind , there's no greater tragedy for a parent than the loss of a child, and to watch that child suffer and die from a dreadful illness; and often, because of the associated stigma, without the support of the extended family and friends, the effects on families were far reaching. There were long-lasting emotional and physical problems not only in the children affected but in their siblings and their parents."* [388] This only served to aggravate and compound the awful suffering experienced by the children and their families.

HIV treatment

197. According to information given to Penrose, a total of 12 bleeding disorder patients at Glasgow Royal Infirmary were found to be infected with HIV by treatment at the centre.[389] However, other patients who became HIV positive through treatment at Yorkhill Hospital or at other UK Centres were subsequently transferred to the GRI. It therefore appears that a total of 23 patients with HIV were registered at the Haemophilia Centre there between 1982 and 1995.[390]

198. In Glasgow, an appropriate system for treatment and counselling of patients with HIV was developed by Dr Forbes. In early 1985, after the initial test results were received, Dr Forbes appointed an experienced counsellor to provide pre-test and post-test counselling to patients in relation to HIV. According to Professor Lowe, patients who tested positive were given detailed advice on the significance of the diagnosis, including the risks of developing symptoms of AIDS and potential transmission risks. Patients who tested positive were reviewed at joint clinics at the Centre attended by Infectious Disease Consultants from Ruchill Hospital[391] Psychological counselling was available by means of referral to a Consultant Psychologist in the AIDS service at

[388] Dr Anna Pettigrew [Transcript 07.12.2020, p132]
[389] Penrose Executive Summary, p9; Professor Lowe, rule 9 Statement para 58.2
[390] Professor Lowe, rule 9 statement para 58.3
[391] Professor Lowe, rule 9 statement, para 53.1

Ruchill Hospital.[392] When the Infectious Diseases Department and Wards moved to the new Brownlee Unit at Gartnavel General Hospital in 1997, the patients' HIV treatment was transferred to the new facility, which was more accessible to the HIV support services based at that site.[393]

199. A broadly similar strategy was evident in the approach adopted at Edinburgh Royal Infirmary, where 23 patients became infected with HIV.[394] Drawing on his experience in managing immune-suppressed patients with leukaemia (including in preventing and treating 'opportunistic infections') Professor Ludlam was able to continue to provide out-patient and in-patient care to those infected.[395] In this he was assisted by Dr Brettle, an Infectious Diseases consultant with expertise in the management of HIV infected patients, who advised in relation to the treatment of each infected patient.[396] When treatment with prophylactic pentamidine inhalations became recommended, a room at the Centre was converted with suitable equipment to enable patients to receive the therapy. Subsequently, this was replaced by oral cotrimoxazole. Professor Ludlam also applied for patients to be involved in the clinical trial of AZT so as to be able to offer as many therapeutic options as possible. As more new treatments for HIV became available, Professor Ludlam concluded that he no longer had the expertise to fully manage their therapy. [397]Dr Brettle took over the management of this aspect of patients' treatment, based at his clinic at the Infectious Diseases Unit at the Western General Hospital.[398] In the view of the Boards the systems put in place for treatment of patients by those like Dr Forbes, Dr Ludlam and Professor Lowe were not only well intentioned and designed to give a good level of open access service to patients and their families but, overall, may be

[392] Professor Lowe r9 statement para 54.1
[393] Professor Lowe r9 statement para 83.4
[394] Penrose Executive Summary, p9
[395] In 1985, the Haemophilia Centre was viewed locally by some as being the expert "AIDS Centre" and some non-haemophilia patients were referred for investigation and management. As Professor Ludlam explained, in 1985 there was no specific therapy for those infected with HIV and the patients were keen to continue to be evaluated at the Haemophilia Centre rather than referred to the Infectious diseases unit. [Professor Ludlam, rule 9 statement, para 369]
[396] Professor Ludlam, rule 9 statement para 45
[397] Professor Ludlam, rule 9 statement para 373
[398] Professor Lowe, rule 9 statement para 54.1

considered to have met or even exceeded the accepted standards of care for the time.

Testing & treatment arrangements – Hepatitis

200. Prior to the availability of a Hepatitis C test, haemophilia centres in Scotland routinely monitored patients receiving blood products for hepatitis, both clinically and by laboratory tests (including for Hepatitis B and liver function tests.)[399] According to Professor Lowe, patients at Glasgow Royal Infirmary were advised of information from biopsy studies indicating that an increasing percentage of patients with NANB hepatitis had progressive liver disease, with risks of subsequent cirrhosis and liver cancer, as was also the case with Hepatitis B. In about 1987 when a small number of patients started to develop clinical features of cirrhosis, patients would be given information in relation to the significance (risks of cirrhosis and possibly cancer), prognosis and management.[400] At Edinburgh, from 1986 joint clinics were arranged with a hepatologist, Dr Peter Hayes when the evidence as to the long-term prognosis of the condition became clearer.[401] Prior to this Dr Niall Finlayson, Consultant Hepatologist, saw patients and provided guidance.

201. In addition, all patients were assessed regularly for Hepatitis B infection. For the "very small" number of patients who had active Hepatitis B, their investigation and management were overseen by Professor Hayes or one of his senior colleagues.[402] The number of patients with Hepatitis B at Glasgow was also low. Professor Lowe recalled that in the period 1975 – 1978, there were four or five patients who were carriers of Hepatitis B attending the Glasgow Centre and one further patient was detected in 1984.[403] The Hepatitis B vaccine was given to patients in 1985.

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[399] Professor Lowe rule 9 statement, para 64.1.1

[400] In terms of prognosis, from 1985 patients with presumed NANB hepatitis were advised as 'a fairly definite estimate" that 13 – 15% of patients who had biopsies had shown evidence of cirrhosis or serious liver disease, based on the Hay and Aledort papers of 1985. Professor Lowe [Transcript, 11.12.20 p21] Professor Lowe, rule 9 statement para 65.2.

[401] Professor Ludlam [Transcript 04.12.2020 p55] rule 9 statement, para 380.

[402] Professor Ludlam, rule 9 statement, para 378

[403] Professor Lowe, rule 9 para 61.1

202. It appears that it was generally considered unnecessary to undertake "HIV type" counselling prior to testing patients for Hepatitis C.[404] Instead, centres such as Glasgow Royal Infirmary proceeded on a similar basis as when testing for Hepatitis B and liver function tests, with which most haemophilia patients were by then familiar. In practical terms, that meant telling the patient there was a test now available that would be used, but not to ask for their express consent or any detailed discussion of the implications of testing. Professor Lowe explained that this was consistent with the approach taken across the UK and recommended by UKHCDO: "*You just did the test and got on with it.*"[405]

203. At Edinburgh Royal Infirmary, Professor Ludlam acted promptly to conduct first generation antibody tests on some patients in 1989 or 1990. However, Professor Ludlam rapidly discovered shortcomings in the first-generation antibody, which showed the potential for both false positive and false negative results.[406].For that reason so as not to give misleading results, patients were not given the result of the first generation test. Instead, they were informed of the diagnosis only after the more reliable second generation test had been carried out. This occurred from 1991 onwards using stored samples and without patient knowledge or consent. At that stage patients were informed that what had previously been referred to as 'hepatitis or non-A non-B hepatitis' was now identified as Hepatitis C. While such an approach obviously resulted in a delay in patients receiving their test results, the effect of that was mitigated by the fact that, as Professor Ludlam put it, this *"was not a new diagnosis, but rather a renaming of the condition"* that they were already aware of.[407] The results of the tests would be explained at patients' next clinic visit, or earlier if it might be appropriate to inform the patient of the result sooner.[408]

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[404] Professor Lowe [Transcript, 11.10.2020 p3-4; p6]
[405] Professor Lowe [Transcript, 11.10.2020 p3-4; p9 - 10]
[406] This problem was also found in other patient cohorts. See: Makris et al *Hepatitis C antibody and chronic liver disease in haemophilia* Lancet Volume 335, Issue 8698, 12 May 1990, Pages 1117-1119 It is noteworthy that this was the first important paper on the incidence of HCV infection in UK haemophiliacs.
[407] Professor Ludlam [Transcript 04.12.2020 p49-53]
[408] For example, if there was evidence of a new infection of acute hepatitis, especially Hepatitis B, because of the risk of spreading the infection to other individuals. [Professor Ludlam, rule 9 statement, para 287]

204. At Glasgow Royal Infirmary, testing began with the antibody test for Hepatitis C, which Professor Lowe recalled was first available in 1991, undertaken at the Regional Virus Laboratory.[409] Initially they used the antibody test and later the RIBA-2 confirmatory test. All patients were tested, with samples taken at routine clinic appointments, or at the first opportunity if they came in for treatment.[410]

205. In terms of treatment for Hepatitis C, patients at Edinburgh Haemophilia Centre were seen at combined clinics in the Haemophilia Centre between the hepatologist Dr Hayes, and a haemophilia clinician. Dr Hayes, after review of the patient, suggested investigations, treatment and its monitoring. Treatment with interferon, and later ribavirin was offered. A patient information sheet on Hepatitis C was given to all patients and a detailed check list was used for each patient to ensure appropriate counselling and investigations had been arranged.[411] At Glasgow, all patients who turned out to be carriers of the disease were referred to the liver clinic run by Dr Mackenzie initially and then, from 1996 onwards by Dr Morris who set up a comprehensive Hepatitis C service.[412] Subsequently a joint clinic was established at the haemophilia centre, with a specialist hepatologist and Hepatitis C nurse in attendance to oversee the prescription of interferon treatment.[413] The Inquiry has heard harrowing evidence of the often intolerable physical and psychological side-effects caused to patients by the early treatments, and the devastating effect on daily functioning and quality of life. Having endured this ordeal, patients' suffering was only compounded when, all too often, the treatment failed to clear the virus. The marked contrast with currently available treatments, being both efficacious and easier to tolerate, only serves to underscore the poignancy of the evidence the Inquiry has heard about this significant aspect of the disease.

206. In terms of counselling and psychological support, an important positive development at Edinburgh was the creation of a haemophilia sister post in 1982.

[409] Professor Lowe [Transcript 11.12.220 p11 – 13]
[410] Professor Lowe [Transcript 11.12.220 p14]
[411] Professor Ludlam, rule 9 statement para 380
[412] Professor Lowe [Transcript, 11.12.20 p11-13]
[413] Professor Lowe [Transcript, 11.12.20 p28 - 29]

Social work support was given through the Royal Infirmary social work service, which had the advantage of being based in the hospital.[414] A clinical psychologist, Dr Alison Richardson was also recruited, and a Consultant Liaison Psychiatrist reviewed and managed patients on a referral basis. In addition, two clinical assistant medical posts were created to undertake routine patient review in response to increased clinical needs in 1985. In a relatively early example of multi-disciplinary working, the clinical assistants carried out their duties as part of a team, along with the social worker, haemophilia sister and nursing staff to provide support to patients.[415]

207. In Glasgow Royal Infirmary, a haemophilia sister post was established in 1980, at the start of home treatment provision. Social work support was given through the Royal Infirmary social work service from the 1970s. A haemophilia staff nurse was appointed in 1987; and a clinical assistant post to undertake routine patient review in response to increased clinical needs in 1992. As in Edinburgh, there was multidisciplinary working of this team from the 1980s, including a physiotherapist and rheumatologist for musculoskeletal complications of haemophilia.

208. In the opinion of the Boards the testing and treatment arrangements in relation to hepatitis in Glasgow and Edinburgh were not only well intentioned but, overall, may be considered to have met or even exceeded the accepted standards of care for the time.

Diagnosis of hepatitis infections acquired from blood transfusions

209. The Penrose Inquiry estimated that 2,500 patients were infected with HCV by this means prior to the introduction of blood donation screening in 1991.[416] In addition, 18 patients were infected with HIV by blood transfusion. Many of those patients were exposed to infections by receiving transfusions of blood or blood components

[414] Professor Ludlam, rule 9 statement para 392
[415] Professor Ludlam, rule 9 statement para 392 - 394
[416] Penrose Inquiry Final Report, para 2.1

in the course of surgical procedures or other non-routine medical care, where there were no particular arrangements for routine follow up by way of testing or monitoring of the kind available, for example, in the context of haemophilia care.

210. In this regard, the Inquiry has heard multiple accounts from patients and their families of difficulties and delays in obtaining a diagnosis after developing symptoms of the disease. It is important to recognise that many of those affected in this way were women, often infected through transfusions given for intra-partum or post-partum complications. In some cases, symptoms were misattributed to unrelated causes. Following diagnosis, questions from doctors about lifestyle factors such as drug use and promiscuity could make patients feel stigmatised, or anxious that the true source of their infection had not been recognised. Moreover, the Inquiry has heard evidence of numerous instances where lengthy and apparently unexplained delays may have occurred in communicating a diagnosis to patients following testing. Some patients infected during the 1980s were only diagnosed following the UK-wide look-back exercise undertaken in 1995.

211. Finally, the Boards wish to record their sympathy and regret for the suffering experienced by patients as a result of delays in diagnosis, and it follows, in access to NHS treatment, for patients infected with Hepatitis B and Hepatitis C through blood transfusion.

CHAPTER 7: RECOMMENDATIONS

INTRODUCTION

212. In terms of the Inquiry's Guidance, the written submissions should set out any recommendations we invite the Chair to make, including recommendations as to compensation. We are also asked to set out our position (if we have one) as to why particular recommendations should or should not be made. We address these matters in this chapter. We make no submission about compensation.

213. In our June Submission, we identified several outline substantive recommendations for the consideration of the Chair and other Core Participants. We also set out something of the background which led us to suggest those recommendations. Having had an opportunity to reflect further on the matter, the Boards now wish to adopt all of their suggested recommendations in this final written submission. For ease, we set them out in full below.

214. Furthermore, whilst reflecting on the Boards' own recommendations, the Boards' Medical Directors have also taken time to consider the outline recommendations put forward by Thompsons solicitors on behalf of the families in their June Submission. They are broad in scope and very detailed. At least to some degree, there appears to be areas of overlap with the Boards' own recommendations. The Boards wish at this stage to offer some brief overview comments on these recommendations. These comments are not intended to be exhaustive but it is hoped that they will be of some assistance to the Chair in his consideration of the matters at this stage. If further clarification or information is required, we would, of course, be very happy to provide that. Finally, we reiterate all that was said in our June submission, and are more than happy to provide whatever other assistance we can to the Chair in considering what recommendations he wishes to make.

THE BOARDS' RECOMMENDATIONS

215. We have articulated our recommendations under the following headings: (i) background; and (ii) recommendations

Recommendation 1 – Reporting of Adverse Events

216. (i) Background:

For treatment of bleeding disorders, Health Boards in Scotland report via the MHRA yellow card scheme but also have regular adverse event reporting to the UK National Haemophilia Database (NHD) which itself then reports (in an anonymised manner) to

EUHASS (European Haemophilia Safety Surveillance). EUHASS prospectively monitors for adverse events related to treatment. It is not known whether all Haemophilia Centres in the UK report in this manner. Furthermore, where they do, it is our experience in Scotland that staffing pressures (both clinical and administrative) can on occasion lead to delays and potentially incomplete reporting.

(ii) Recommendation

Alongside routine pharmacovigilance measures, the reporting of adverse events to the National Haemophilia Database (NHD) with onward anonymised reporting to European Haemophilia Safety Surveillance (EUHASS) should be encouraged or mandated in line with appropriate consent practices. The clinical and administrative staffing necessary to facilitate a consistently high standard of adverse event reporting should also be ensured at all UK Haemophilia Centres. These measures would ensure continuation of the current enhanced surveillance for any emerging issues relating to historical, or current, treatments for people with bleeding disorders.

Recommendation 2 – Psychological Support for the Infected & Affected

217. (i) Background

NHS Scotland currently provides vital, dedicated psychology support for the infected and affected, as well as to other patients and families affected by bleeding disorders. This support is provided via the Scottish Haemophilia Psychology Support Service and the Scottish Infected Blood Psychology Service. In terms of the Haemophilia Psychology Support Service, funding has not been assured beyond 2024. So far as elsewhere in the UK is concerned, it is understood that access to dedicated psychology support services is currently variable.

(ii) Recommendation

The Boards recommend that specialist psychology support should be directly available via all Haemophilia Centres for infected and affected members of the bleeding disorders community. In addition, easily accessible specialist support

services should be available for those infected and affected by blood transfusion associated infections. To ensure ongoing provision and avoid geographical inequality, either local service commissioners should be recommended to provide long-term funding for these specialist psychology services, or centralised funding should be recommended

Recommendations 3 – Specialist Bleeding Disorders Physiotherapy Services

218. (i) Background

Joint damage with associated pain and loss of function is a major cause of physical morbidity for people with bleeding disorders. It also has an adverse impact upon the psychological health of a patient group already badly affected by the consequences of treatment-associated infection. Specialist physiotherapy is recognised as a core part of haemophilia care with respect to assessment and optimisation of joint health. Availability of access to this varies greatly across Scotland and the rest of the UK and, where unavailable, this is recognised as a significant clinical need.

(ii) Recommendation

In order to optimise joint health for patients with bleeding disorders, and to reduce regional inequality in this regard, either local service commissioners should be recommended to provide funding for specialist bleeding disorders physiotherapy services or centralised funding should be recommended.

Recommendations 4 – Regional Networks of Haemophilia Clinicians

219. (i) Background

As bleeding disorders are rare, most Haemophilia Centres only have a small number of dedicated specialists.

(ii) Recommendation

In order to help clinicians with decisions regarding complex cases, and to assist in policy decisions at individual centres, service commissioners should support the setting up (if appropriate) and the running of, regional networks of clinicians. These networks should provide regular forums for case and policy discussion for clinicians. The necessary administrative and clinical resources should be provided. A forum for patient involvement in policy decisions should be available within such networks. The Scottish Haemophilia Centre Directors' Meeting (which is held on a bi-monthly basis) is an example of such a network which is already in operation; in relation to it, patient input comes via the Scottish Inherited Bleeding Disorder Network (SIBDN).

Recommendations 5 – Developing Clinical Guidelines

220.(i*) Background*

*T*he UKHCDO and British Society for Haematology currently provide guidance on optimal treatment for people with bleeding disorders. Those organisations and the National Haemophilia Database also raise awareness of developments in patient safety concerns. This work is of great value in terms of both keeping clinicians up to date on best practice and enabling rapid identification of new safety concerns.

(ii) *Recommendation* – These national organisations should be supported with the resourcing necessary to carry out their roles in producing guidance on the optimal treatment of people with bleeding disorders and raising awareness of any developments or patient safety concerns amongst clinicians. They should be encouraged to continue with their valuable work, in broadening the scope of their guidelines and updating these as practice changes.

Recommendations 6 – Clinical Audit

221.(i) *Background*

West Midlands Quality Review Service (WMQRS) audited both Edinburgh and Glasgow Comprehensive Care Centres (CCCs) on behalf of the UKHCDO against the

UKHCDO standards in 2019.[417] The expectation thereafter was that further auditing would be "rolled out" across Scotland to include all of the Scottish Haemophilia Centres. Unfortunately, WMQRS went out of business during the pandemic. Prior to the UKHCDO audits, there had been regular (approximately every 3 years) peer review audits of Scottish Haemophilia Centres and this process was paused when the UKHCDO peer review began. There are currently discussions amongst the Scottish Haemophilia Centre Directors about restarting this process if there remains a lack of clarity in relation to when the UKHCDO process will restart.

(ii) *Recommendations*

Regular audit of standards of care should be performed in centres treating people with bleeding disorders. Peer review with patient representation, such as performed by the UKHCDO or else the Scottish Haemophilia Centres provides the optimal model in this regard. Subject to interruptions imposed by the pandemic, it is suggested that the optimal time interval for audits might be not less than once every five years.

Recommendation 7 – Prescription of Recombinant Coagulation Factors

222. (i) Background

Multiple measures have been put in place over time to improve the safety of coagulation factor concentrates. One of the greatest improvements has been the transition from plasma derived products to recombinant factor products. In the UK, recombinant factor is now almost universally prescribed where appropriate licensed products are available.

(ii) Recommendations

[417] An Edinburgh visit took place on 22nd January 2019; the report date was May 2019. The Glasgow visit took place on 15th and 16th May 2019; the report date was September 2019.

Recombinant coagulation factor products should be offered in favour of plasma derived ones where clinically appropriate. Service commissioners should ensure that such treatment decisions are funded accordingly.

COMMENT ON OUTLINE RECOMMENDATIONS PROPOSED BY CORE PARTICPANTS

223. We observe that some of the recommendations proposed in the submission on behalf of the core participant clients represented by Thompsons Scotland in June 2020 (referred to, for brevity, as "Thompsons' Recommendations") do not relate directly to the Territorial Health Boards' areas of responsibility. Where that is the case, it would be more appropriate for others to comment. For example, those recommendations which would require a recurrent funding stream for third sector organisations would be more appropriately commented on by central bodies.

224. In relation to the recommendations that do fall within the remit of the Boards, our overview comments fall into three main categories:

1. **Recommendations which will improve patient care and experience**.

225. There are a number of recommendations proposed which the Boards consider would improve the standards of care experienced by patients of NHS Scotland. The Boards agree in principle with these recommendations and consider that these can be delivered consistently across all of NHS Scotland:-

    a. Psychological support (called "psychosocial" support in section 6 of Thompsons' recommendations) As discussed above, this service is currently delivered for those affected and the Boards consider that there are opportunities to extend the support to those with bleeding disorders more widely. It has already been demonstrated that this service can be delivered effectively on a remote basis. The Boards have also submitted a proposed recommendation designed to secure ongoing and consistent service provision in this area. (See their recommendation 2 above)

b. Physiotherapy (section 7 Thompsons' recommendations) This is a highly valuable service and can be delivered on a networked basis, making sure expertise is available to practitioners closer to patients' homes. The Boards have also submitted a proposed recommendation designed to secure consistent service provision in this area. (See their recommendation 3 above)

c. Long-term monitoring of the affected and infected (section 11 of the Thompsons' submission) could be supported and undertaken by the Scottish Inherited Bleeding Disorder network and by local managed clinical networks

d. Testing of carers of individuals and their spouses with appropriate information, discussion and support can be undertaken through local arrangements (section 13 of Thompsons' recommendations)

2. **Recommendations where some modification may be necessary.**

226. There are also a number of proposed recommendations which, it is submitted, would require some modification from their current form, for example**,** to enable consistent and sustainable delivery across NHS Scotland:

a. Palliative care resources (section 12 Thompsons' recommendations) and delivery mechanisms vary across Scotland with integration in some, but not all, areas with local hospices and community teams. That expertise is specialised in its own right and relevant in considering the holistic needs of the individual. Those with advanced liver disease and associated conditions are best cared for within the existing palliative care services. However, facilitating giving local palliative care teams easy and reliable access to expert advice from haemotologists in relation to the particular and specialised needs of the individuals concerned would ensure the best advice can be followed by local teams.

b. Medical Records (section 23 of Thompson's recommendations): NHS Scotland Health Boards are expected to follow the national policy/legislation on this topic:

   i. All NHS organisations are obliged under Data Protection and Freedom of Information legislation to make arrangements for the safe keeping and eventual disposal of all types of their records. The records they create are subject to the Public Records (Scotland) Act 2011. The Scottish Government's *Health Records Services: Retention and Destruction of Personal Health Records Policy* of 2011 provides the framework by which Boards are able to meet these statutory obligations.[418]

   ii. The National Digital Health and Care Strategy is the approach Boards follow in developing aspects of this policy, such as enabling patient access to areas of the records.

   iii. There is already a clear mechanism for all records held about an individual to be released through a Subject Access Request.

   iv. Inevitably there are on occasion, tensions or lack of shared understanding between the patient's views about what should be recorded where and for what purpose and the views of the professionals. In most settings that can be reconciled through discussion.

   v. The Medical Records Act covers the creation of medical records for the purposes of providing a record of patient care in a wide range of settings completed by many disciplines of staff and often outwith any long-term or ongoing relationship between professional and patient.

3. **Areas where practice in clinical services has already changed**

[418] Health Records Services: Retention and Destruction of Personal Health Records Policy - gov.scot (www.gov.scot)

227. In the Boards' submission there are a number of proposed recommendations which relate to areas where improvements in practice relating to the delivery of clinical services have already been implemented in the areas where shortcomings have been identified. Such changes in practice have often been marked. It would be important that any recommendations which may be considered appropriate, or required at all, should take account of and reflect the current position in these areas. Examples include the following:

    a. Today, there is clear professional commitment to greater involvement of stakeholders in decisions about their care. The principles of Realistic Medicine and shared decision making are widely referenced and adopted across NHS Scotland.

    b. Testing for all individuals for all bleeding disorder patients and those receiving blood transfusion is widely available and not restricted

    c. The undergraduate and postgraduate curricula of many professions including nursing, medicine, pharmacy and clinical scientists covers events relating to the responsible use of blood and the attendant risks. Today, there is a clear focus on this, although most of the subject matter is not in the remit of the Royal Colleges. The terms "natural clearance" and "cure" referred to (paragraph 17.2) are not ones in common current use and their replacement with sustained virological response is congruent with current terminology (section 17 of Thompsons' submission)

    d. There has been extensive change in guidance policy and statutory expectations in Scotland regarding the following (see section 21 of Thompsons' submission)

        i. Complaints: all territorial health boards follow the NHS Scotland Complaints Handling Procedure, with recourse for patients to the Scottish Parliamentary Ombudsman

        ii. Whistleblowing: the National Whistleblowing Standards which came in to force in April 2021 are followed by all boards with an independently

appointed Non Executive Director for Whistleblowing and a review mechanism led by the INWO.[419]

iii. Organisational duty of Candour is set out in the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure (Scotland) Regulations 2018 and there is an obligation on each Board to publish and annual report and to lay this before Parliament

iv. Consent: the General Medical Council has recently set out its expectations for doctors in updated guidance *"Guidance on professional standards and ethics for doctors: Decision Making and consent"* brought into effect in 2020

v. The Scottish Government is out to consultation on the role of the Patient Safety Commissioner that they have announced

e. Research and patient and public participation: This is now a standard aspect assessed in most research studies and funding applications

228. These submissions are made in the hope that they assist the Chair in the preparation of his report. If there are any other matters in relation to which the Chair considers the Territorial Health Boards may be able to provide further assistance, they will be happy to do so to the best of their ability.

Simon Bowie KC

Barney Ross, Advocate

Instructed by NHS Scotland Central Legal Office

16 December 2022

[419] National Whistleblowing Standards | INWO (spso.org.uk)