THE INFECTED BLOOD INQUIRY

NHSBT: CLOSING SUBMISSIONS

CONTENTS

PRELIMINARY STATEMENT

The Inquiry's approach to its task

1. It is an important discipline, in all significant and long-term endeavours, for those involved to be able on occasions to step away from what is being dealt with in the moment so as to be able to review the exercise as a whole. Here, that is as true for a participant like NHSBT as it is for the Inquiry itself. Undertaking that task (for the purpose of drafting these submissions) against the backdrop of the Inquiry's work over the last 5 years or so, is very worthwhile. It is also, frankly, a humbling exercise.

2. This is both because of the nature and because of the extent of the Inquiry's achievement over these years of evidence gathering and presentation at hearings. That achievement is easy to lose sight of when one has been deep in the Inquiry process throughout. It has of course been in honouring the Inquiry's commitment to put the Infected and Affected, and their terrible experiences, at the heart of its investigation. But beyond that, it has also been in ensuring that those experiences – for so long, of course, unheard or ignored – are now woven into the fabric of all of the evidence it has called, from whatever quarter: from that of the individuals who suffered, and also from that of the politicians and civil servants, scientists, clinicians and experts, all of whom have also given such important evidence.

3. Thus, it is not just that (as a quick review of the witness list over the years would confirm) the Inquiry both commenced and then concluded by giving the Infected and Affected the opportunity to tell the stories of these experiences. It is also that – and this is what is *most* striking to those who have had the opportunity to attend the hearings throughout – it has achieved something that in prospect would have been surprising. It has given all taking part a strong sense of collective endeavour. This is certainly so from the point of view of NHSBT, which has throughout tried to deliver on its own promise of fulsome engagement and assistance. It is also so (NHSBT's representatives detect) across the range of Core Participants, whether Infected and Affected or not.

4. The seeds and indeed shoots of this sense of collective endeavour have been there all along. They were evident even at the opening hearings in Church House in September 2018; it was plain that there was a desire on the part of the participants as a whole for a positive approach. The atmosphere in the hearing room then was, initially, and perhaps inevitably, palpably tense. But even at that stage there was a striking generosity of spirit, which included a positive response in the room to what was said by those speaking for the institutional CPs, once they had demonstrably committed themselves to the Inquiry's task.

5. That spirit has continued throughout the last four years. Attendance at the hearings has been characterised on all sides by friendliness at an individual level and a gradually gathering sense of a common task in the job of getting to

the truth and ensuring that this sort of thing can never happen again. That this is so is itself perhaps the best testament to the task undertaken by the Chair and the Inquiry team, who have been assiduous in ensuring that the experience of those who have suffered is woven into its proceedings in the way described above.

The ramifications of that approach

6. All of this is of course precisely as it should be. It has made the task of NHSBT and its representatives that much easier to undertake; in terms both of the spirit in which it is done and of the ability to focus, without unnecessary distraction, or (worse) any sense of an adversarial approach, on the various common tasks in hand. It is important nonetheless for all - NHSBT, all other CPs, and most of all the Inquiry and its team - to bear in mind the additional ramifications of this approach on the mind-set of all concerned. Aspects of these will be dealt with in detail later in these submissions (see in particular Section 2 below, on reviewing the past in its context). But it is worth identifying them in broad terms now.

7. The starting point is of course that these matters have all to be considered in the context (ever present in the minds of all involved in the Inquiry) that we are largely dealing with matters between fifty and thirty years ago. And it is obvious that this passage of time not only represents delay in the detailed investigation of what happened, and thus injustice for those who have suffered; it also prejudices, at least to some extent, the search for truth, something which affects all participants.

The consequences of the passage of time: fading recollection

8. Thus, the first point here is that it gives rise to an inevitable loss, to varying degrees, of independent recollection on the part of witnesses. Partly for that reason, and partly the result of other factors as well, including the inevitably incomplete nature of the documentary evidence now available, it also gives rise to the potential for inadvertent distortion - whether because the account is inaccurate or simply incomplete - of what is recollected. This might be because something has been completely forgotten; or because something has been recollected but without full context. And by the same token, while documentary evidence is obviously key to prompting recollection, an incomplete documentary record carries similar danger. We develop this further below.

Evaluation of past events now

9. The second point, perhaps more important to note (precisely because harder to recognise or to hold in mind), is the fact that the perception now of past events is altered by the passage of time, because we are viewing them through the lens of 21st Century thinking, cultural norms and customs, and indeed moralities.

10. We may well be aware at an intellectual level that the cultural background has changed over time. We may well be similarly aware that it would not be fair, when considering the reasonableness or otherwise of individual, or even collective, actions or decisions back then, to exclude from consideration the cultural context in which those actions and decisions were taken. However, notwithstanding this, we still, inevitably, apply the judgment of hindsight.

11. Thus, when assessing - or even just trying to understand - those past actions or decisions, it is necessary to ensure that one is viewing them (at least to some extent) through the lens of the time, including that of the then contemporaneous professional practices and norms. A true understanding of past events must be informed by knowledge of what those past practices were, and any judgment as to past actions, inactions or decisions, requires knowledge of the context in which those occurred, and for that context to be borne in mind.

Developing knowledge

12. Thirdly, and even more importantly here, those points do not simply apply to the changes of standards and codes of conduct (i.e. changes in behaviours, etc.). They apply, with even greater impact, to the overarching scientific context here: the changing and developing states of knowledge. Again, we expand upon this below, but the short point is that it is very hard, even when one tries to do so, to exclude knowledge that we have.

13. The practicalities of excluding hindsight, when we need to do so, are actually more complex than they might appear. We can attempt to put ourselves in the position of those who did not know what we know. But it is much harder when doing that to understand the significance then of the fact that this was not then known, or of lines of inquiry or indeed answers that (we now know) were 'wrong'. The analogy for this that we expand upon below is that it is like knowing the answer to a crossword clue once it has been solved; it is impossible to put oneself in the position of not knowing it, and one often cannot understand how it is that one didn't solve it earlier. We cannot truly 'unlearn' our own knowledge; hence we are unable truly to put ourselves in the position of, or to understand, our past ignorance.

The Inquiry's Lens: The Infected and Affected

14. Finally, we refer back to what we have said at the outset. NHSBT has throughout both understood and welcomed the fact that the scrutiny of past events has both taken the experiences of the Infected and Affected as its starting point, and then gone on to weave them into the fabric of the Inquiry's work. But given that this is the approach, it is we submit vital for the Inquiry to bear in mind the extent here of the potential consequences, identified immediately above, of seeing only through this lens.

15. This applies to the examination of the events as they took place in real time and to any explanations given to the Inquiry of why things were done the way they were, or why they were not done differently. In particular it means that it can be difficult to keep in mind what at that stage seemed to be valid and competing potential alternatives (whether as hypotheses or as possible actions), which had not been tested then, but which have now been discredited.

16. We know that the Inquiry is determined to do justice on all sides in the findings as to the past in its report, and we have little doubt that these last matters are all things which it already has in mind. We have introduced them in this way at this stage simply because they should inform the scrutiny of the context of these events, and therefore they need to be expressed. But we would stress that none of these points is intended to signal any sort of departure from what we said at the beginning of these remarks, and we hope that those opening sentiments are themselves woven throughout these submissions.

The Infected and Affected themselves

17. We end these remarks by returning to the position of the Infected and Affected themselves. The evidence that the Inquiry has heard over its five years has been profoundly moving. The witnesses who have given evidence have told stories of great suffering. They have spoken of losing their children, siblings, parents and partners to terrible diseases; of suffering tremendous ill health, both physically and mentally; of stigma and discrimination; and of a lack of assistance and support, so that many had to face the world isolated. For those who have attended over the five years, it has been moving and humbling to hear and read that evidence.

18. The Infected and Affected have been the touchstone of this Inquiry; all with individual stories that come together to map a tragedy that has run for many decades. It is impossible to go through individual stories here with the gravity and respect they deserve, but we hope that the report that follows the Inquiry is able to do so. Without their evidence, the depth of the experiences of the Infected and Affected would have been obscured or lost. Thus, NHSBT wishes to express its gratitude for the Infected and Affected for their evidence, in circumstances where the stories told were of great pain and suffering, and to recognise the dignity and courage with which that evidence has been give.

19. However, most importantly, we wish to restate what we hope has been clear throughout: that we recognise the hurt, pain and suffering of those who have been infected, or affected by such infection, through blood and blood products. We express our deepest sympathies and for any respect in which it is found that the blood services, or the blood they supplied, was the cause of that suffering to any person, we apologise unreservedly.

1. SECTION 1: INTRODUCTION

1.1 It is sensible first to explain NHSBT's approach to these submissions, and their structure.

A. Approach

1.2 NHSBT committed at the outset of this Inquiry to do all it can to assist in the Inquiry's task, with frankness and transparency. It has sought to do this throughout, reflecting the collective spirit referred to in the preliminary statement above.

1.3 That assistance has essentially consisted in providing to the Inquiry as much relevant information (historical and as to the present) as it can. It has performed that task by means of (i) the disclosure of documents (and waiving privilege in them wherever possible); (ii) providing witness statements in response to Rule 9 ('**R9**') Requests; and (iii) facilitating the giving of oral evidence by its witnesses.

1.4 These written submissions represent the next stage of that assistance, and we hope that they are a helpful and efficient distillation of those earlier processes into a single document.

1.5 We intend these submissions to be both objective (in substance as well as tone) and comprehensive in scope. This objectivity is important, for all the reasons already canvassed. Put shortly, this is not litigation, and we are not acting as litigation lawyers. Of course, our role is to act for, and to protect the interests of, NHSBT. But in the circumstances (and given our instructions) what that really means here in terms of our submissions is simply that we must do our best to maintain fairness and balance.

1.6 As to scope, the submissions are intended to be comprehensive in the sense of being a pretty full record of the evidence before the Inquiry on the matters which are of concern to it, insofar as they do or might relate to the English blood service. Thus, they cover: (i) the role of the blood service generally; (ii) the history of the relevant infections; (iii) the measures taken to deal with them; including of course the blood service's role in that; (iv) relevant outcomes; and (v) possible recommendations.

1.7 The submissions are therefore intended to be both wide-ranging in scope and as comprehensive in evidential detail as is proportionate (or possible) given the materials available. A short way of putting it would be that we hope we give the full picture.

1.8 We hope that this will all be useful for the Inquiry. We are aware of the possibility of some duplication with work the Inquiry is doing already (chronologies and the like); but it is important that we are able to identify for the

Inquiry those features to which we suggest particular attention should be paid; so we make no apology either for that, or indeed for the length of the submissions themselves.

B. The structure of the submissions

1.9 The structure is therefore as follows.

- Preliminary statement
- Section dealing with the Inquiry's task and its approach
  - *Section 1: Introduction*
  - *Section 2: Reviewing the past in its context*
- Sections dealing with the blood service and the blood supply
  - *Section 3: The blood service and its role*
  - *Section 4: Decision-making & reliability of the blood supply*
  - *Section 5: Running the blood service*
  - *Section 6: Self-sufficiency*
- Sections dealing with particular infections and responses to them
  - *Section 7: Hepatitis generally*
  - *Section 8: HIV*
  - *Section 9: Non-A Non-B Hepatitis / Hepatitis C*
  - *Section 10: HIV lookback*
  - *Section 11: HCV lookback*
  - *Section 12: vCJD*
- Sections dealing with other related matters
  - *Section 13: Consent*
  - *Section 14: Record keeping*
  - *Section 15: Teaching & transfusion practice*
  - *Section 16: Minimising risk of transfusion transmitted infection*
- Concluding sections
  - *Section 17: Recommendations by the Inquiry*
  - *Concluding statement*

1.10 We should add the following in relation to Section 17: Recommendations, which covers NHSBT's submissions on the question of what recommendations the Inquiry should make. We there expand upon and refine the interim submissions provided in June of this year, to reflect the further evidence that the Inquiry has

recently heard on relevant topics and update on other relevant matters. However, for the most part we do not, in this section, deal with the interim submissions advanced on recommendations back in June by other CPs. That is because we think it simpler and more appropriate to respond (as necessary) to the final submissions on recommendations to be made by other CPs. We will therefore do so in oral submissions in January next year.

C. Names and references

(1) Naming conventions

1.11 The names, and structure, of institutions changed throughout the period focused on by the Inquiry. Our approach in these submissions has been to adopt a general name for the institution save for where historical context calls for a different approach. The most common examples are explained below.

1.12 Throughout these submissions, various terms are used to refer to the blood service. 'NHSBT' has been used to describe the current blood service in England that is a core participant in the Inquiry. 'NBA' has been used to describe the predecessor special health authority to NHSBT formed through the changes in 1993/1994. 'NBTS' has been used to refer to the blood service in England and Wales from its creation to creation of the NBA. The term 'blood service' is used as a general term which takes its meaning from context; 'blood services' refers to all the blood services of the UK and again takes its meaning from context. When quoting directly or indirectly from evidence, the terminology used in that evidence is typically adopted.

1.13 The relationship between the English and the Welsh blood services is historically idiosyncratic. At various points they have come together to be: the blood service for England and Wales; the blood service for England with North Wales; and the Blood Service for England with North Wales and additionally South Wales. Due to this complexity, we have left the matter of the relationship with Wales primarily to the updated NHSBT family tree [**WITN0672007**] which provides the best information on that relationship. Regard should be had to that document when reviewing these submissions if the relationship between England and Wales requires to be clarified.

1.14 Throughout these submissions, various terms are also used to refer to the Department of Health and Social Care. We have adopted 'DH' as the general name except where context calls for a specific name (typically 'DHSS' or 'DHSC'). When quoting directly or indirectly from evidence, the terminology used in that evidence is typically adopted.

1.15 Finally, for Transfusion Transmitted Infections ('**TTIs**') we use the modern name unless identified otherwise. This typically happens in those sections focused on a specific TTI. Thus, HIV is referred to throughout the majority of

these closing submissions, although there remain some references to HTLV-III.

1.16 For the assistance of the reader, we re-attach at the end of these submissions the table of acronyms included in Dr Miflin's written statement WITN0672006 This is reproduced to assist and not every acronym in that table appears in this document.

(2) References

1.17 Insofar as has been possible, we have tried to provide the Relativity reference for documents. As appropriate, we have also provided summaries of the nature of the document. Where a Relativity reference is not been found, we have provided sufficient information we hope to enable the document to be traced.

2. SECTION 2: REVIEWING THE PAST IN ITS CONTEXT

A. Introduction

2.1 To a historian, the task of understanding the context in which the events of decades ago took place, and the related task of working out the extent to which that context should affect one's present consideration of them, are both very important and very familiar ones. But they nonetheless still present real difficulties. The same applies here to all those involved in this Inquiry, with the additional obstacle that, since we are not historians, these are not familiar tasks. One consequence of this is that it does not come as second nature to us consistently to bear these obstacles in mind when analysing these events of decades ago. We have already touched to some extent on this in our preliminary statement above. We consider them further now.

B. General: the context of the times

2.2 For those of us who were alive and aware in the 1970s and 1980s, our memory works well, but only in very specific ways. We can remember events that were particularly important to us personally: both that they did happen and how they made us feel. But even in the case of such events, we may well be unable to remember their precise chronology, or all the detail of what happened.

2.3 As to more public events, it is not difficult for us to summon up their general historical sweep. In the '70s: the three-day week (and its associated power cuts); the winter of discontent; the appointment of Margaret Thatcher as Prime Minister; and, abroad, the end of the Vietnam War and Watergate. In the '80s: HIV / AIDS, the Falklands war; the Iran-Iraq and Soviet-Afghan wars; and the beginnings of the internet, and of emails as correspondence; all of course among many others. So, again we can remember them happening, but we do not necessarily remember when, or even in what order (we are reliant upon the archives for that).

2.4 What is much harder for us to do is to recall the social, and the practical, day-to-day, context in which these things happened. This is made clear to us whenever we see archive film of the times (as we have done at this Inquiry): we get a slight jolt of surprise when we are reminded of what people looked like, or their clothes or their cars; or some of what they used to say. This slight jolt demonstrates to us how ingrained the habit is of seeing the past through the lens of the present; and (related but separately) of projecting the present, along with its assumptions, back into the past.

2.5 Both the sweep of underlying societal and technological changes, and their practical, day-to-day manifestations, are important for the Inquiry for all sorts of reasons. They are relevant to society. They are relevant to governments, to the NHS and to the other public health services in the UK. They are relevant to

the practice of medicine, which has changed fundamentally because of progress in medicine itself, in science, in culture, and in technology. And they are relevant to the users of those services and their lived experiences. We hope that some further exploration of this is helpful.

(1) Societal differences

2.6 First, to understand the context in which all concerned were operating, it is necessary to bear in mind the wide social and legal transformations of the last forty years. As well as the landmark events referred to above, there were major differences between expectations and habits, then and now, and between attitudes, then and now.

Expectations and habits

2.7 First, we must bear in mind the different context of people's expectations and habits day-to-day. It is striking, and often surprising at first, to be reminded about the changes there have been over this time in the nuts and bolts of people's lives.

2.8 One obvious and important difference relates to the normal methods, and the normal speed, of communications and information gathering. Instant communication was emphatically not the norm. Obviously, there were telephones. But there were no mobile 'phones, no texts, no emails, and only limited access to the internet, at least until the very end of this period. The point here is not that instant remote communication was impossible (it was not – you could communicate by telephone or by telex). The point is that it was not the norm. The expectation was that anything that was not either an emergency, or immediately personal business, would be dealt with on paper. And this took time.

2.9 This meant that expectations as to communications over distance were completely different then. Such communications took days at least; and the expectation was often for them to take weeks. In most cases no one regarded that as strange or problematic.

2.10 Perhaps the best example of this is the terms on which bills were to be settled at that time, which seem quite remarkable to us now. The standard wording on most bills stated that they should be paid within a month (or, sometimes, 4 weeks). Often, they would (as a matter of pride on the part of the customer) be dealt with more quickly than that; but that is not the point. The point is that the general social assumption, the expectation, was that that was an acceptable period for responding.

2.11 This was emblematic of attitudes more generally about communication. Families kept in touch, but often by letter or postcard rather than by 'phone call or text.

2.12 We do not wish to make too much of this: obviously there were many decisions to be made or actions to be performed that were urgent and had to be effected immediately. However, the default position in this era was one of less speed, and, bluntly, less impatience. That must be at least part of the explanation for the surprise that we now feel at the apparently slow response times on ostensibly important matters. Even where this does not excuse them (and in some cases it does), it does in part explain them.

Attitudes

2.13 Secondly, there were many commonly held social attitudes during the '70s and '80s which would now seem anachronistic, and some that now seem to have been wholly inappropriate, even making allowances for the different social context of those times. We stress that we mention this now not in any way to excuse them, it is rather to identify them as factors that would have represented obstacles to relevant action or change at the time.

2.14 In particular there was very commonly a real discomfort with any honest or serious discussions about sex. This was present in most households, and even extended, as the Inquiry has heard, to some clinicians. It has been reflected in the evidence that the Inquiry has heard from all sorts of quarters – including the evidence from the highest echelons of politics, and the evidence from those who were the subject of such unfair stigma and abuse. It is a discomfort which constrained public consciousness and discourse, and possibly for many in private as well, in a strange hinterland between comedy ('Carry On …' and Dick Emery), prurience, and, hidden behind those things, and most relevant to this Inquiry, simple disapproval. (And for some, it must be said, this shaded into disgust, if not at the idea of sex itself, at least at the idea of discussions about it.)

2.15 The consequence was that there was very little public debate about sex, and very little by way of forum in which to have any serious discussion about sex, even when the need arose, apart possibly from in academia and in medical circles.

2.16 This feature of the times – ignorance, combined with socially-enforced silence, about sex – was inevitably a fertile breeding ground for widespread homophobia (on occasions express and acute; otherwise as low-level but ever-present background noise). People were presumably aware of homosexuality. But many refused to acknowledge or accept it. Its treatment in popular culture was often by demeaning stereotypes, designed to ridicule, and with the effect (conscious or otherwise) of bolstering and enforcing an "othering" of homosexuality and homosexuals.

2.17 But there were other, less pernicious, but also significant, types of consequence to this societal thinking that are highly relevant here. The

evidence heard by the Inquiry has confirmed that the inability freely to discuss matters relating to sex during the '70s and even the '80s created real difficulties in putting necessary initiatives into effect – for example, generally, those relating to public awareness of HIV/AIDS, and more specifically here, those relating to donor selection. The idea of public, or in many cases even private, discussion of whether sex was vaginal, oral or anal would have been unthinkable during the '70s and '80s and ran a high risk of being counter-productive.

2.18 This was essentially for two reasons. First, because of a squeamishness in addressing it on the part of decision-makers (including, as referred to above, some of the most senior politicians). But secondly, also because of a real, and indeed possibly justified (given these very prevailing attitudes), concern on the part of decision-makers that addressing these matters directly with the public would not achieve the desired result, because sections of the public would recoil rather than take in the advice.

2.19 Of course, at one level we all know all this. The point is, though, that we don't always factor it into our thinking as much as is appropriate.

(2) Differences in the practice of medicine

Demographics in the medical profession

2.20 Here we deal briefly with demographics, and with technology, before turning to medical culture, and medical ethics, and their reflection in the law.

2.21 A combination of shifts in attitudes and in the demography of the medical profession have led to changes in practice since the period up to 1995. For example, in 1963 there were 22,159 GPs in England and Wales, 19,951 of whom were recorded as male and 2,208 of whom were recorded as female. In 2018 there were 17,366 male and 21,736 female GPs[1].

2.22 Alongside this has been a continuing tendency towards centralisation of medical practice, leading to increasing consistency across regions, and facilitating consistency of increasingly detailed guidance to practitioners.

Technology and the medical profession

2.23 We have touched above, in broad terms, on some of the technological advances since the '70s and '80s. As well as their societal impact, these advances have also changed the management and operation systems of the health services generally, including the blood services. They represent very significant improvements in the creation and dissemination of research material, created new possibilities for record-keeping, testing and patient

[1] NHS Digital – Historical workforce statistics in lead-up to NHS70 https://digital.nhs.uk/news/2018/workforce-factsheet

information services; and have increased the speed of adaptation to new changes.

2.24 In the '70s and '80s themselves, by contrast, clinicians were working with tools that were rudimentary: no e-mail or internet, or indeed access to computers. News and research journals travelled by post. Conference attendance was comparatively rare. MS DOS wasn't even in general use until the mid- to late-'80s, and so in the '70s and early '80s doctors (in common with the rest of the population) were relying on some combination of typewriters, fax machines and handwritten notes.

Medical culture and ethics, and the common law

2.25 There have also been transformations to the practice of medicine. These include changes to the doctor-patient relationship in respect of sharing information; views on medical paternalism and consent; and, multiple legal and policy initiatives emphasising patient choice. These changes were then, in turn, reflected by changes in societal and legal norms, as well as by professional regulation.

2.26 The common law has reflected the shifts in societal attitudes and in medical ethics described above. Statements of principle from *Bolam* (1957)[2], to *Montgomery* (2015)[3], have demonstrated the evolution of the legal tests on the standard of care to be applied in clinical negligence cases, the doctrines of consent, and the requirements of disclosure and duties to inform patients of relevant information.

2.27 *Bolam* enshrined the principle that a doctor's actions or advice were unimpeachable if they fell within the range of reasonable medical response, by tested reference to expert medical opinion, and for many purposes this is still good law. However, it could also be described as the legal articulation of medical paternalism.

2.28 The common law responded to the cultural and social developments in the intervening decades, and specifically acted to protect patient autonomy. The paternalistic approach was thought increasingly inappropriate in relation in particular to the topic of disclosure of information to patients regarding risks. This is therefore a good example of the wider evolutionary change of medical practice towards patient-centred care and, ultimately, its reflection in the common law.

2.29 As such, when it came, the 2015 decision of the Supreme Court in *Montgomery*, relating to informed consent, marked a significant departure from

[2] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. See also *Hunter v Hanley* [1995] SLT 213 (Scotland); *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871
[3] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

the general *Bolam* principle, in relation to the specific question of the duties of disclosure to patients regarding risks. The underlying principle sounds unremarkable now; the Court stated that:

> *'…An adult person of sound mind is entitled to decide which, if a consent must be obtained before treatment interfering with her bodily integrity is undertaken'*[4]

2.30 This decision then enshrined principles which were summarised in the expert evidence on medical ethics: self-determination, partnership, support, and choice[5]. These principles, upon which there has been particular focus over the last 20 years or so, are accordingly reflected not only in professional regulation but also now in the common law, evolving to reflect such cultural change.[6]

2.31 The corollary – and what is important for present purposes -- is that earlier (in many cases now superseded) statements of principle similarly reflected both the ethics and the day to day thinking of the time. This confirms that it is relevant, not only in the context of patient autonomy, but across the board in this Inquiry, to consider the standards and the medical context of the time when considering any decisions made and actions undertaken by clinicians and healthcare professionals of the time.

2.32 Indeed, this '*context specificity*' was something that the ethics experts recognised as part of their oral evidence. It is sufficient to take two examples. First Professor Savelescu:

> *'There's another distinction which I think is very important in this debate, and that's between moral relativism and context specificity. So what can be right in one context can be wrong in another, and that doesn't mean that you don't have some universal or moral objectively true principles in both of them. It means the facts are different.'*[7]

Second, Professor Kerridge:

> *'That's not to say that context and history are irrelevant. It's not binary. I think we're – maybe this is why, possibly, it's not quite as clear as we wanted it to be, because we are trying to say that there are ideas or principles or ethical norms that are incredibly stable across time. […].*

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[4] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 at [87]
[5] Expert Report to the Inquiry: Medical Ethics **[INQY0000241]** at [pg17]
[6] The position ultimately reached in *Montgomery* had been expressly rejected 30 years earlier by the majority of the House of Lords in *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871; although there had been support for it by the sole dissenting judge Lord Scarman. The Supreme court in Montgomery, 30 years later in 2015, referred to the GMC publication (*Good Medical Practice* (1998), and *Seeking patients' consent*: *The ethical considerations*, to *Consent: patients and doctors making decisions together (2008),* and to developing case law on human rights, under *'the stimulus of the Human Rights Act'* as reflecting that the courts had '*become increasingly conscious of the extent to which the common law reflects fundamental values'*.
[7] Oral evidence of Medical Ethics Experts 26.01.2021 **[INQY1000090]** at [78/5].

> *…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 other 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 becomes clear that those are just not acceptable and were actually never acceptable.'*[8]

2.33 The importance of context specificity means that it is relevant, in terms of understanding the past and in terms of assessing the conduct, decisions and actions of people in the past, to take into account the mores, standards and customs of the time.

(3) The blood services in the past

2.34 The changes in the organisation of the blood services during this period are described below. These changes transformed the organisation, capabilities, and practice of the blood services. They introduced new levels of consistency in practice; for example, through the centralisation of the organisation and the transformation of the relationship with central government. The evidence that the Inquiry has heard makes it plain that blood service professionals were trying to maintain the supply of blood and make it as safe as it could be, in the context of the times and systems within which they were working.

2.35 Detailed accounts of the history of the English blood service, which are helpful in demonstrating the degree to which it was initially a patchwork operation, are set out in the witness statements of Dr Angela Robinson [**WITN6926003**][9] and Dr Gail Miflin [**WITN0672006**].[10] This is explored in more detail below in sections on '*The Blood Service and its Role*' and '*Running the Blood Service'*.

2.36 At this stage it is sufficient to say that it is crucial to bear in mind the point (obvious but only once identified) that the context here also includes all of the other important life-enhancing and life-saving services and functions being provided by the blood services. For example, in 1986 Dr Gunson redefined the responsibilities of the Regional Transfusion Centres ('**RTCs**') which give a good summary of their work at that time [**NHBT0000028**][11]. In addition, Dr Martlew's written statement sets out the services provided by the Liverpool RTC [**WITN4034001**][12] referring to her paper opposing the closure of that centre

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[8] Oral evidence of Medical Ethics Experts 26.01.2021 **[INQY1000090]** at [80/12].
[9] Second Written Statement of Dr Angela Robinson [**WITN6926003**]
[10] Written Statement of Dr Gail Miflin [**WITN0672006**]
[11] *Fifty Years of Blood Transfusion*, a supplement in *Transfusion Medicine* produced by Drs Gunson and Dodsworth **[NHBT0000028]** at page 29.
[12] Written statement of Dr Vanessa Martlew [**WITN4034001**] at [136 – 141]

[**DHSC0004351_045**][13]. In addition, audits of RTCs can assist; see, for example, the paper detailing the medical audit of Manchester RTC on 19 February 1992 [**NHBT0009743_001**].

(4) External events and their impact

2.37 It is also right to note the practical impact of certain external events, central to the times but not necessarily to the evidence that the Inquiry has heard.

2.38 Three examples, each of which had a particular effect on the operations and the functioning of the blood services are as follows:

a. the specific impact upon the resources and deployment of the medical profession of the Gulf War; and

b. more generally, the chronic effects of deindustrialisation in many parts of the UK, resulting in factory closures,

c. the adoption of computing across public services.

C. Other contextual factors

2.39 We have, so far in this section, concentrated specifically on the changes in the context of the times which we submit need to be kept in mind throughout when considering the decisions and the actions of thirty to fifty years ago. We now turn from contextual changes since those times to other factors relevant to that consideration, which factors relate more to the features of our own consideration now of these things which might impact inappropriately on the assessment of that past.

2.40 Again, we stress that we do this simply to ensure that these matters are borne in mind when those assessments are undertaken.

(1) Reliance upon memory of remote events

2.41 Much of the evidence heard by the Inquiry consists simply of personal recollection, often assisted by relevant documentary record, itself often incomplete.

2.42 Memory is of course a powerful evidential resource, whether that evidence is given to the Inquiry in writing or orally. Those who have given evidence have done a remarkable job of recollecting events that happened some thirty, and even forty years previously. However, that evidence is, by definition, difficult to test now. Furthermore, the timescales involved mean that there are important limitations to its reliability. Those limitations should be considered when the Inquiry assesses this evidence.

[13] A paper entitled '*A fully functional and comprehensive blood service centred in Liverpool to provide for Merseyside and North Wales*' produced by Dr Martlew and dated 21.09.94.

2.43 We repeat here what we have said on this in the preliminary statement and add the following.

2.44 First, what is encoded in a witness's memory is determined by what they attend to, what they have stored as important, and their own needs and expectations. Their memories will also have been coloured by the contemporary understanding of history. This includes here importantly the knowledge of, and often the hearing of, the tragic stories of the Infected and Affected, their families and loved ones. It is in many ways a good thing that their evidence has been delivered in the knowledge of what subsequently happened, since it adds perspective and humanity.

2.45 Secondly, a huge amount of material has been disclosed to the Inquiry. For many of our (mostly elderly) witnesses reviewing and scanning potentially relevant material has been necessary to prompt memories and clarify events many years before. That process, of presenting witnesses with selected contemporaneous written documentation, after a significant period has elapsed, will itself have had an impact on the evidence to the Inquiry. Invariably in refreshing witnesses' memories, looking at these documents may also itself alter witnesses' memories.

2.46 Thirdly, this is further complicated by the way that the Inquiry's knowledge has developed over its duration. With each additional batch of documents, and questions to the witnesses, the Inquiry's understanding of events has developed iteratively. Accordingly, the questions posed, and the answers given, reflect the developing nature of this understanding.

2.47 Finally, there is the problem of memory of one aspect of the past without the context of the others. Recall prompted by the Inquiry's investigations lacks that context, and there is therefore a risk that other priorities form no part of the recollection

2.48 We have no doubt that all concerned at the Inquiry are well aware of these points. Once again, none of these points is intended to represent criticism of the way in which the Inquiry has performed its function; they are made simply in the interests of fairness, and in the hope that they will help the Inquiry to keep them in mind when undertaking its consideration of events.

(2) The impact of hindsight and of the development of science

2.49 We have touched on this to some extent in in the preliminary statement, and we expand those points here.

2.50 First, the perception now of past events is itself altered by the passage of time, simply because we are viewing them through the lens of 21st Century thinking, cultural norms, customs, and moralities.

2.51 We are, at an intellectual level, aware of the changes referred to above. While we are entitled to (and should) see the events of those times from the perspective of our current thinking on such matters, we know at that level that it would not be fair, when considering individual or collective decisions and actions back then, to exclude from consideration the cultural context in which those actions and decisions were taken. We know that a true understanding of past events must be informed by knowledge of what those past practices were, and any judgment as to the past actions, inactions or decisions requires full knowledge of the context in which those occurred. (The difficulty is perhaps demonstrated by imagining a judgement in the future on our own conduct and decision-making now, taking into account only the standards of the future and not - to any extent at all - those of today.)

2.52 The problem however is that we instinctively apply modern thinking to these matters in any event. This is inevitable and indeed proper. But we need to bear the fact that it happens in mind as we assess the past.

2.53 It is important to recognise that these points do not simply apply to the changes of standards, codes of conduct, and behaviours. They apply, with even greater impact, to the overarching scientific context here: the changing and developing states of knowledge.

2.54 There are obvious aspects to this, apparent to all who have been hearing the evidence of the last four years. Put at their simplest, we have knowledge now, for example about HIV and HCV, about the risks of transmission of those infections through the blood supply, and about the measures that can and should be taken to prevent this taking place, that those dealing with matters in the 1970s-1990s did not have.

2.55 It may on the face of it seem to us all that it should be a relatively straightforward exercise to keep in mind the fact that we are now significantly better informed than people at the time. However, the practicalities of excluding hindsight (in those circumstances where it should be excluded) are more complex than they might appear.

2.56 We know that we know many of the answers to the questions were then unanswered (For example: what was the nature of NANB? How serious was it? And in relation to HIV/AIDS: what is the nature of this infection? Is it a virus? Is it one or a number of viruses?).

2.57 We can attempt to put ourselves in the position of those who did not know the answers to those questions. In doing that we can imagine not knowing them; but it is much harder to give due colour or weight to the significance back then of what we now know to be ‘wrong’ answers, or lines of enquiry that led nowhere – scientific blind alleys or worse.

2.58 This applies most particularly in the context of the cutting edges of scientific progress. But it is equally important in relation to steps dependent upon, and subsequent to that scientific endeavour, which are necessary to make practical progress in the light of it. Thus, it can be acutely relevant in understanding, for example, the explanations for delays in the implementation of scientific or other steps, which steps have subsequently proved obviously sensible. The danger, put shortly, is that these steps may seem with hindsight, always to have been obviously sensible when, at the time, they were not.

2.59 The particular danger here is that in considering decisions as to what should be done to minimise risk, for example, it is not obvious (viewed in prospect only) to be sure of the ramifications of taking / not taking any particular step; indeed, for this reason it is not always obvious what would be the 'cautious' approach. The right answer is often, by definition, not obvious, or even apparent.

2.60 A useful analogy for the review now of such situations is the challenge of the cryptic crossword puzzle. We do not know the answer to a clue until we have solved it. Similarly, we do not until then know how long it is going to take to do so. Once we have solved the clue it often seems to us that it was completely obvious, and it is hard to understand why we didn't identify it before; it feels like we must have been being stupid, in taking so long to solve the problem.

2.61 That reaction (understandable, but in fact often wrong-headed) is, we submit, an important one to bear in mind in this context. There is a danger here that in assessing the conduct of those tasked then with finding answers or deciding on strategy, we are distracted by our hindsight – own knowledge of those answers – into missing or ignoring the fact that these things were often emphatically not obvious to those people dealing with the problem at the time. Again, almost by definition, they didn't become obvious until science advanced so as to mean that that was so.

2.62 In short: the problem is two-fold: we cannot 'unlearn' what we now know; and, while we may know that fact, we don't always bear it in mind.

(3) Developments in terminology

2.63 Finally, it is worth flagging up a verbal danger which it is important for those assessing developments over time to guard against. Often, terminology changes; but that does not mean that there have been changes of substance. New expressions do not necessarily connote new practices.

2.64 There is a particular example of these dangers that has cropped up repeatedly in this Inquiry. The phrases 'the precautionary principle' and 'the precautionary approach' have been used by some almost interchangeably. We explore later in these submissions the origin of the former, its meaning, and its applicability, past and present to clinical decision-making and risk management. We also explore the distinctions (as we understand it) between the former and the latter.

2.65 For present purposes the point is a simpler one. The phrase 'the precautionary principle' was not used in the context of clinical matters until a period after the 1980s. However, that being the case does not mean that the general approach it describes, or even just some parts of that general approach, were not in play in the period before that terminology developed. Simply put, one should look to the substance of what was done rather than merely considering the label that was applied contemporaneously.

2.66 We deal more fully with the questions of management of risk and with the meaning of the term precautionary principle, and its ramifications, below.

D. Conclusion on context

2.67 The upshot of all this is that it is crucial, in order fairly to understand (and evaluate) the events focused on by the Inquiry, to situate them in the context of the times; and to appraise decisions in light of the pressures, limitations and preoccupations of the period that applied. And, as stated earlier in these submissions, it is most of all crucial to remember that when judging the events of the past, we must be aware of applying the lens of today.

3. SECTION 3: THE BLOOD SERVICE AND ITS ROLE

A. Introduction

3.1 The history of the blood service in England and Wales has been set out in documents that NHSBT has previously submitted to the Inquiry: please see Dr Miflin's witness statement [**WITN0672006**][14] and the updated NHSBT family tree exhibited to that statement [**WITN0672007**].[15] While oral evidence was not heard from Dr Miflin, her answers to sections 1 and 3 are particularly pertinent here, and NHSBT notes that the CTI presentation on the history of the blood services in the UK [**INQY0000307**][16] covers much of the same ground.

3.2 We do not repeat the content of these documents. Instead, in this section, we identify some of the critical features about the blood service, its role within the NHS, and the role of its clinicians. Understanding the distinct position of the blood service is important context to the thinking and decisions focused on by the Inquiry.

3.3 The emphasis in this section is on the blood service in the historical setting focused on by the Inquiry. However, much of what is discussed here remains relevant (even if only as context) to NHSBT today.

B. The blood supply

3.4 The central role of the blood service within the wider NHS in England has been to obtain a supply of blood from voluntary, unremunerated, donors and to make that supply available for transfusion (in the form of whole blood and blood components) and for use in blood products. The role of the blood service in 1946 and 1986 is set out at tables 2.4 and 3.4 of [**NHBT0000028**][17] respectively. On the creation of the National Blood Authority ('**NBA**') on 1 April 1993, its functions were set out in the NBA Order 1993 (as amended by the NBA (Amendment) Order 1994). The relevant provisions are set out in Dr Miflin's statement [**WITN0672006**].[18] In 2005, NHSBT succeeded the NBA, the relevant provisions and directions about its role are set out in Dr Miflin's statement [**WITN0672006**].[19]

3.5 In satisfying this core role, the blood service has throughout endeavoured to provide a safe and sufficient supply of blood. 'Safe' in this context not only includes safe from transfusion transmitted diseases, but goes on to include

[14] Written Statement of Dr Gail Milfin [**WITN0672006**]
[15] NHSBT Family tree [**WITN0672007**]
[16] The history of the blood services in the UK [**INQY0000307]**
[17] H Gunson and H Dodsworth, *Transfusion Medicine* (1996) **[NHBT0000028]**
[18] Written Statement of Dr Gail Milfin [**WITN0672006**] at [39-40]
[19] Written Statement of Dr Gail Milfin [**WITN0672006**] at [42-46]

many other serious hazards of transfusion.[20] Among other things, 'safe' refers to the quality of the blood. 'Sufficient' here means a supply of blood sufficient to meet clinical need in England.[21] It refers to the quantity of the blood. Importantly, sufficiency in itself is a safety issue: a failure to meet clinical need can pose a safety risk for individual patients or the wider health service.[22] Thus, for the blood service, safety and sufficiency are not necessarily in tension but represent different facets of providing a reliable supply of blood for clinical needs.

C. Recipients

3.6 The blood service owes a duty to recipients; many blood service witnesses have recognised this.[23] In exploring this duty, the blood service does not seek to avoid or minimise this; instead, we say it is very important to put that duty in its proper context.

3.7 The way that the blood service satisfies the duty it owes to recipients as individuals is primarily by taking steps at the macro- or public health level to ensure that there is a reliable supply of blood for clinical needs. Focusing on steps taken historically, this might be through ensuring the safety of the blood supply from TTIs (e.g. the introduction of HIV testing) or other serious hazards of transfusion (e.g. ensuring a closed system for taking and processing donations to avoid bacterial contamination). The blood service also ensures there is sufficient blood such that recipients are not deprived of clinically required transfusions or treatment (e.g. through the increased use of red cell concentrates to obtain more plasma for supply to the fractionation laboratories). These are all steps that can be taken at a service-wide level to ensure that there is a suitable supply of blood for clinical use.

3.8 However, save for in limited circumstances, the blood service did not interact directly with the recipients of blood, blood components, and blood products. Instead, the treating clinician sat between the recipient and the blood service. For those recipients who received fractionated products between the blood service and the treating clinician was a fractionation laboratory (in England, usually Bio Products Laboratory ('**BPL**')). The delivery of care included administrative staff and IT systems which added another layer of complexity. Thus, unlike the relationship with the donor (considered below), the blood service did not have a direct relationship with recipients.[24]

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[20] A good summary of the hazards of blood and transfusion are set out in the SHOT reports that the Inquiry has access to. See also Professor Bellamy's statement on SHOT generally [**WITN7312001**]
[21] Although self-sufficiency is a difficult term (to which see section 6 on Self-Sufficiency).
[22] This was a common theme among RTDs and other blood service staff. For a clear enunciation of this principle see Oral Evidence of Professor Richard Tedder [**INQY1000256**] dated 14.10.2022 at [75/25]
[23] See for example [**NHBT0005791**] at [pg2] and Written Statement of Dr Patricia Hewitt, [**WITN3101006**] at [4].
[24] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [72-73]

3.9 This means that the blood service had no treatment relationship with an individual patient. As such, it could not be involved in individual treatment decisions.[25] The clinical freedom of the treating clinician has been an important feature of the health service in the period which is the focus of this Inquiry.[26] The blood service's lack of a relationship with recipients is part of the context of that freedom.

3.10 Explaining this is not an attempt to avoid any responsibility to or for the patient. It simply means that the work of the blood service was rarely (if ever) rooted in the facts of a particular recipient's case. While the blood service can, with the benefit of hindsight, reflect on the granular detail of an individual recipient's treatment, it was rarely (if ever) involved directly in that treatment at the time. The blood service could not, for example, advise an individual recipient as to the benefit of one treatment over the other. Indeed, in circumstances where a fractionating body sat between the treating clinician and the blood service, the relationship that the blood service had with the recipient was even further removed.[27]

3.11 As a result of this more remote relationship from the recipient, the treating clinician was also the conduit for the reporting of adverse transfusion events. Monitoring the hazards of transfusion was difficult for the blood service as it rarely had direct contact with recipients. [28] In more recent years, such reporting is monitored through (among other things) the SHOT haemovigilance scheme.

D. Donors

3.12 The centrality of the donor to the blood service has been a consistent theme in both the written and the oral evidence of NHSBT.[29] The blood services in the UK could not meet their core functions without the donor. As a corollary to this, the blood service needs to protect its blood donors, and indeed recognises that it owes a duty to them. This has both a practical dimension, in maintaining the trust and goodwill of donors in the service so that blood is donated, and ensuring people follow the rules and regulations surrounding donation. It also has an ethical dimension. The blood donor undergoes a medical procedure for

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[25] Although they may sometimes have provided an advisory on-call service for specific complex treatment cases. Today, NHSBT has an on-call service which provides for such advice.
[26] See generally section 16(C). For example, Oral Evidence Dr Diana Walford [**INQY1000138**] dated 21.07.2021 at [48/1]
[27] Albeit not so removed at a policy level. RTDs sat on BPL committees and BPL was part of the CBLA along with the RTCs in the 1980s.
[28] See for example the comments of Professor Contreras in the context of the limited reporting by hospitals of jaundice events: Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [66/18]
[29] See for example: section 2 of the NBTS submission to the Royal Commission on the NHS (1977) [**CBLA0000612**] '*The cornerstone of the NBTS is the voluntary blood donor*'; and Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [74]

altruistic reasons; the blood service must properly protect their health and wellbeing and ensure proper use of their gift.

3.13 The blood donor is the individual with whom the blood service has a direct relationship. The service communicates with the donor, consents the donor, examines the donor, and performs medical procedures on the donor. While it may be a trite point, this is highly unusual within the health service. Indeed, today NHSBT is almost unique[30] in interacting (and therefore owing a duty) to someone other than the patient and their significant others.

3.14 Thus, to analyse the work of the blood service over the decades, it is necessary to understand how the duty to recipients and the duty to donors fit together. In almost all circumstances, the duty to donors is not in tension with the duty to recipients. Donors themselves recognise the importance of steps to protect the safety and sufficiency of the blood supply, consistently with the gift relationship that underpins a voluntary and unremunerated donation.[31] However, there are limited circumstances where a tension does arise. One example, explored below, is the difficult issue of the introduction of a screening test for a disease which has a high false positive rate[32]. Where the blood service engaged with the questions raised, such engagement was not somehow to favour the donor in any way but rather to protect the reliability of the blood supply within the framework of duties owed to both donors and recipients.

E. Expertise in the blood service

3.15 Another important feature of the blood service is the specific nature of its expertise. Primarily, its clinicians were haematologists working in the sphere of blood transfusion and the taking and processing of donations. Thus, the focus of their skills was related to donors, the management of donated blood, and transfusion. For example, blood service clinicians were not generally involved in the treatment of haemophilia, and thus were not expert in this field in the same way as treating clinicians.

3.16 Clinical freedom was relevant to the relationship between RTDs and the clinicians and patients in respect of transfusion; although advice from the RTDs was available when requested, ultimately it was the treating clinician who was treating the patient. Many RTDs were involved in teaching and advisory work on the use and management of blood and blood components, but were generally not in role of discussing and agreeing possible treatment with the

[30] Unusual cases exist, such as hospitals dealing with haemopoetic stem cell donors and gamete donors. The fact remains that few have the responsibilities and duties to the donor that the blood services do

[31] See, for example, the analysis of why blood donors give blood in Richard Titmuss' *The Gift Relationship: From Human Blood to Social Policy* (1970) **[HSOC0019917]** (Chapter 13(v) and Appendix 6)

[32] Dr Hewitt goes into considerable detail in considering how these duties interact in her Written statement **[WITN3101006]** at paras 24-106.

patient. The backdrop of the historic approach to clinical freedom was an aspect of the extent to which work RTDs were able to intervene in individual transfusion decisions. Their efforts (as described more fully in Section 15 below) were focused on advising, educating and audit of transfusion practice; the nature of clinical freedom in the past was different to that of today. [33]

3.17 The context included that the staff of the blood service were scientists as well as doctors, most notably virologists and microbiologists concerned with the safety of the blood supply. As several NHSBT witnesses have discussed, these staff typically were involved in the testing of blood and, to differing extents, the research of disease and development of testing. However, they were rarely clinicians directly treating patients, nor were they generally frontline clinicians in GUM clinics or other therapeutic/diagnostic roles.

F. Relationship with the rest of the NHS

3.18 The structure of the blood service in England and Wales over the years is set out in more detail in the documents cited in section 5 below. These are not repeated here. NHSBT is notably the only Core Participant with NHS in its name, but it performs a very particular role, principally providing a service to the rest of the NHS. Whether as a loose confederation of RTCs or as a special health authority, the blood service has existed structurally and functionally as a distinct entity. Save for very limited circumstances[6], it did not historically have direct access to patients in relation to their individual care.

G. Relationship with government

3.19 The role of the RTD was both clinical and managerial. It required clinical management of donors directly, and recipients (and/or their treating clinicians) indirectly. It involved management of an important part of the system which ensured a reliable supply of blood and components (and other services) – **footnote -** see for example the description by Dr Martlew of the services provided by the Mersey and North Wales RTC **[WITN4034001]** and **[NHBT0009743_001]** and NHSBT's web-site for the current position https://www.nhsbt.nhs.uk/what-we-do/blood-services/) to the health service.

3.20 Both roles required interaction with local governance (particularly in respect of the need for funding from RHAs) and national government (particularly in respect of obtaining permission to introduce policies).[7] In addition, specific

[33] As noted above, today NHSBT has a significant advisory role and offers an on-call service to assist treating clinicians

[6] Such limited circumstances include therapeutic apheresis.

[7] Dr Miflin in section 5 of her witness statement provides a number of pertinent examples of such interactions. Written Statement of Dr Gail Mifflin **[WITN0672006]** from [441]

RTDs had a significantly greater role in advising the DHSS[8] (for example Drs Tovey and Gunson as the consultant advisors in blood transfusion). However, the role of the RTDs in treatment was very largely one of supply and advice and education. That is important because, as is explored in some of the substantive sections below, advice would be given by the RTDs, but sometimes not followed as part of the overall decision making by government.

3.21 In addition, RTDs executed a management function over their RTCs. They were compelled to budget and ensure that sufficient funding was available for their core role (to ensure a reliable supply of blood to satisfy clinical need). They were required to negotiate with RHAs or, where possible, the DHSS on funding. In undertaking these roles, they had to operate within the financial bounds of their individual RTCs and maintain the confidence of clinicians, government, recipients, and donors. To do so, difficult holistic decisions, balancing a range of competing needs, had to be made. A failing of the confidence of any of blood services' stakeholders would have a significant negative impact on the reliable supply of blood for clinical use.

H. Conclusion

3.22 The blood service was in an unusual position throughout the period focused upon by the Inquiry. It owed a duty to both donors and recipients. It provided blood and other components as required, and advice when requested by clinicians, in their treatment of recipients and was required to meet the needs of those clinicians and patients. It supplied blood, blood components and related services, subject to the policies and funding decisions of the RHAs and central government made on its behalf (albeit usually with its advice as part of that decision-making process). This backdrop is essential to understanding the multi-faceted work and decisions of the blood service.

[8] Throughout these submissions we refer to the Department of Health and Social Care as DH (short for the 'Department of Health') save for in circumstances where we give the department the specific name that it had during a particular period (e.g. DHSS).

4. SECTION 4: DECISION-MAKING & RELIABILITY OF THE BLOOD SUPPLY

A. Introduction

4.1 In this section NHSBT sets out key considerations that influenced the blood services' decision-making during the period focused on by the Inquiry.

4.2 NHSBT's risk management includes consideration of threats to the blood supply, blood safety, donors, and involves the use of an internationally recognised risk-based decision-making framework. Other considerations include scientific advice, economics, and ethical advice. Each of these areas is explored below.

4.3 Most of this section focuses on the historical approach to decision-making, in particular looking at decision-making during the period with which the Inquiry is concerned

4.4 After that, we set out the position for decision-making in the blood service today following the introduction of the risk-based decision-making framework.

4.5 Finally, we deal with the considerations that underpin the introduction of a screening test, an issue of significance to the Inquiry.

B. Considerations influencing decision-making

4.6 The transfusion of blood and blood components '*is not, and is unlikely ever to be risk free*' [**WITN0672006**].[34] Thus, from the perspective of transmission of a TTI '*the safest transfusion is the one not given*' [**WITN6926001**].[35] However, when viewed from the context of the lifesaving transfusion, the opposite is true. Thus, the difficulty lies in striking the balance between the benefits of transfusion and the risks of complication flowing from transfusion. Given that transfusions are used for a wide range of conditions, and there are inherent risks, the balance must always be considered. This means that both risk reduction measures and consent are critical.

4.7 Infectious diseases which are transfusion transmissible are a risk to blood safety. Such diseases pose ongoing challenges for those with responsibility for the reliability of the blood supply. Of course, obviously, reliability in this context means reliability both as to the quality and as to the quantity of available blood.

4.8 As we set out in our opening statement, NHSBT and the blood services have had a long-standing responsibility for ''*the safety and supply of blood, organs, stem cells and tissue*' as well as encouraging donation, raising the quality of the blood and transplant services and the other responsibilities set out at

[34] Written Statement of Dr Gail Miflin [**WITN0672006**] at [352/1030]
[35] Written Statement of Dr Angela Robinson [**WITN6926001**] at [175]

paragraph 7 of NHSBT's opening statement [NHSBT OS].[36] All these responsibilities go to the objective of maintaining the reliability of the blood supply. The quality and quantity aspects of the blood service's role go back a long way. They are part of all aspects of its operational function which include the '*collection of blood from voluntary donors, the processing and testing of blood donations, and the supply of blood to hospitals*' [**WITN0672006**].[37]

C. Mix of Risks - sufficiency and supply

4.9 The objective of the blood service was (and is) to provide a reliable supply of blood for clinical needs. In achieving that objective, for the supply to be reliable it must be safe in quality (in that it is free from TTIs), safe in quantity (in that there is a sufficient supply), be cost-effective, and balance recipient and donor impacts. This requirement is demonstrated by DH's aims in the establishment of the NBA on 1 April 1993 [**WITN0672006**][38] which included:

- to maintain and promote blood and blood-products supply based on the outstanding system of voluntary, unpaid donors
- to implement a cost-effective strategy of ensuring an adequate supply of blood and blood products to meet national needs
- to ensure that the high standards of safety and quality in the blood supply are maintained throughout the blood service
- to ensure that blood products meet a consistent standard of safety and quality
- to ensure the cost efficient operations of the transfusion centres and the Bio Products Laboratory both individually and together as parts of the national service

4.10 In short, these listed aims included: sufficiency of supply, cost-effective supply, safety of supply, quality and safety of blood products, and cost efficient operations. As was explored in section 3 above, in our submission sufficiency of supply for clinical needs is a safety issue.

4.11 When approaching the management of the risks to the reliability of the blood supply, the Blood Services have always had to balance the questions of the safety of the blood itself, maintaining a sufficient quantity to supply clinical needs, and the cost of achieving these aims.

4.12 In addition, when considering whether to introduce a test or additional donor deferral the blood services must consider the additional benefit to the safety of the blood supply against the risk to a sufficient quantity of blood, and thus safety of a recipient on the basis of supply. A modern example where this was difficult

[36] NHSBT Opening Statement dated 26.09.2018
[37] Written Statement of Dr Gail Miflin [**WITN0672006**] **at** [10/35]
[38] Written Statement of Dr Gail Miflin [**WITN0672006**] **at** [10/37]

was during the flu and Covid pandemics where the risk of deferring large numbers of donors had to be considered.

4.13 Measures to maintain blood safety in respect of freedom from TTIs fall into two categories: first, donor selection and donor testing policies; and secondly, surveillance to ensure such policies work effectively.[39] It should also be noted that in managing risks to blood safety, the blood service's success in delivering its objectives depends on donors [**WITN0672006**].[40] As described in Richard Tedder's oral evidence:

> *'…it was a question how you get to know your donors, how you select your donors, how you process the material that you have harvested from the donors, how you treat that, how you use it, and how you keep a weather eye on adverse events.'* [**INQY1000256**][41]

4.14 The blood service may require an individual to volunteer information relevant to the question of whether they should give blood. To achieve the optimal disclosure of sensitive information from donors, the blood service needs a relationship of trust and goodwill. To secure and maintain trust and goodwill, it must ensure that it is meeting donor needs by considering the ''*impact on 'donors'* of any policies introduced – including personal impacts on donors [**WITN0672006**][42], as well as how the policy may influence the likelihood of repeat donations.

4.15 The factors in achieving a reliable blood supply can sometimes be in tension. The blood service historically has had to balance the safety of the blood, through controls on the collection, processing, and testing of blood, with maintaining a safe level of supply of such blood to satisfy clinical demand. Risk mitigation strategies are therefore aimed at managing the transfusion transmission risk of pathogens in the context of the need to maintain supply.[43] Because of the many considerations that go into making policy decisions relating to safety, over time the blood services have developed a risk-based decision-making approach for blood safety. This approach acknowledges that although blood transfusion is an integral part of medical practice, risk is inherent from 'vein-to-vein'. Data from SHOT shows that most of the currently identified risk is hospital-side, although vigilance for emerging TTIs remains. The details of this risk-based approach are considered at the end of this section.

4.16 The blood service's approach reflects the situation elsewhere in medicine, and policy more generally, where decision-making is always a balancing act. As expressed by the Medical Ethicist, Professor Kerridge during oral examination:

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[39] Written Statement of Dr Gail Miflin [**WITN0672006**] at [355/1040]
[40] Written Statement of Dr Gail Miflin [**WITN0672006**] at [87/255]
[41] Oral Evidence of Professor Richard Tedder [**INQY1000256**] dated 14.10.2022 at [7/10]
[42] Written statement of Dr Gail Miflin [**WITN0672006**] at [242/1220]
[43] The maintenance of supply can also be influenced by appropriate blood use policies – the 30% reduction in the demand for blood over the last decade is largely due to the improved / more appropriate use of red cells.

> *'…not only are there lots of values at play, but it's commonly the case that all of these values are at play all of the time. […] There's few times in medicine where there aren't issues of risk or benefit or avoidance of harm or respect or some degree of concern for equity or access.'* [**INQY1000090**][44]

4.17 In achieving a reliable supply of blood for clinical needs, clinicians were (and still are) faced with choosing the options with the best balance of benefit over harms adjusted for their probabilities.

D. The precautionary principle

4.18 In relation to risk management, the precautionary principle has been raised several times as a relevant organisational principle in public health, and a principle relevant to the blood services' operations.

4.19 The precautionary principle is the principle that the burden of proof for potentially harmful actions (or inaction) by the relevant person or institution rests on the assurance of safety. It requires that, where there is a risk of serious harm, scientific uncertainty must be resolved in favour of the prevention of risk. Medical ethicist Professor Kerridge defined it as the idea that: *'if there's an identifiable risk, and if there's a risk of an adverse event happening in the future that we can take steps to avoid it'* [**INQY1000090**][45]

4.20 The Experts from the Public Health and Administration Group described how the precautionary principle [**INQY1000250**][46]:

> *'… highlights the fact that you need to consider risk assessment, risk communication and risk management and that brings together science and politics because, ultimately, risk management is a political 'decision'* [**INQY1000250**][47]

4.21 In evidence the public health experts also pointed to the importance of disease surveillance, national alert systems and the need for an interdependent trans-jurisdictional approach to managing risk. The expert evidence of public health experts Dr Susan Hopkins and Professor Colin Melville demonstrates the comparative sophistication of the present disease surveillance infrastructure and systems.[48]

4.22 The precautionary principle did not come into common usage until late in the 1980s. It was a principle derived from the management of new and emerging

[44] Oral Evidence of Professor Ian Kerridge [**INQY1000090**] dated 21.01.2021 at [19/6]
[45] Oral Evidence of Professor Ian Kerridge [**INQY1000090**] dated 21.01.2021 at [91/21]
[46] Public Health and Administration Group Transcript 3 October 2022 110/20
[47] Public Health and Administration Group Transcript [**INQY1000250**] dated 3.09.2022 at [110/20]
[48] Infected Blood Inquiry transcript 15 November 2022

technologies in the context of environmental risk[49]. That the specific terminology 'precautionary principle' was not used prior to this time reflects that this was a specific philosophical principle with a specific application. During the 1980s, however, precautionary *approaches* were taken to managing safety. It is important to bear in mind that these were, however, not necessarily applications of the specific principle.

4.23 Importantly, there is a range of different formulations of the precautionary principle. During the medical ethicists' oral evidence, it was stated that '*there are at least seven, probably 20 different definitions'.*[50] It is crucial, in evaluating the engagement of the principle, to recognise that inherent in its application is an analysis of risk. A definition was given in the expert report which was cited during the Public Health experts' session:

> *'… the precautionary principle was originally developed [...] to address risks to the environment but was subsequently expanded to also encompass risk to public health. The principle requires that 'proactive action be taken to prevent or minimise threats to human health or the environment, notwithstanding the absence of full scientific certainty about the nature and scope of such threats.'* [**RLIT0001745**][51]

4.24 Risks can be analysed by reference to foreseeability, significance, the availability of risk mitigation strategies and the cost of those strategies. Professor Kerridge during the Medical Ethics' session explained that any application of the precautionary principle is subject thus to several questions; in effect, as highlighted above, to undertake a balancing exercise. Those questions include:

> *'… how foreseeable that risk is, how significant that risk is, what strategies are available to reduce that risk, and what's the cost of those strategies.'* [**INQY1000090**] [52]

4.25 The challenge of the balancing exercise, as described by Dr Hopkins, is that:

> *'…people can do things to such an extreme that it can cause other complications or consequences, or it could cause, you know, treatment not to be delivered that might be life-saving on the one hand, because of a potential challenge down the line'*[53]

4.26 She then explained that is why a framework exists through the regulatory organisations to determine what is reasonable and that it's really about '*making sure you've thought through consequence'.*[54] Therefore, even where the

[49] The term originated in the writings of Hans Jonas during the 1980s, see: https://webpages.scu.edu/ftp/kwarner/7-163TheEthicsOfPrecaution.pdf
[50] Oral Evidence of Professor Julian Savulescu [**INQY1000090**] dated 21.01.2021 at [93/2]
[51] Liam Donaldson report under the heading "Department of Health" [**RLIT0001745**]
[52] Oral Evidence of Professor Ian Kerridge [**INQY1000090**] dated 21.01.2021 at [91/20]
[53] Oral Evidence of Public Health Experts, Dr Hopkins [47/16]
[54] Oral Evidence of Public Health Experts, Dr Hopkins [48/6]

precautionary principle is applied there remain value assessments to be 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.

4.27 For this reason, in circumstances where there is an absence of evidence on which to make a risk-based policy decision the precautionary principle may well be applied. But when there is sufficient evidence with which to make such a risk-based decision, then a framework is best used to weigh up and balance all of the elements that need to be factored into decision-making. Historically, the blood services have always tried, where possible, to make decisions based on a rational and evidential assessment of risk.

4.28 Importantly, within a holistic approach is also the requirement to consider what is lost by taking steps to avoid the risk. In the context of a resource constrained environment, what may be lost is the availability of resources in another area of healthcare provision, which will come with its own associated risk (and consequent impacts on patient safety or loss of the opportunity for the delivery of other treatments).

4.29 The medical ethicists note that the evaluation of risk is not clear cut, as it will depend on the position of the appraiser:

> '…*what a risk means is profoundly determined by who's making that assessment and on what methodological grounds they are doing it.*'[55]

4.30 A quote from Peter Flanagan in the Krever Commission report gives the context in which the precautionary principle is to be applied:

> *'The assessment of risks will also depend on the other risks which arise in the same context. Risks do not arise in a vacuum and there is often no harm-free option in applying the precautionary principle. In managing countervailing risks, the blood service had (and has) to consider the range of relevant factors which went/go to the overall objective of maintaining the reliability of the blood supply. Risks to patient safety arise as an aspect of ensuring the safety of blood actually transfused. However, risks to safety also arise in respect of the level of supply to ensure that blood can be transfused at all. Further, risks also flow from a limited budget and its impact on other aspects of blood safety.'* [**WITN6933001**][56]

4.31 The perspective adopted by Peter Flanagan was the need to '*strive for "optimal safety" adopting the precautionary principle within an effective governance framework that assures timely, appropriate and effective decision-making'* [**KREV0000001**][57]

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[55] Oral Evidence of Public Health Experts, Professor Kerridge [96/12]
[56] Written Statement of Dr Peter Flanagan [**WITN6933001**] at [372-373]
[57] The Krever Report [**KREV0000001**]

4.32 It is clear, in the context of vCJD that the magnitude of the severity of the impact of vCJD on infected individuals, and the fact that the extent of that impact could not be known, led to an application of the precautionary principle that, in turn, led to a significant expenditure on measures to prevent the risk of the spread of infection in the blood supply. We look at the issue of vCJD in more detail in section 12.

4.33 The Expert Report on public health states that cost can be a relevant consideration:

> *'…it is also important to note that some interpretations of the principle suggest that cost-benefit analysis should be undertaken in determining whether or not precautionary measures should be adopted in relation to risks posed to public health whereas others do not'.*[58] *The report goes on to note that 'the assessment of risk and the need for precautionary action has at times involved a less than robust application of established scientific risk assessment techniques with insufficient cost-effectiveness and proportionality criteria in assessment risks to the blood supply (Farrell, 2012, pp167, 174)'.*[59]

4.34 This reflects the fact that cost management always plays a role in a system with finite resources as we consider in the section on the role of economics in decision-making further below.

4.35 It has been suggested at times in the course of the Inquiry's proceedings that the references to a '*shift'* in approach in relation to risk appraisal, evidenced by [**NHBT0000044_095**]; a short discussion paper prepared by Professor Contreras and Dr Barbara for the Advisory Committee on Transfusion Transmitted Diseases ('**ACTTD**'), were in fact references to the application of the precautionary principle. We submit that this was not the case and that this is demonstrated by the evidence. Specifically, had there been a '*shift'* in the official approach adopted this would have been reflected much more extensively in official documents.

4.36 In that paper the first paragraph stated that the:

> *'attitude towards transfusion safety has veered away from the concept of "maximum benefit at minimal cost" towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced.'* [**NHBT0000044_095**]

This does demonstrate the approach taken by some of the RTDs, and the change in risk perception in some aspects of the blood services. What this statement demonstrates is that throughout the history of the blood services

[58] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [117/18]
[59] Minutes of the 14th meeting of the UK Advisory Committee on Transfusion Transmitted Diseases [**DHSC0006982_049**] dated 12.01.1993

the maximum benefit to the blood services' stakeholders remained of critical importance; however, that over time where the extent of the risk warranted it, measures would be introduced notwithstanding the significant costs involved. Thus at most, the statement reflects a policy of effectiveness in the context of cost constraints. However, at no point in time was there a change in organisational policy reflecting this statement by Professor Contreras.

4.37 The view of NHSBT is best reflected in the statement of Angela Robinson at paragraphs 302-315 [**WITN6926001**]:

> *'I do not agree with the concept of 'maximum benefit at minimal cost'. This is not how the blood service worked. I understand how Professor Contreras has expressed this in her letter, but I do not agree that this is how we approached safety of blood.*
>
> *It was not a case of minimal cost. We had to do a cost benefit analysis when something new was to be introduced, but the concept of maximum benefit at minimal cost is not how I would express this.*
>
> *If a new test was required then it was introduced in the most cost-effective manner possible, for example through national purchasing and contracts for cost of kits etc. More important was the balance of risk on donors and recipients and that was dependent on the sensitivity and specificity of tests and means of confirmatory testing. […]'*

4.38 When asked about whether there was a shift in thinking, in oral evidence Professor Contreras stated: *'...it was my own thinking and my team's thinking, and general thinking as well, that we had to introduce any testing, regardless of cost.'*[60] This applied to her view on the introduction of routine Anti-HBc screening in January 1993 [**DHSC0006982_049**].[61] However, Professor Contreras in a different context also stated that tests need '*sensitivity and specificity in order to get the right donors positive.'*[62] What this demonstrates is that blood service clinicians such as Professor Contreras were concerned with implementing effective tests at proportionate cost, but that the perspective on proportionality may have shifted over time, and in retrospect, with full knowledge of the harm suffered.

4.39 Finally, it is worth pointing out that the principle being advanced in that quotation that *'if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced',* appears on the face of it enthusiastically to embrace such new procedures so long as they appear to work. That actually seems very different from the cautious approach to such methodologies enshrined in the 'precautionary principle' proper. It all makes much more sense when seen for what it is (as described by Professor

[60] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [117/18]
[61] Minutes of the 14th meeting of the UK Advisory Committee on Transfusion Transmitted Diseases [**DHSC0006982_049**] dated 12.01.1993
[62] Oral evidence of Professor Marcela Contreras [**INQY1000166**] dated 03.12.2021 at [28/22]

Contreras herself): a desire to minimise risk, without being constrained by cost. As such, it might be said to be a cautious, or precautionary, approach in the sense that it is prioritising the minimisation of risk. But it is emphatically not a statement of the precautionary principle applied in a real-world context where balancing risks across a cost-constrained environment is a necessity.

E. Role of economics in decision-making

4.40 In her statement Dr Miflin notes that the transfusion services 'work within the confines of the NHS structure and budget and decisions should be made in this context eg on the basis of cost-effectiveness within the greater system'.[63]

4.41 Invariably decisions made by the blood services were made within the constraints of its funding envelope. As Dr Walford made clear in her oral evidence, government in the health sphere is required to prioritise managing spend, and before the establishment of the National Blood Association it was for the regions '*to determine how much money they were going to accord their regional Transfusion Service'* [**INQY1000138**].[64] Once a clinical improvement was recommended by the NBTS clinicians, each RTD would typically have to secure funding from their RHA to proceed with its implementation.

4.42 If DH did not commit centrally funded money, each RTD had to go to their RHA to make the case for additional funding locally. The RHAs would give central money sometimes ring-fenced to transfusion centres to do something like HIV testing, but not always. How money was divided up:

> *'…in terms of the priorities in the NHS between the Blood Transfusion Service and all their other priorities was a matter for Regional Health Authorities and their regional chairmen and, as I say, it was very variable'* [**INQY1000138**] [65]

4.43 Funding considerations weighed particularly heavily on the blood service at times of national austerity. Many politicians commented on the difficult financial position faced by the Department of Health in funding the blood services and the provision of blood and blood products. For example, Baroness Bottomley described the experience of securing the Department of Health's funding from the Treasury as one where her '*whole life was spent engaged in armed combat trying to win my budget and fight to the bitter end*'[66]. Indeed, when discussing the provision of funds for the Macfarlane Trust in 1989, she explored extensively how funds had to be cut out of the Health Education Authority

[63] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1030]
[64] Oral Evidence Dr Diana Walford [**INQY1000138**] dated 21.07.2021 at [195/1]

[65] Oral Evidence Dr Diana Walford [**INQY1000138**] dated 21.07.2021 at [195/10]
[66] Oral Evidence of Virginia Bottomley dated 28.06.2022 at [78/18]

Budget[67], funding for Broadmoor Hospital, and the Disability Service Authority [**INQY1000216**].[68]

4.44 In NHSBT's submission there were both significant funding discrepancies between RTCs and differences in the bureaucratic processes that all impacted upon decision-making. Not all RTCs were equally funded, '*some regions were so much more generous to their Regional Transfusion Centres than others'* [**INQY1000138**].[69] Where the blood service wished to do something beyond the constraints of its budget, it had to apply either to the region, or to DH for additional assistance. Professor Contreras described how '*Some Regional Transfusion Centres never met with the Regional Health Authority. They were devolved to the district and the district had other priorities. So many were very short of cash*' [**INQY1000165**][70]

4.45 As stated by Dr Brian McClelland in oral evidence funding was not always simple for the blood services:

> *'…there are examples where Regional Health Authorities have actually acted promptly and effectively in funding important developments in the transfusion -- regional transfusion services, as they were. Obviously, there are other examples when that did not happen. The Common Services Agency, which has now changed its name, was quite a bureaucratic outfit and, of course, it was -- there was also a question of competition with many other services, and I would say the relationship between the transfusion directors and the Common Services Agency was never an easy one and there were frequent occasions in which not only was funding not allocated […].'* [**INQY1000177**][71]

4.46 In addition to the regions funding the RTCs to different levels, blood services in different areas had competing priorities in relation to the allocation of public funding. The blood services had multiple different expenditures to manage within the budgets that they received from the RHA. This included large scale capital expenditure – for example buying and replacing equipment, securing, and updating premises. This created difficulties for regions during times of significant change, for example during deindustrialisation when RTCs had to find new donors to replace donors from factories who attended as part of workplace donations.

4.47 It was the view of some of the blood services witnesses that budgetary constraints prevented changes from being made that were in their view necessary. As Dr McClelland noted:

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[67] She went on to describe this cut, which cut funding for AIDS education, as *'robbing Peter to pay Paul* Oral Evidence of Virginia Bottomley dated 28.06.2022 at [95/12]
[68] Oral Evidence of Virginia Bottomley dated 28.06.2022 at [93/5]
[69] Oral Evidence Dr Diana Walford [**INQY1000138**] dated 21.07.2021 at [195/1]
[70] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [29/5]
[71] Oral Evidence of Dr Brian McClelland [**INQY1000177**] dated 27.01.2022 at [9/4]

> *'…some extravagant claims were made that what the transfusion service was demanding was frankly unreasonable and excessive, on occasions when it was actually, in my view, certainly necessary expenditure to provide a safe and effective service.'* [**INQY1000177**][72]

4.48 There was also the general issue of "*trying to do this year's work on the historical funding allocation of the previous year […] it was always a struggle'.* [**INQY1000163**].[73] Long term projects were also affected:

> *'…issues are long-term -- you need a long-term planning frame. We're talking about scaling up and development over -- progressively over a number of years. And that's -- wasn't handled -- there wasn't a proper platform for handling that in local areas or Regional Health Authorities.'* [**INQY1000163**][74]

4.49 In the absence of additional funding from the RHA, the RTCs were restricted in the speed of their adoption of developments of the service recommended by the National Directorate, following its establishment.[75]

4.50 Dr Gunson's response to the HCV litigation in 2000 summarised some of these issues where he set out the funding difficulties before the establishment of the National Blood Authority some years later WITN4034001. Issues included:

> *'168. The National Directorate was established in 1988. However, in the absence of a national budget they had to lead by persuasion. This led to the formation of a National Blood Authority as it was perceived that the clinical developments required e.g. self-sufficiency in plasma, could not be achieved in a timely manner without full managerial control including the budget.*
>
> *230. I recall that it was beneficial in that it improved the coordination of plans for plasma procurement and fractionation. I found it helpful to understand other people's working difficulties. When it all came under one budgeting Health Authority the serious impact of dropping the costing of handling charges for procurement of plasma by BPL made immediately obvious the deficit in the budgets of the Blood Centres. This meant the NBA as a single coordinating authority could then authorise alteration of handling charges for locally prepared blood products to overcome the shortfall in funding at the Blood Centres.*
>
> *712. Had the service been nationalised about 15 to 20 years earlier it would have been much easier to progress towards national self-*

[72] Oral Evidence of Dr Brian McClelland [**INQY1000177**] dated 27.01.2022 at [9/4]
[73] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [23/23
[74] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [24/6]
[75] Written statement of Dr Vanessa Martlew [**WITN4034001**] at [263] also see further comments at [167], [285] and [720]

sufficiency in plasma but this would have required quite a lot of foresight and additional funding sooner.' WITN4034001 [76]

4.51 In addition to the general constraints were difficulties faced by RTDs in getting funding for certain areas of operations. Dr Robinson sets out in her written statement the issues with funding for research:

'…there was no funding whatsoever for research. Money had to be found from elsewhere in the budget if any work on research was to be undertaken, or self-funded in some way. I recall at the time that I was doing research on the quality of plasma and on the machines we used, that it was fortunate that I had the Hospital chemical pathology laboratory next door to the YRTC and we could collaborate on a lot of the research and investigations, but my RHA did not have any research funding I could apply for and this had to come out of my budget. This was the position both before and after devolution. Once the NBA came into existence there was a central funding pot.' [**WITN6926001**][77]

4.52 We do not ourselves consider the role of DH decision-making; however, we note that the Inquiry has received a helpful overview on this from DH officials and ministers. It is material that much of the allocation of funding was done on the basis of Quality Adjusted Life Years ('**QALYs**'). These were summarised by Hilary Pickles in oral evidence: '*It's a way of comparing apples and pears and benefits for extension in life and improving the quality of life*'.[78]

F. Role of ethics in decision-making

4.53 A wide range of different ethical considerations impacted upon the approach taken by the blood services. The starting point, of course, was the responsibility of doctors to '*do no harm*'. Further details of the blood services' guidelines and policies which codified many ethical issues for blood service clinicians and staff please see the sections on 'Running a blood service' (section 5) and 'Teaching and transfusion practice' (section 15) below.

4.54 The ethical obligations to donors should be viewed in the context of the '*gift relationship*'. The blood donor undergoes a medical procedure for altruistic reasons; the blood service must properly protect their health and wellbeing, and also ensure proper use of their gift. As set out by Dr Robinson in her written statement '*the importance of this should never be underestimated, as without the courage and altruism of donors there would be no blood service'* [**WITN6926003**].[79] It is therefore acknowledged that there is an:

[76] Dr Gunson's response to the HCV litigation in 2000 WITN4034001
[77] Written Statement of Dr Angela Robinson [**WITN6926001**] at [62-65]
[78] Dr Hilary Pickles Oral Evidence [148/21]
[79] Second Written Statement of Dr Angela Robinson [**WITN6926003**]

> *'ethical responsibility and duty of care towards recipients of potentially infectious blood components such that they deserve to be identified, counselled, tested and offered treatment where appropriate.'* [**WITN0672006**] [80]

In addition, the blood service has separate duties to donors and recipients, please see section 3 above, on the 'Blood service and its role'.

4.55 A second area in which there have been significant changes is in relation to the role of the patient. Prevailing norms in relation to patient consent, and the level of '*paternalism*' demonstrated by the health services evolved considerably over the time period covered by the Inquiry. It was not until 1995 that the General Medical Council (GMC) published the first edition of the Good Medical Practice ethical guidance which outlined the standards of care patients should expect and doctors should work towards. It placed a significant emphasis on trust and honesty and guiding principles. Now there is widespread acceptance that patients should be fully informed of risks. However, this welcome development must be tempered by an understanding of the complexities of risk estimation, risk communication, medical culture and the realities of clinical practice. This is important in the context of, for example, the obligation to inform patients who may have received transfusions from HCV positive donations, and informed consent prior to testing.

4.56 Ethical considerations also played a role in contacting donors, including in circumstances where the donor may have excluded themselves from future donations and may not wish to be involved. The blood services thus spent time delicately balancing the needs of the recipient and the donor. By treating the donor well, educating them on the importance of providing accurate information about their health status, and the need to comply with donor acceptance criteria the services had the best chance of maintaining a reliable supply of blood.

4.57 Ethical permission was also needed for trials and studies, which could lead to additional delays in getting permission and funding **NHBT0000076_037**.[81]

G. Role of scientific advice in decision-making

4.58 A significant amount of evidence has been heard by this Inquiry about the role of scientific advice in government. In relation to the particular structures through which the blood services advised government please see the answer to question 23 in Dr Miflin's statement (and the other answers therein signposted) [**WITN0672006**].[82]

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[80] Written Statement of Dr Gail Miflin [**WITN0672006**] at [372]
[81] Minutes of a meeting of the National Study on Surrogate NANBH Markers in Blood Donors on 9 June 1989 **NHBT0000076_037**
[82] Written Statement of Dr Gail Miflin [**WITN0672006**]

4.59 More generally the oral evidence of Baroness Bottomley [**BB OE**][83] set out important points in relation to advice, including on the role of the Chief Medical Officer ('**CMO**'), and the relationship between the CMO and their minister, and how a minister was unlikely to have the knowledge to challenge the scientific basis of any advice given.

4.60 Currently, NHSBT is accountable to DH, and thus liable to instruction from Health Ministers, who in turn may receive advice from the Advisory Committee on the Safety of Blood, Tissues and Organs ('**SaBTO**') and other advisory bodies. It should be noted that major policy decisions on blood safety were taken by DH, the latter usually following advice from SaBTO (or its predecessors). NHSBT may also receive advice from groups producing relevant guidelines or information, e.g. Joint UKBTS Professional Advisory Committee ('**JPAC**'), the British Society for Haematology, National Institute of Health and Care Excellence ('**NICE**'), and the NHS Central Alerting Service [**WITN0672006**].[84]

4.61 There have been multiple previous configurations for how scientific advice was provided to government that are relevant to NHSBT. These are not described in full here, the key issues that influence the provision of scientific advice are set out in the written statement of Dr Miflin, and include:

a) That the influence of the RTDs over central government policy making varied over time [**WITN0672006**][85]

b) Whether DH took measures to ensure advice given between RTDs was applied uniformly and effectively in the regions [**WITN0672006**][86]

c) The speed at which the advice was considered by relevant decision makers [**WITN0672006**][87]

d) Whether there was a link between the advice given, and the funding that was made available to RTCs [**WITN0672006**][88] and

e) The level of independence of the advice

4.62 In many areas specific working parties were set up to consider discrete issues in order to advise government (e.g. Record Keeping) [**CBLA0001742**][89]. Frequently, a note would be produced following the meeting of a Working Party. However, it is noted that prior to the establishment of a national blood service, these working parties, and their remit, were established on an ad-hoc basis.

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[83] Virginia Bottomley 28 June 2022.
[84] Written Statement of Dr Gail Miflin [**WITN0672006**] at [pg36]
[85] Written Statement of Dr Gail Miflin [**WITN0672006**] at [pg 96]
[86] Written Statement of Dr Gail Miflin [**WITN0672006**] at [pg 96]
[87] Written Statement of Dr Gail Miflin **[WITN0672006**] at [pg 11]
[88] Written Statement of Dr Gail Miflin **[WITN0672006]** at [pg 134][387]
[89] Regional Transfusion Directors meeting for 22 September 1983 [**CBLA0001742**]

H. The position now: the Risk-Based Decision-Making Framework ('RBDMF')

4.63 As set out in the written statement of Dr Miflin, risks are now systematically considered within the context of the Alliance of Blood Operators' Risk-Based Decision-Making framework and taken within the context of the NHS as a whole [**WITN0672006**].[90] This was adopted by the NHSBT board in 2015. The framework was developed on a four-part foundation that encompasses:

a) a series of Risk Management Principles stating what must be observed in making decisions about risk

b) a communications and consultation policy describing expectations for the consultation and education of stakeholder groups and of the general public

c) a set of Risk Tolerability Criteria defining when a risk can be deemed acceptable considering the benefits gained and

d) a policy for conduct of natural and social science assessments, including economic and social concern assessments, to ensure that they serve as credible inputs to risk management decisions [91]

4.64 It includes the following risk management principles

a) Beneficence – must do more good than harm

b) Fairness – safety decisions must be timely, fair, independent and sensitive to cultural values

c) Transparency – transparent and accessible to stakeholders and members of public,

d) Consultation – stakeholders are given opportunity to provide input

e) Evidence & judgment – decision includes analysis of risk, mitigation options, benefits, impacts and costs

f) Practicality & proportionality – allocation of effort and resources is proportional to level of risk

g) Vigilance – evolving risk situations must be monitored

h) Continuous improvement – all aspects of blood safety risk management must undergo period review and improvement

4.65 The framework uses the following processes

[90] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1466]

[91] See the Alliance of Blood Operators' Elements and Structure of the Framework: https://www.allianceofbloodoperators.org/abo-resources/risk-based-decision-making/rbdm-framework.aspx

a) Problem formulation - which include identifying the risk management options

b) Participation strategy – e.g. including the views of stakeholders such as patient or donor groups or charities

c) Assessment – this involves an assessment of proportionality, a risk assessment, a health economic assessment, an operational risk assessment (impact on sufficiency of supply, legal and compliance assessment, the practicalities of implementing any of the options being considered, the impact on component or service quality amongst other things)

d) Evaluation – this is the most important stage and includes taking the outputs of the above assessment and combining them with risk tolerability. RT defines the risk as intolerable, tolerable or acceptable and this will depend on a number of factors. These include the degree of risk eg how severe the transfused disease is, the economics or cost of mitigation and societal and contextual factors: ethical considerations in the distribution of risks and benefits; concerns and priorities associated with a particular risk source, or approach to risk management, expressed or held by stakeholders and the public.

e) Decision – following this evaluation a series of risk management options are determined and scored to come to a recommended decision

4.66 Some benefits of the framework include the following points; this framework is scalable, consistent across countries, well-being of transfusion recipients is central to blood safety decision-making. It helps align resources with health outcomes and produces evidence-based decisions. Secondly, the decision-making process generates a series of assessments conducted by a team of subject matter experts. The focus is on practicality and proportionality – in order to devote health service effort and resources in a manner that is appropriate to the risk and complexity of the decision, and effectiveness of the intervention

4.67 An important point is that the RBDMF doesn't preclude the use of the precautionary principle where the risk assessment concludes there is not enough evidence to make a risk-based decision.

4.68 NHSBT takes the view that this framework is the best means of managing risk, enabling the blood services to make decisions in the context of emerging risks, evolving technologies, societal issues, and economic realities. Indeed, this is also the view of many international blood services including all those in the Alliance of Blood Operators. Additionally, all four UK Blood Services, JPAC and SHOT have adopted this framework which replaced our previous UK BS safety policy decision-making framework.

I. Tests and their introduction

4.69 In respect of safety policy decision made, a decision on the introduction or otherwise of a test is part of the decision-making framework. Commentary on this particular aspect of decision-making is provided below. The introduction of tests, and the approach to decision-making in respect of such introduction has been explored in detail as part of the Inquiry. There are several questions to be raised in relation to decisions as to the introduction of a particular type of test by the blood services. These include:

a) Whether the virus/disease warrants a test

b) Whether a test exists

c) Whether the test is sufficiently reliable for use

d) Whether the test can be scaled for high throughput

e) Whether there is a confirmatory test.

4.70 These issues are considered in detail below and are relevant to the question of decision-making by the blood services in respect of the introduction of HIV, HCV, HBsAg, anti-HBV, anti-HCV and ALT testing (among others).

(1) Whether the virus/disease warrants a test

4.71 The first step is to determine whether the prevalence and severity of the virus/disease in the population warrants a test.

4.72 In some cases, a disease is not sufficiently serious and highly prevalent and therefore does not warrant a test. Examples of this are parvovirus and cytalomegalovirus ('**CMV**'). However, in cases where a particular population would be affected by a transfusion of blood or blood products infected with CMV then only CMV-screened components are issued (this would arise in the case of immunosuppressed recipients).

4.73 In other cases, deferral of donations is used rather than testing to prevent the risk of non-endemic diseases entering the blood supply. Examples include zika, dengue, borrelia and other tick-borne encephalitides. Deferral is easier, quicker to implement and cheaper than screening. Other countries may test for the same viruses either because they are endemic or due to greater prevalence in the population.

(2) Whether a test exists.

4.74 The second question is whether there is a test that can be used, either as a direct test for the virus/disease, or a surrogate test.

(3) Whether the test is sufficiently reliable for use

4.75 An example of the difficult balancing act the blood service must undertake is to determine whether a test is sufficiently reliable to introduce. Several factors go

into decision-making by health services on this point. These include impacts on the recipients of blood and blood products in relation to supply and safety, impact on donors and costs.

4.76 The reliability of a test is an essential factor for a clinician to consider when determining whether to offer a patient a test [**INQY0000241**]. [92]

4.77 Two crucial factors in identifying the reliability of a test are its sensitivity and specificity.

4.78 The sensitivity of a test is the '*extent to which a test correctly identifies those with a "disease"*', this is also known as the 'true positive rate'. The specificity is the '*extent to which a test correctly identifies those without the disease'*,[93] this is known as the 'true negative rate'. A test with 100% sensitivity would identify all those with the condition correctly. A test with 100% specificity would identify all people without the disease correctly. In general, tests which are highly sensitive have low specificity. This means that they correctly catch cases of the disease but may also identify (incorrectly) people without the disease as having the disease (false positives).

4.79 The sensitivity of a test operates as a function of the population of individuals truly positive for a disease. So, for a test that is 90% sensitive, 10% of the true positives will receive false negatives. The specificity of a test operates as a function of the entire population tested. So, for a test that is 90% specific, 10% of the entire population tested will receive false positives.

4.80 There are significant practical issues associated with false positive test results. One such issue is that, if a patient undergoes screening and receives a positive test result, this can lead to anxiety and depression in individuals as they face the consequence of living with a disease they do not have.

4.81 The Expert Report on Psychosocial Issues noted that false positive results, when patients have later been informed that the result had been falsely positive, have been associated, in the context of HIV, with:

> *'shock followed by elation for a few weeks then a chronic phase of anger and resentment about the wasted time and opportunities whilst thinking they were HIV positive. Readjustment was characterised by chronic stress, depression, anxiety and panic attacks.'* [**EXPG0000003**].[94]

Role of the Underlying Incidence of Disease

4.82 The rate of false negatives or positives will depend on the underlying incidence of a disease in the population. The performance of a test in a particular population is shown by the positive and negative predictive value of the test.

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[92] Expert Report to the Inquiry: Medical Ethics [**INQY0000241**] at [pg65]
[93] Expert Report to the Infected Blood Inquiry: Hepatitis, [pg12]
[94] Expert Report to the Infected Blood Inquiry: Psychosocial Issues [**EXPG0000003**]

The positive predictive value ('**PPV**') of a test is the probability that, when a person's test result is positive, they truly have the infection/disease, whereas the negative predictive value ('**NPV**') describes the probability that, when a person's test result is negative, they truly do not have the infection/disease. Generally, a higher prevalence of the disease in the population will increase the PPV and decrease the NPV.[95]

4.83 Take the following example at the extreme poles of the spectrum:

a) In both scenarios there are 10000 people. The likelihood of a false positive is 5% (5% of those who are not HCV positive are identified as being HCV positive). The likelihood of a true positive is 100% (all of those who are HCV positive are correctly identified).

b) Scenario 1: One person is HCV positive, 9999 are HCV negative. 0.01% of the population is infected.

c) Scenario 2: 1000 people are HCV positive, 9000 are HCV negative. 10% of the population is infected.

d) In Scenario 1 the test identifies one true positive, and 499 false positives. The PPV is 0.2%.

e) In Scenario 2 the test identifies 1000 true positives and 450 false positives. The PPV is 69%.

4.84 The PPV is much higher in Scenario 2 than Scenario 1. This is simply a function of the fact a higher proportion of those who test positive do actually have the disease.

4.85 One important point to be drawn from this is that the specificity and predictive value of a test in a low incidence and prevalence population, can thus be poorer than in a higher prevalence population. As Dr Barbara noted: '*the predictive value of a positive result hinges on the prevalence of the marker in a given population*' [**INQY1000176**][96]

4.86 Therefore in situations where the positive predictive value of a test is low, it is often essential to have confirmatory assays to determine whether the positives or negatives identified are true or false. [**INQY1000176**][97]

4.87 There is a range of factors that go into the decision-making process about whether a test should be introduced. A clinician should decide on whether to offer the patient a test based on the best interests of the patient, but there should also be consideration of '*broader public interests which should usually occur at higher levels, such as government departments, colleges, NHS, etc.*'[98] This will often be determined by the predictive value of the test's introduction.

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[95] Expert Report to the Infected Blood Inquiry: HIV [**EXPG0000004**]
[96] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [60/13]
[97] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [60/13]
[98] Expert Report to the Inquiry: Medical Ethics [**INQY0000241**] at [pg61]

Where the positive predictive value is low, or there is a risk of the identification of false positives, there may be merit in delaying test introduction.

(4) Whether the test can be scaled for high throughput

4.88 One further question is whether the test exists in a format that a high throughput service, such as the blood service, can use. For example, in relation to vCJD a test did exist (brain biopsy) but this was not appropriate because of its nature. Another example is detecting vCJD prions in blood samples using protein misfolding cyclic amplification (PMCA), however this was found not to be scalable.

(5) Whether there is a confirmatory test.

4.89 A confirmatory test is a test capable of affirming an initial screening test, or not, and providing a reliable basis for diagnosis and subsequent action. As such it is necessarily a different test from the original method and a repeat of the same test is not confirmatory in this context.

4.90 For some tests, the presence of confirmatory tests to confirm the analysis may strengthen the case for introduction. A fuller description of confirmatory tests is available at section 9 in relation to their importance for establishing the presence of HCV.

J. Conclusion

4.91 In conclusion, NHSBT is convinced, along with the majority of international blood services (including all of those in the Alliance of Blood Operators), and all other UK blood services, that this framework is the best means of managing risk, enabling the blood services to make decisions in the context of emerging risks, evolving technologies, societal issues, and economic realities.

5. SECTION 5: RUNNING THE BLOOD SERVICE

A. Introductory

5.1 For most of its life the blood service has been a loose confederation of RTCs.[99] This has been central to how it has developed, and to how it has approached many of the issues being explored by the Inquiry. This section explores some of the more day-to-day aspects of the blood service in England and Wales, including its structure, funding, and general approach to obtaining donations. It aims to provide an important backdrop to the sections which follow, while also engaging with some specific issues about donors.

a) There are a lot of documents already before the Inquiry that deal with the history and nature of the blood service. These include:

b) The CTI presentation on the blood service in the UK [**INQY0000307**]

c) Written Statement of Dr Gail Milfin [**WITN0672006**]

d) The updated NHSBT family tree attached to the Written Statement Dr Gail Miflin [**WITN0672007**]

e) The article by Dr Gunson and Helen Dodsworth entitled Fifty Years of Blood Transfusion published in Transfusion Medicine in 1996 [**NHBT0000028**]

5.2 This section does not repeat the content of those documents; indeed, wherever possible it uses citations direct to the CTI presentation. Instead, it addresses matters at a higher level and makes submissions on some important themes about the running of the blood service.

B. Structure of the blood service

5.3 The structural relationship between the four services in the UK is discussed in the CTI presentation [**INQY0000307**]. The relationship specifically of Wales with the English service is dealt briefly in Sections 1 and 3, and in the updated NHSBT family tree [**WITN0672007**]. None of the underlying factual structure of the service in the UK is repeated here.

(1) Working towards central management

5.4 From the formation of the Regional Hospital Boards ('**RHBs**') in 1948 to the formation of the National Blood Association in 1993 the blood service in England and Wales from a loose confederation of RTCs. The RTCs were administered by their RHBs, later the RHAs, with funding coming from those institutions. Thus, matters of funding were subject to the competition of other

[99] This phrase is used frequently throughout the evidence. See for example **[CBLA0000612]** at [pg3]: '*The NBTS is, therefore, a loose confederation of 14 Regional Transfusion Centres, independently financed, each providing services which vary considerably from Region to Region and three central laboratories financed by the DHSS.*'

regional priorities.[100] Funding was rarely provided directly by DH (to which, see the funding provided pursuant to Dr Owen's scheme to move the blood service towards self-sufficiency as an example). The Consultant Advisor to the DHSS on Blood Transfusion[101] held no executive authority and could only work by persuasion. The same was true of the National Director when the National Directorate was established.

5.5 RTCs were distinct from hospitals and the blood banks within hospitals. Thus, senior staff in the blood service had no executive authority over the functions inside hospitals (including clinical practice).

5.6 Structure was a perennial issue for the service. The difficulties of being a national service administered regionally was apparent as early as 1961 [**INQY0000307**].[102] A move to a unified single service was desired by the RTDs and rejected by DH at various points in the 1970s and 1980s:

a) At a special meeting of RTDs on 16 April 1970 it was unanimously agreed that the service should be a centrally financed and administered one which permitted national planning, specialised functions and improved efficiency. This was rejected by the DHSS and control of the RTCs was instead moved to the RHAs. Alongside this, the Central Committee for the NBTS, later the Advisory Committee on the NBTS, was established. Both of those committees had no executive authority nor centrally provided funding [**INQY0000307**].[103]

b) In May 1977 the blood service (with Dr Lane) submitted a proposal for reorganisation to the Royal Commission on the NHS. This proposal encouraged central management with executive control and central funding [**INQY0000307**].[104]

c) On 28 February 1980 Dr Tovey produced a paper which repeated the desire of the RTDs to have the blood service constituted as a body with central coordination. He also provided some first steps for responding to these management problems. As a result of these suggestions the DHSS formed the Advisory Committee on the NBTS [**INQY0000307**][105].

d) Over the period 1983 to 1985 the case for a nationally managed service was again advanced. In February 1985 Dr Fraser wrote to the DHSS on behalf of Dr Gunson incorporating feedback from all RTCs and requesting a nationally coordinated service [**INQY0000307**][106].

[100] The CTI presentation on the blood service in the UK [**INQY0000307**] at [11]
[101] For the relevant period Dr Maycock, then Dr Tovey, then Dr Gunson.
[102] The CTI presentation on the blood service in the UK [**INQY0000307**] at [14]
[103] The CTI presentation on the blood service in the UK [**INQY0000307**] at [20-23]
[104] The CTI presentation on the blood service in the UK [**INQY0000307**] at [30-33]
[105] The CTI presentation on the blood service in the UK [**INQY0000307**] at [41-42]
[106] The CTI presentation on the blood service in the UK [**INQY0000307**] at [49-50]

e) In October 1987 DHSS Central Management Services carried out an investigation into NBTS. One recommendation of that report was creating a Special Health Authority ('**SHA**') to manage the blood service centrally [**CBLA0002392**].[107] This was rejected and the National Directorate of the NBTS was instead established. Again, the National Directorate had no executive control over both RTCs and RHAs. The National Directorate itself (although not the RTCs) was funded centrally from DHSS [**INQY0000307**].[108]

f) In June 1990, Dr Gunson produced a paper which again raised the issue of central management, and his concern that the National Directorate would not be viable beyond October 1991. Considering the timelines involved, this paper appears to be the starting point from which the NBA eventually grew (via a structural review by Ernst & Young).[109]

5.7 More detail about the case advanced by the RTDs for the centralisation of the service is provided in the answers in Dr Miflin's written statement to questions 5 and 18 [**WITN0672006**]. The CTI presentation and Dr Milfin's written statement also discuss some of the reasons why the NBTS was not formally instituted as a single service until 1993. In NHSBT's view, this primarily turned on issues of cost and a political commitment to devolution of control of health to RHAs.

5.8 Throughout the remainder of these submissions there are various cases where express problems arising from the decentralised structure and funding of the blood service are explored. One example of this is the work of the blood service in trying to achieve self-sufficiency. However, there are also the intangible negatives of delay and confusion which come with a lack of central coordination, executive authority, and funding. These issues, arising at a time before the quick communication of information, are an ever-present factor when one considers the ability and performance of the blood service in responding to issues.

(2) Internal communication and meetings

5.9 Communication between RTDs have been an important feature of the blood service. Formal mechanisms for this purpose existed from an early stage within the English service, with the RTD meetings running back into the early 1950s (see e.g. the RTD meeting on 10 October 1951 [**DHSC0100058_007**]). Many such committees have existed over the years; the Inquiry has various sets of minutes that illustrate this. The written statement of Dr Miflin sets out some examples of these committees (although this is far from covering everything,

[107] Report, "The National Blood Transfusion Service: An Organisational Study", (October 1987) [**CBLA0002392**]
[108] The CTI presentation on the blood service in the UK [**INQY0000307**] at [57-60]
[109] The CTI presentation on the blood service in the UK [**INQY0000307**] at [70-84]

particularly if working parties are included) [**WITN0672006**].[110] Across the committees in place involving RTDs in the 1970s, 1980s and 1990s, there was a distinct lack of executive authority. In line with the position of the blood service and its management more generally, most of these committees did not have power to direct a specific course of action. Instead, the approach was one of obtaining consistency by consent.

5.10 During the Inquiry, a question about the change of the purpose of the RTD meetings was raised. This matter is discussed in the minutes of the final meeting of the RTDs on 18 January 1989 [**NHBT0018188**]. A note which appears to be from an attendee is available at [**SBTS0000628_011**].[111] Considering both notes and Professor Contreras' oral evidence [**INQY1000166**][112] (she suggested that the end of the RTD meetings was a proposal of Dr Gunson presented as a '*fait accomplit*'), it is unclear how the conclusion was reached. It is also unclear what the extent of the discussion was; while the note says there was '*no discussion of the advantages and disadvantages of dissolving the RTD meetings'* [**SBTS0000628_011**], the note itself records some form of contribution from members on this issue. Dr Wagstaff invited comments and objections.

5.11 The impact of the abolition of the RTD meetings is unclear. While this point of contact between RTDs was removed, this was at a time when the National Management Committee was being established. Other bodies were also established around this time, including the Advisory Committee on Transfusion Transmitted Infections('**ACTTI**') which included members of the English and Scottish service. As the note of the meeting itself recognised [**SBTS0000628_011**], the lack of executive control in the committee was a '*frustration*' and it appeared that the RTDs thought the *'divisional meetings to be a more useful forum than the National RTD meeting*'. This was also early in the period of the National Directorate and the National Management Committee had only recently been convened. Professor Contreras also noted in her evidence that the RTD meetings were a significant undertaking requiring days taken out of normal working time.[113]

5.12 These meetings were chaired by Dr Wagstaff who stated that:

> *'279. The meeting discussed Dr Gunson's proposals and the need for change. The Committee Structure associated with the National Directorate was welcomed and as the discussion of a medical/scientific*

[110] Written Statement of Dr Gail Miflin [**WITN0672006**] at [218-229]
[111] The CTI presentation on the blood service in the UK [**INQY0000307**] at [65] suggests this is a note from R Stewart. This is unclear as no one by that name is recorded as being in attendance at the meeting.
[112] Oral Evidence of Professor Marcelas Contreras [**INQY1000165**] dated 02.12.2021
[113] Oral Evidence of Professor Marcelas Contreras [**INQY1000165**] at [23/1].

> *RTD meeting developed it became clear that any managerial role for the RTD meeting was regarded as superfluous.*
>
> *280. It was agreed that there was value in meeting once a year for a one-day scientific symposium and it was agreed that this should be quite separate from the BBTS Meetings and should take place in the spring.*
>
> *281. Dr Gunson confirmed that contact with the SNBTS would be maintained by regular meetings between himself and Professor Cash. Dr Pickles confirmed that the DH accepted the changes and Dr Gunson confirmed three avenues of communication with the Department which would be maintained.*
>
> *282. I therefore asked those present if they wished for the RTD meetings to be discontinued and be replaced by an Annual Meeting open to all NBTS Consultants with a Scientific Agenda and this was agreed unanimously.'* [**WITN6988001**][114]

5.13 With the benefit of hindsight, considering the difficult events that followed in the 1990s, the changes made to the nature of the RTD meetings was regretted by some, but at the time it appeared that the meetings' use was limited and that they were being superseded. In our submission the decision looking prospectively was a reasonable and understandable option open to the RTDs.

5.14 One further feature of the blood service is the extensive informal cooperation which has existed over the years. It is hard to capture the extent of this informal communication, particularly when it concerned communications where there is no formal record. However, some of this comes through in the written correspondence available to the Inquiry.[115] Indeed, while committees and meetings provided the opportunity for the structured dissemination of information and decision-making, informal communications were often the fastest route that information was disseminated.

5.15 Overall, there were some difficulties in the internal communications processes of NBTS. The modification of the nature of RTD meeting was also unfortunate. However, in our submission these issues are all explicable in circumstances where there is a lack of central organisation and executive authority. While there is no guarantee central organisation around an executive authority would have resolved such internal communication processes, in our view the move to the NBA marked a distinct improvement in the approach to management of the service. Communication was a part of this.

C. Structure and function of an RTC

[114] Written Statement of Dr Wagstaff [**WITN6988001**] at [279-282]
[115] Also see the comments of Dr Gail Miflin in her written Statement [**WITN0672006**] at [216-217]

5.16 In their written and oral evidence, the RTDs gave evidence as to the structure and facilities in their RTC. For many, annual reports are also available to illustrate the development of each institution over time. We do not review this evidence in detail here as each of the RTCs was unique and had its own strengths and weaknesses (along with the RHB/RHA that funded it). The core and specialist activities of an RTC were set out by Dr Gunson in 1986. These are quoted in [**INQY0000307**].[116] It is worth bearing these in mind when considering the work of a RTC.

5.17 The process by which an RTC would approach a donation was slightly different depending on the processes adopted. Until the Red Book became the guiding document for transfusion practice, various agreed approaches and guidelines were available. However, there was no mechanism in the blood service to require consistent implementation across RTCs (and, as the evidence suggests, there were regional differences between RTCs). In a sense, not requiring rigid adherence was valuable in that it allowed RTDs to respond to local issues (most notably at North London Blood Transfusion Centre (NLBTC) which took donations from the highest risk region in the country). However, it could lead to unfortunate variations in practice across the country (exacerbated by funding issues).

5.18 Without going into detail on each of the steps by which a donation was taken and processed, the route to a donation was as follows:

a) RTCs would take donations from new and returning donors. While most donors would be returning donors, there was turnover each year which meant that a panel would need refreshing.

b) New donors would typically be recruited through various means, including television and radio advertising. Some examples of how RTCs (either individually or collectively as the blood service) would encourage donations through advertising are set out in Dr Miflin's statement. [**WITN0672006**].[117]

c) Donors would either attend permanent clinics at RTCs or attend temporary clinics held at community locations around the country. These would typically be in local halls or churches. This temporary accommodation posed a difficulty in that the available resources (e.g. separate rooms for privacy) could be a difficulty.

d) On attending at a session a donor would be health checked. This is explored in more detail below. The process of health checks changed over time as the makeup of staff at a donation, and the protocols involved, similarly changed and developed.

[116]The CTI presentation on the blood service in the UK [**INQY0000307**] at [54-55]
[117] Written Statement of Dr Gail Miflin [**WITN0672006**] at [865]

e) A donation would then be taken and entered into the system. Most donations were taken as part of biannual donations of whole blood, but some donors were specifically targeted for special features of their donation (e.g. specific antibodies). Plasmapheresis donors could give blood much more regularly.

f) Following donation, the donated blood would be tested and typed. As the period focused upon by this Inquiry went on, the number of screening tests applied to blood increased. Such testing was a significant endeavour considering that over two million donations a year would be typically taken in England and Wales in the 1980s.

g) Once blood was cleared as part of the testing and typing process, it was nearly ready for use. The next steps depended on whether the blood was: (1) issued to treatment centres (mostly hospitals) as whole blood; (2) processed into components at the RTC and then sent on to treatment centres; (3) processed into components at the RTC and then sent on to fractionation laboratories (with the remainder used at treatment centres).

h) Plasma provided to fractionation laboratories was usually provided pursuant to the targets that were set for RTCs (explored in Section 6). Blood provided to treatment centres might be sent as part of the usual blood allocation provided by an RTC or be provided pursuant to an order.

i) On dispatch of the blood, records were required to be maintained by the recipient locations. However, for the reasons explained in our Section 14 on Record Keeping, significant difficulties were experienced with this.

5.19 Dispatch of the blood or blood component was, typically, the last direct contact that an RTC would have with that donation. This is important in understanding why the blood service was distinct from treating clinicians (explored above in Section 3). The control that the blood service had over the reliability of the blood supply primarily related to controls that could be implemented prior to issue. As noted in Section 4, for TTIs the focus was the processes of donor selection and donation screening[118]. Only more recently have processes (such as leucodepletion) been used by the blood service to influence the safety and quality of blood. For example, heat treatment and the size of donation pools for the creation of fractionated products were outside of the remit of the blood service.

D. Donors and donor selection

(1) The goodwill of donors

[118] Of course, as was explained in The Blood Service and its Role, blood safety extends beyond TTIs and the blood service took many steps to ensure the overall safety of the blood (e.g. implementing a closed process to avoid bacterial contamination).

5.20 The role and relationship of the blood donor with the blood transfusion service has already been explored in Section 3 above which commented on the centrality of donors to the success of the blood service in providing a reliable supply of blood for clinical use. Without donors in sufficient quantities (and, indeed, a growth of the donor base to match increasing clinical need), the reliability of the blood supply is threatened. This is not to undermine the sense of duty and goodwill that donors have. Consistent with the gift relationship, they understand the need to provide both a sufficient quantity and quality of blood. However, it is incumbent on the blood service as part of maintaining the reliability of the blood supply to maintain the goodwill and duty that donors feel towards the act of donating. Goodwill is easily lost and hard to gain.

5.21 In our submission, concern about harm to the goodwill of donors (and thus their propensity to donate) was an important risk that had to be weighed when considering the risks and benefits of a particular course of action. Several NHSBT clinicians spoke about this issue, for example Professor Tedder:

> *'The introduction of a screening test when you are uncertain of its specificity and its sensitivity could do more harm. It could reduce – it could have reduced the availability of blood because of donors being unprepared – not prepared to subject themselves to this. […].*
>
> *I can understand why there might have been concern in the transfusion service not to risk introducing something which could do more harm, through rendering blood unavailable to use, rather than making people safer in the sense of removing people out of the donor panel that you don't want.'* [**INQY1000256**][119]

5.22 The evidence available to the Inquiry does not include information on donors and the relationship between goodwill and propensity to donate. However, harm to goodwill was a risk when introducing a policy, and particularly a policy which may lead to a serious but incorrect outcome. That risk, which posed a threat to the reliability of the blood supply, was an appropriate one to consider in the assessment of introducing a policy.

5.23 Indeed such a risk as described was unlike a typical shortage of blood. If there was a shortage of blood due to exceptional demand, a call for donors would likely result in increased attendance at sessions (to which see the recent example in 2022 below). However, if there was a drop of goodwill in donors, which then caused a shortage of blood (e.g. because some did not want to take the chance of receiving a false positive test for HIV), this would be different; this risked impacting the effectiveness any call for new donors. Put another way, there was a risk that donors that heard on the news that donating might

[119] Oral Evidence of Professor Richard Tedder [**INQY1000256**] dated 14.10.2022 at [60/3]

lead to them being incorrectly identified as having antibodies for HIV would choose not to donate.

5.24 Maintaining the goodwill of donors was (and remains) an important aspect of ensuring the reliability of the blood supply. It was reasonable for our clinicians to identify this risk and balance it in reaching the decisions they did on different issues.[120]

(2) The selection of donors

5.25 There are various aspects relevant to how the blood service selected donors. In the first instance, blood donors had a propensity to be from specific backgrounds and to share certain characteristics. This was a feature considered in Richard Titmuss' book *The Gift Relationship* [**HSOC0019917**][121], particularly in Chapters 6 and 7 where US and UK donors were presented side by side. A, if not the, key feature which distinguished the UK from the US was that UK donors were (on the whole) voluntary unremunerated donors donating blood. The relationship was not a transactional one centred on funds, and thus the demographics attracted were not donating out of a desire or need for remuneration. Many of the blood service witnesses recognised the importance of the voluntary unremunerated donor as offering comparative safety.

Form NBTS 110A

5.26 From this starting point of the voluntary unremunerated donor, health checks were applied to exclude those thought to be at risk. Form NBTS 110A was provided to donors as part of the process of donating blood; the form set out in a short and accessible format some of the key health indicia which would require consideration by the medical officer at a session. Various versions are available to the Inquiry, including one from 1967 [**PRSE0000636**][122] and another from 1983 which covers '*unexpected loss of weight*' [**PRSE0003547**][123]. This appears to have been an addition at the time the AIDS leaflet was also produced – see the letter of Dr Wagstaff at [**PRSE0000161**][124]. A more expansive version of NBTS 110A was issued in 1985 and included reference to AIDS [**DHSC0046337**].[125]

5.27 NBTS 110A was used as part of the process of consenting and processing a donor for donation; donors were asked to confirm that they had read the form

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[120] Oral Evidence of Professor Richard Tedder [**INQY1000256**] dated 14.10.2022 at [75/1]
[121] Richard Titmuss, The Gift Relationship, From Human Blood to Social Policy (published in 1970) [**HSOC0019917**]
[122]Report from working party of the Regional Transfusion Directors' Committee on Screening of blood donations for anti HTLV-III in Regional BTCs [**PRSE0000636**] dated 11.07.1985
[123] Poster entitled Welcome to the Donor Session [**PRSE0003547**]
[124]Memo prepared by Dr Wagstaff to colleagues on AIDS Leaflet [**PRSE0000161**] dated 6.07.1983
[125] National Blood Transfusion Service, Guidance for the Selection, Medical Examination and Care of Blood Donors, revised 1985 [**DHSC0046337**]

and did not have factors listed in the form applying to them. In 1985 a process of signing to confirm that the form had been read was included (although, in part, this also related to consenting donor screening) [**PRSE0000636**].[126]

The memorandum on the selection, medical examination, and care of donors

5.28 NBTS 110A represented a summary of some of the information provided for staff at donor sessions included in the NBTS memorandum on the selection, medical examination, and care of donors. That memorandum more expansively addressed the various medical conditions of concern to the blood service with direction on management of donors more generally. The memorandum appears to have been updated regularly (and, at least in the case of the NLBTC, appears to have been subject to internal revisions also).[127] Versions of these guidelines are available to the Inquiry, and include revisions from 1977 [**PRSE0003820**], 1983 [**NHBT0053225**], 1985 [**DHSC0046337**] and 1987 [**NHBT0086924**]. By 1990 the criteria had become part of the greater guidance on the blood transfusion service (the Red Book) which is explored in section 15.

5.29 One provision of the memorandum was that a history of jaundice was included as requiring deferral for one year. This appears to have initially been included in the memorandum as a result of the advice of the Advisory Group on the Testing for the Presence of Hepatitis B Surface Antigen and its Antibody. This advice was reported in DHSS circular HC(76)48 and authorities were asked to '*take action*' as a result of this [**DHSC0002181_051**]. In part, this may have been a response to the recognised issue that there were many sources of jaundice which did not threaten the blood supply (e.g. HAV)[128]. It appears the text memorandum was modified as a result of this expert advice; Dr Napier noted in his oral evidence that advising on this issue was in the remit of that expert advisory group and RTDs would take such advice[129]. This issue of expert knowledge is addressed further in respect of NANBH/HCV below in section 9.

5.30 The position on the ground relating to this provision is unclear. The AIDS leaflets for 1983 did include hepatitis B[130] in the final paragraph in the '*who is at risk from AIDS?*' section [**PRSE0004076**][131]. Jaundice also appeared on the

[126] Report from working party of the Regional Transfusion Directors' Committee on Screening of blood donations for anti HTLV-III in Regional BTCs [**PRSE0000636**] dated 11.07.1985
[127] A 1987 version of the memorandum from NLBTC includes many amendments in the year 1988 **[NHBT0086924]**.
[128] Oral evidence of Dr John Napier **[INQY1000163]** dated 30.11.2021 at [104/15] and oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [84/21].
[129] Oral evidence of Dr John Napier [**INQY100163**] dated 30.11.2021 at [116/20] and [118/5]
[130] Indeed, the drafting of the AIDS leaflet is explored in section 8 below. The draft produced by Dr Gunson and Dr Walford identified hepatitis generally.
[131] NBTS leaflet 'AIDS and how it concerns blood donors' (1983) **[PRSE0004076]**

NBTS 110A and so should have been notified by donors. Some RTDs indicated that they excluded permanently notwithstanding the text of the memorandum: e.g. Dr Entwistle[132], or the approach was modified to only permit cases of childhood jaundice e.g. Dr Brian McClelland[133]. Thus, the true situation is unclear. It may well be that the memorandum did not keep track with the practice on the ground (which may well be supported by the text of 1983 AIDS leaflet). However, insofar as the failure to update the guideline document in line with developing knowledge led to infection the blood service apologises.

Examining donors

5.31 The practice of donor examination and exclusion was a difficult balance because of the practicalities of this process. The existence of both NBTS 110A and the broader guidelines are examples of this. In our submission it was simply not practicable to require donors to voluntarily give up their time to read many pages of guidance setting out a wide range of diseases and conditions (many of which they would not have been aware of or understand). Thus, NBTS 110A acted as a one-page shortcut that donor attendants could check with a donor and flag any concerns to the medical officer. Along with the AIDS leaflet once introduced, it highlighted important symptoms which the blood service was most interested in to maximise the prospect of identifying risks to the safety of blood while also allowing donor sessions to progress.

Conclusion

5.32 The process was not a perfect one. Various blood service witnesses recognised that much turned on the prospect of the blood donor proffering information. It was difficult, if not impossible, for a clinician to effectively examine a donor by simply looking at them.[134] Considering that over 2.2 million donations a year were being taken by 1980 in England and Wales[135], it was also not practicable for a medical officer to examine and interview each donor. Considering that many donations were taken at temporary events, the lack of privacy was a further factor against examination.[136] Instead, by using voluntary unremunerated donors rather than paid donors, there was no incentive for donors to mislead or withhold information from the service.[137] Further, the

[132] Oral evidence of Dr Colin Entwistle [**INQY1000167]** dated 06.12.2021 at [64/16]
[133] Oral evidence of Dr Brian McClelland [**INQY1000177**] dated 27.01.2022 at [102/4].
[134] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021at [81/16] and Oral Evidence of Dr Brian McClelland [**INQY1000177**] dated 27.01.2022 at [27/13]
[135]Expert Report to the Infected Blood Inquiry: Statistics by the Statistics Expert Group (SEG) **[EXPG0000049]** at [pg67]
[136] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [106/16]
[137] Other than possibly the incentive of a test for AIDS without going to the GP or GUM clinic, to which risk the service was alert and keen to avoid.

approach generally adopted was one where, if doubt existed about a donor, then they would be deferred.[138]

5.33 Overall, the matter turned on those factors (identified in the sections preceding this one) that the blood service had to balance to ensure a reliable blood supply.

(3) Prison donors and other donation sessions

5.34 The issue of prison donation was addressed in Dr Miflin's written statement [**WITN0672006**].[139] Prison donations were a small contribution to the blood supply. The position in England and Wales was set out in the minutes of the meeting of the Working Party on Transfusion-Associated Hepatitis on 27 September 1983 [**PRSE0001299**]. Those minutes indicate a mixed picture with about half of the RTCs still undertaking prison donations, and a distinction being drawn between prisons on the one hand and open prisons on the other. Of those RTCs still using prisons, all save for one (Leeds) was moving away from such donation practices. Edwina Currie gave a written answer to a Parliamentary question on 11 February 1987 which indicated that blood collection from closed prisons and borstals in England and Wales ended by the end of 1984, with open prisons ending by the end of 1986 [**NHBT0057149_087**].[140]

5.35 Mirroring the comments of Dr Miflin in her written statement [**WITN0672006**],[141] NHSBT apologises for the slow approach adopted in withdrawing donor sessions in prisons. Once it became apparent that such sessions posed a higher threat of TTIs than the general population, they should have been withdrawn in a timely manner.

5.36 Aside from prison donations, donations at military institutions, workplaces, and as part of the family unit have all been identified as increasing the risk of a failure by a donor to self-exclude. This is particularly pertinent in the context of the AIDS leaflet where donors were asked to exclude based on specific categories of information which typically a person might want to keep private (such as homosexuality or intravenous drug use). Various blood service clinicians recognised that this posed a concern for the safety of the blood supply: Professor Contreras recollected discussions to avoid military personnel being lined up to give donations by their senior officer.[142] She recognised that, in the 1970s and 1980s, there was additional difficulty as the armed forces often barred individuals who were not heterosexual. Dr Wagstaff recognised that family members might feel some degree of obligation to donate and thus be more likely to conceal this relevant information than the typical donor.

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[138] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [106/18]
[139] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1409]
[140] Written Answer of Mrs Edwina Currie [**NHBT0057149_087**] dated 11.02.1987
[141] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1439]
[142] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [99/21]

5.37 To differing degrees, these issues reflect the balance that needed to be struck in ensuring the reliability of the blood supply. In respect of military donations and workplace donations, the ability to attend a location with a significant number of viable donors was good for ensuring security of supply. Dr Entwistle described military donations as '*incredibly beneficial to the Service*'.[143] In respect of workplace donations, Dr Hewitt noted that around half of the sessions held by the service were workplace donations.[144] Dr Harrison also noted that the end of workplace donations (prompted by the decline in industry discussed in the Contextual Factors section) was an issue in the Oxford region.[145] As to family donations, these were not within the control of the blood service[146]. Certainly, measures such as the questionnaire at NLBTC (which permitted a person to notify the service discreetly that their blood should not be used for transfusion) were an important aspect of responding to these difficulties in high-risk areas. As was the scope (sometimes used) for donors to contact the RTC after a donation.

5.38 Considered with the benefit of hindsight, these issues likely warranted a more significant response to minimise risk. Certainly, if the success of the donor questionnaire at NLBTC had been foreseen and implemented across the blood service, this would have been a positive step earlier in the process to allow for confidential deferral. As it stands, the RTC with the highest risk population benefitted from this approach.

5.39 However, at the time, the imperative for those managing these (present but nebulous) risks was to balance the response to them against the need to maintain an adequate quantity of blood for clinical need. As Dr McClelland noted, in the 1980s the blood service was in a situation where significant pressure was applied to maximise output of blood and plasma at a time when the full extent of the risks in doing so were not acutely appreciated. He described the situation in respect of supply as there being '*slightly in the sort of wartime atmosphere of the transfusion service*'[147]. With these pressures present, the balancing in favour of securing blood supply using military and workplace sessions (and not seeking to separate family groups) is understandable. Thus, while with the benefit of hindsight this might now be regarded as an approach which underweighted the pressure that could be applied in social and work settings to achieve donations, at the time there were significant pressures militating against reducing the available routes through which donors could make donations.

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[143] Oral evidence of Dr Colin Entwistle [**INQY1000167**] dated 06.12.2021 at [12/9]
[144] Oral evidence of Dr Patricia Hewitt [**INQY1000170**] dated 09.12.2021 at [22/2]
[145] Written Statement of Dr Jean Harrison [**WITN7046001**] at [79]
[146] And steps to manage this issue in temporary sessions, such as separating individuals before donation, would have been very difficult.
[147] Oral Evidence of Dr Brian McClelland [**INQY1000177**] dated 27.01.2022 at [97/13]

E. Running the blood service today

(1) Generally

5.40 In her statement Dr Miflin sets out the structure of NHSBT today in her answer to question 4 [**WITN0672006**].[148] Her statement gives considerable detail about the running of the blood service today. The institution, centrally managed and funded, stands significantly apart from the blood service prior to the formation of the NBA. Even compared to the NBA, NHSBT is a far larger institution which provides a host of additional services (most notably being the authority in charge of transplantation in the UK). Many of the flaws in the blood service apparent in the 1980s and 1990s have been resolved in the intervening years.

5.41 However, notwithstanding the extensive list of distinctions between the service today and the service prior to 1993, the core of the blood donation aspect of the service remains the same. NHSBT relies on the donation of voluntary unremunerated donors to supply healthcare providers with whole blood, blood components and some blood products.[149] To achieve enough donations, NHSBT relies on its reputation and the goodwill of donors. With the recent decision of the Commission on Human Medicines to advise the Department for Health that UK-sourced plasma can now be recommenced, which was accepted by ministers, we are once again relying more on the blood supply provided by our donors.[150]

5.42 That reputation and the goodwill of donors was recently important in resolving the amber alert that NHSBT declared between 12 October 2022 and 8 November 2022. Alongside hospitals reducing their use of blood (leading to a drop of 20% in orders), appointments for donations were filled to an average of 99% per week (compared to the 94% pre-alert) meaning that on average an extra 5,200 appointments were booked each week. While the biggest challenge here has been the difficulty of recruiting sufficient permanent front-line staff, the response of NHSBT's donors has been amazing. Even in normal times NHSBT needs 150,000 new donors each year to grow and diversify the donor base[151].

5.43 Thus, if proof were needed, we can see that the position remains that the maintenance of the reputation of NHSBT and the goodwill of donors to continue their voluntary unremunerated donation is absolutely central to NHSBT being able to continue to provide a reliable supply of blood for clinical use.

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[148] Written Statement of Dr Gail Miflin [**WITN0672006**]

[149] Although, with the advent of recombinant factor concentrates and other methods for treating clotting disorders, the products produced today have changed.

[150] See Written Statement of Dr Gail Miflin [**WITN0672006**] at [295-299] on the reintroduction of the use of UK-sourced plasma

[151] The detail of this amber alert event is provided in NHSBT's new story published on its website on 8 November 2022: https://www.blood.co.uk/news-and-campaigns/news-and-statements/blood-supply-shortage-alert-to-hospitals-in-england-ends/ .

5.44 We do not propose to comment further on the current position of NHSBT here; Dr Miflin's statement addresses this in detail [**WITN0672006**].[152] However, when making recommendations about NHSBT today it is important to recognise the important distinctions between NHSBT today and its predecessor institutions in the 1990s and further back in time.

(2) Donor selection today

5.45 Today donor selection is still a crucial part of maintaining the reliability of the blood supply. Donor selection guidelines are governed through JPAC and the current version of the Red Book (also discussed in the transfusion practice section below). While these matters are largely determined by JPAC, SaBTO may advise on donor eligibility in respect of specific classes of donor who have been historically identified as 'high risk'.

[152] Written Statement of Dr Gail Miflin [**WITN0672006**]

6. SECTION 6: SELF-SUFFICIENCY

A. Introduction

6.1 Self-sufficiency has been a core principle for the blood service since the mid-1970s. In some form or another, all witnesses representing the UK's blood services have recognised its centrality. As a principle, it is crucial in its own terms as a way of the blood service providing a reliable supply of blood for clinical use (both in terms of quality and quantity). However, it is also crucial to the Inquiry as a theme which explains many of the other actions taken by the blood services (and other actors involved in ensuring a reliable supply of blood).

6.2 This section of NHSBT's submissions focuses on the principle as a goal, and the steps taken to achieve it (particularly in the 1970s and the first half of the 1980s). However, this is not the only place that it is considered. Self-sufficiency is an important principle which informed the decisions of all the blood services in the UK and should as such be borne in mind throughout these submissions.

6.3 The remainder of this section is in three parts. First, we address the principle of self-sufficiency and how targets were set. Secondly, we consider, at a high level, those factors which limited the success of the blood services in reaching self-sufficiency. Thirdly, we consider the timeline more closely.

B. Setting targets for the blood service

(1) What was meant by self-sufficiency?

6.4 The setting of targets for the blood service was ultimately done with the Government policy of self-sufficiency in mind. Thus, to understand targets, it is necessary first to understand what was meant by self-sufficiency.

6.5 The evidence available to the Inquiry, both in contemporaneous documents and live evidence, indicates that there was no single accepted definition for self-sufficiency. This is a point made in the Counsel to the Inquiry ('**CTI**') presentation on Supply in England and Wales with which NHSBT agrees [**INQY0000333**].[153] (paragraph 8-9) Indeed, we identify the following points of ambiguity:

a) Whether self-sufficiency was to be assessed by reference to the need of all patients irrespective of actual choice of treatment, or whether it was to be assessed by reference to the need of only those patients for whom the choice of treatment would (if supply permitted) be UK produced product [**HCDO0000015_021**].[154]

[153] Jenni Richards QC, Matthew Hill; Chronological Presentation on Domestic Production and Self-Sufficiency (England and Wales dated 1 January 2022 **[INQY0000333]**

[154] As a matter of clinical freedom, some clinicians opted for non-domestic products at different times over the years. This was explored in oral evidence with the haemophilia centre directors. For a

b) Whether the need of each patient was to be assessed by reference to them living a life unrestricted by haemophilia or assessed by reference to them living '*a normal sedentary lifestyle*' [**OXUH0003612_001**].[155]

c) Whether the need of each patient was to be assessed as including provision for home treatment.

d) Whether the need of each patient was to be assessed as including prophylactic treatment.

e) Whether the meaning was different in different constituent nations of the UK [**INQY1000199**].[156]

f) Whether the meaning changed over time.

6.6 That there were differing understandings of self-sufficiency is also apparent from the evidence of blood service witnesses: compare, for example, the views of Dr Harrison **[WITN7046001]**[157], Dr Wagstaff **[WITN6988001**[158], Dr Williamson **[WITN0643010]**[159], Dr Hewitt **[WITN3101009]**[160], and Dr Boulton **[WITN3456002]**.[161]

6.7 This suggests that the concept of self-sufficiency has always been nebulous and requiring of definition. That ambiguity made proper forecast of demands for blood products difficult. It would have been appropriate, in line with the general calls for a centralised blood service in England and Wales, for a single body to have been established in 1975 (alongside the UK Government's announcement of its commitment to self-sufficiency) to manage progress towards the aim centrally. Lacking such centralised direction, the issue was bedevilled by a lack of long-term foresight along with variable funding by RHAs and central government.

(2) What set the demand for plasma in principle?

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documentary example, see the comments of Dr Jones at the UKHCDO meeting on 21 September 1990 [**HCDO0000015_021**]

[155] Terminology cited in the CTI presentation, taken from [**OXUH0003612_001**]

[156] Such a suggestion was made by Dr Snape in his Written statement and explored in his oral evidence. See the oral evidence of Dr Terry Snape **[INQY1000199]** dated 29 March 2022 from [126/9]

[157] [**WITN7046001**] **paragraph** 213: '*I understand self-sufficiency to mean that the whole country would not have to import any foreign blood product. I consider that this should mean the UK produced enough domestic material for all haemophiliacs and all other users. I worked on the assumption that people would not choose foreign product*'

[158] [**WITN6988001**] **paragraph** 205: '*To me, it meant the production of blood and blood products sufficient to meet the demands put on us by the clinical users. The Department of Health asserted that there should always be clinical freedom to prescribe products preferred by the medical staff concerned. This meant that there was, in practice, a proportion of Factor VIII which was supplied from outside the NHS. In those circumstances, self-sufficiency to me meant the provision of everything else, excluding the Factor VIII purchased from commercial sources*'

[159] [**WITN0643010**] **paragraph** 207

[160] [**WITN3101009**] **paragraph** 48

[161] [**WITN3456002**] **paragraph** 258

6.8 The starting point for consideration of demand (and therefore understanding self-sufficiency) was to make an estimate of the amount of blood required for clinical needs. As Factor VIII (and albumin, at least in the 1970s **[DHSC0001318]**[162]) it was the product with the most demand, the limiting factor on supply was plasma. In principle, there were two sources that set the demand level for plasma for fractionation.

6.9 First, the demand for plasma was described by the estimated needs of haemophilia treating clinicians to provide treatment to haemophiliacs. The CTI prepared a presentation which included an appendix on Factor VIII demand estimates [**INQY0000336**].[163] Two things are striking about that presentation: (1) the variance in the estimates provided each year by different individuals and bodies; and (2) the consistent increase in demand in the 1970s and to 1981. Considering the lack of clarity in the definition of self-sufficiency, the changing understanding of the number of haemophiliacs in the UK and changes in approach to treatment, this variance and consistent increase is explicable. However, it had the effect of making the goalposts on self-sufficiency elusive and continually moveable.

6.10 Alongside demand for plasma to satisfy clinical need sat the UK's fractionation capacity. In principle, fractionation capacity need not define the demand for plasma. This is because other products, most notably cryoprecipitate, could be produced at RTCs without fractionation to satisfy demands for Factor VIII protein. However, as is discussed in Section 8(D) of this report. The clinical freedom of those clinicians meant RTDs could do little to change this requirement. Thus, while not strictly a factor informing demand for plasma in principle, the reality was that fractionation capacity was such a factor. The CTI have prepared a presentation on this also, mapping the capacity of BPL/PFL [**INQY0000337**].[164] It is notable from this that fractionation capacity consistently lagged significantly behind demand for Factor VIII concentrate in the 1970s and 1980s.

6.11 Thus, it was some combination of these two factors which defined the demand that RTCs were tasked with satisfying through taking donations from donors.

(3) Who estimated demand for plasma in practice?

6.12 The prediction of demand was primarily a matter for haemophilia centre directors and the director of BPL. The detail of individual predictions is set out

[162] [**DHSC0001318**] Report of the Working Group on Trends in the Demand for Blood Products, December 1977. The point at which albumin production appears to have fallen away as the governing criterion is the preliminary report of the Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood Products dated June 1981 [**CBLA0001377**]

[163] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales. Appendix 1 Factor VIII Demand Estimates dated March 2022 [**INQY0000336**]

[164] Chronological presentation on the Domestic Supply of Blood Products in England and Wales. Appendix 2 BPL/PFL capacity production and plasma supply [**INQY0000337**]

in the CTI's presentation on demand [**INQY0000336**].[165] In the 1970s significant groups considering demand were the Expert Group on the Treatment of Haemophilia (e.g. [**PRSE0004706**]);[166] a joint meeting of HCDs and RTDs on 31 January 1974 [**CBLA0000187];**[167] and the Working Group on Trends in the Demand of Blood Products (e.g. [**DHSC0003616_124**]).[168] While RTDs did attend some of these meetings,[169] the evidence suggests that estimates of Factor VIII protein required were made by HCDs, whereas the RTDs undertook the conversion of demand to a plasma requirement.

6.13 While RTDs became increasingly involved in these estimates in the 1980s, the evidence suggests HCDs drove the estimates of Factor VIII protein itself. The critical estimate for the 1980s, 435,000kg of plasma, was derived from estimates of demand in the region of 100 million international units. Such a figure appears in the report of the Scientific and Technical Committee for the Central Laboratories[170] dated 26 March 1979 as being '*seen as the eventual requirement by some clinicians*' [**BPLL0008430_001**].[171] On 23 April 1981 there was a meeting of HCDs and RTDs at which the figure for the mid-1980s of 100 million i.u. was agreed, which was derived from the statistics up to 1979 provided by haemophilia centres [**DHSC0002207_019**].[172] However, it is noted in the preliminary report of the Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood Products that '*[r]epresentatives of the Haemophilia Directors estimate that by the mid-1980's the annual requirement for FVIII will reach 100 M i.u. for the United Kingdom*' [**CBLA0001377**].[173] The RTDs estimated from this figure that approximately 500,000kg of plasma would be required. At a further meeting of HCDs, RTDs and DHSS on 15 September 1981 this figure was revised downwards to 435,000kg [**CBLA0001448**].[174]

6.14 Broadly, the committees undertaking the predictions of demand were tasked with advising the DHSS. This was set out in the terms of reference of the Expert Group on the Treatment of Haemophilia [**PRSE0004706**],[175] and was the task

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[165] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales. Appendix 1 Factor VIII Demand Estimates dated March 2022 [**INQY0000336**] at [3]
[166] Minutes of the Expert Group on the Treatment of Haemophilia dated 20 March 1973 [**PRSE0004706]**
[167] Minutes of a joint meeting of Haemophilia Centre Directors and Blood Transfusion Directors held on 31 January 1974 **[CBLA0000187]**
[168] Minutes of the second meeting held of Working Group on trends in the Demand for Blood Products re: Factor VII and albumin dated 13 July 1977 **[DHSC0003616_124]**
[169] At the meeting on 31 January 1974 there were 41 representatives of haemophilia centres and 5 representatives of RTCs: see paragraph 64 of [**INQY0000333**]. Dr Darnborough attended meetings of the Working Group on Trends in the Demand for Blood Products: see e.g. [**DHSC0002359_043**].
[170] The minutes are headed National Blood Transfusion Service, although the parent body of this committee is unclear. Members included staff from RTCs, DHSS and BPL/PFL.
[171] Minutes of the National Blood Transfusion Service on 26 March 1979 [4] at [2]**[BPLL0008430_001]**
[172] Minutes of the Joint Meeting of Representatives of Haemophilia Centres/Blood TransfusionService Directors dated 23 April 1981 [**DHSC0002207_019]**
[173] Preliminary Report of the Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood Products dated 1 June 2018 paragraph [2] at [4] [**CBLA0001377**]
[174] Minutes of the Joint Meeting of Representatives of Haemophilia Directors, Blood Transfusion Service Directors and DHSS on 15 September 1981 at paragraph [10] at [3] [**CBLA0001448]**
[175] Minutes of the Expert Group on the Treatment of Haemophilia dated 20 March 1973 **[PRSE0004706]**

identified for the Working Group on Trends in the Demand for Blood Products [**DHSC0003616_124**].[176] The work undertaken in 1981 which concluded on a plasma demand of 435,000kg was similarly directed by the DHSS to recommend a plasma fractionation target for the redevelopment of BPL (taking into account the NBTS's ability to produce plasma) [**CBLA0001448**].[177] As is explored further below, significant decisions to pursue (and, ultimately, fund instead of the RHAs) increases in plasma supply were often a decision in the hands of the DHSS.

6.15 Thus, the role of RTDs in respect of the setting of high-level targets for demand appears to have been to react to the demands of committees (and, when it occurred, those of the DHSS in approving and moving forwards with estimates and requirements). This is consistent with the role of the RTDs, as removed from the recipient, and even the fractionation process. While they did attend meetings concerning these issues, their role was primarily in identifying how to obtain the plasma (or, indeed, the conversion of demand in i.u. to demand for plasma). It would appear they had relatively little input in the identification of clinical demand itself.

(4) The impact of continually changing estimates

6.16 From the CTI presentations it is apparent that there was a proliferation of estimates which made planning difficult. That difficulty was exacerbated by continual upwards trend of demand which (until around 1981) quickly outstripped even the previous highest estimates. Concrete steps to increase supply (at both the donation and fractionation level) would be advanced over time only for their outcome to be dwarfed by the increased demand over the same period. Long term planning was difficult and broadly absent.

6.17 A microcosm of this issue is the £500,000 investment secured by David Owen with the aim of self-sufficiency for AHG being an interim figure based on advice of the Expert Group on the Treatment of Haemophilia[178] (see the CTI presentation [**INQY0000334**]). In his statement for the HIV Litigation Dr Lane commented on this funding that (emphasis in original):[179]

> *'In retrospect, however, the Owen initiative rebounded on the Service in that it supported growth in <u>demand</u> for Factor VIII but only a basis for limited supply and growth in <u>output</u> from NBTS and BPL.'*[180]

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[176] Minutes of the second meeting held of Working Group on trends in the Demand for Blood Products re: Factor VII and albumin dated 13 July 1977 [**DHSC0003616_124]**

[177] Minutes of the Joint Meeting of Representatives of Haemophilia Directors, Blood Transfusion Service Directors and DHSS on 15 September 1981 at paragraph [10] at [3] [**CBLA0001448]**

[178] These figures, and the revision upwards, are discussed at [**INQY0000336**] **paragraph** 8

[179] Dr Lane made similar such comments at the time: see [**BPLL0001508**] at paragraph 123 of [**INQY0000333**]

[180] Dr Richard Lane, Fifth Draft of Proof of Evidence for the HIV Haemophilia Litigation [**CBLA0000005_002**], paragraph 179

6.18 Dr Owen, when advised of an increase in the estimates for plasma on 18 July 1976, considered that:

> *'This was inevitable and comes as no surprise at all. This only demonstrates once again why we must reform the National Blood Transfusion Service.'* [**DHSC0100006_145**].[181]

(5) Who set targets for individual RTCs?

6.19 The setting of targets for individual RTCs is more unclear. Such targets could be set as part of a national target (for example, in respect of the £500,000 investment encouraged by Dr Owen), or at a more local level between the RTDs. Broadly, the setting of local targets was as a proportion of the national target:

a) Dr Robinson noted in her statement that

> *'The target was based on the Factor VIII required nationally and then apportioned between the different regions. Therefore, our target didn't necessarily equate to the demands of the local population.'* [**WITN6926001**][182]

b) An example is the report of Dr Tovey and the divisional chairmen of the RTDs dated November 1980, where targets for RTDs were allocated on a regional population basis to respond to the future proposed capacity of BPL at 30 million i.u., but with the overall figures mediated through yield of the plasma at each RTC [**CBLA0001209**].[183] The report was to be sent to RHAs and RTDs so that they could plan to meet these requirements.[184]

c) In the late 1980s, the target applied across NBTS was a population number of 8.82 tonnes per million population by 1990. This was set as a service objective which then devolved down to the RTCs based on their population [**HSOC0003393**][185] **NHBT0071562_002** [186]

6.20 On some occasions RTDs would exceed demand and ask BPL to fractionate plasma in excess of targets. For example, it would appear the initial prompt for

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[181] Letter from G.E. Grimstone Department of Health and Social Security, to Mr Dutton re: the production of Factor VIII and corresponding meeting minute dated 21 June 1976 **[DHSC0100006_145]**
[182] Written Statement of Dr Angela Robinson at [68] **[WITN6926001]**
[183] Dr G H Tovey, Paper for the Advisory Committee on the National Blood Transfusion Service titled 'Supply of Plasma to the Blood Products Laboratory' which discusses the current state of supply in the UK together with table summarising the current and possible future supplies of plasma to BPL based on 1979 figures dated 1 November 1980 **[CBLA0001209]**
[184] These targets appear to have been linked to the upcoming introduction of the pro rata system.
[185] Agenda of the first meeting of the Plasma Supply and Blood Products Working Group dated 21 September 1988 **[HSOC0003393]**
[186] Letter from Mr Gunson to Dr V J Martlew regarding Plasma Supply, enclosing a report of the DHSS Medical Committee, titled: "Report of the Medical Sub-Committee to the Plasma Supply and Blood Products Working Party", and a chart by hand depicting Plasma Supply Build-Up dated 19 December 1988 **NHBT0071562_002**

consideration of stopgap was Sheffield RTC [**CBLA0000660**][187] and West Midlands RHA asking BPL to fractionate more plasma than it could satisfactorily undertake (see the meeting of BPL and DHSS on 25 October 1977 [**CBLA0000682**]).[188] On other occasions, RTCs exceeding their targets would counterbalance a shortfall elsewhere [**PRSE0001355**].[189]

C. Factors constraining the blood service in achieving self-sufficiency

6.21 Before undertaking a review of the timeline of plasma provision, it assists to begin by considering those long-term factors which continually impeded success in achieving self-sufficiency in the 1970s and 1980s. It was only by October 1990 that the Government's position was that clinical demand for home produced Factor VIII had been reached [**INQY0000336**].[190] The quality of the estimates, considered in the first part of this section, was a factor in this. A further three factors also bear consideration.

(1) Funding

6.22 First was funding. The CTI presentation recognises that funding (particularly in the 1970s) was a significant problem [**INQY0000333**].[191] Indeed, the blood service was faced with a nationally mandated requirement to make the nation self-sufficient without the concomitant funding (either at a national or regional level) [**CBLA0000005_002]**.[192] As Dr Lane noted in his HIV litigation statement, a move to self-sufficiency required '*continuing investment, to increase the production of Factor VIII beyond [the 275,000-donation goal of the Dr Owen investment]*'.[193]

6.23 The evidence on funding difficulties is extensive, but one example from a meeting of BPL and DHSS on 25 October 1977 is illustrative of the broader issue [**CBLA0000682**]:

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[187] The letter from Dr Wagstaff to Dr Maycock making this request is dated 27 September 1977 and is at [**CBLA0000660**]

[188] Note of meeting held at BPL on 25 October 1977 [**CBLA0000682]**

[189] This could include situations where there were shortfalls in labile products. See for example the RTD meeting on 20 January 1988 [**PRSE0001355**] where a 50,000-donation shortfall of red cells were considered and the possibility of purchasing from other regions explored

[190] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales Appendix 1 Factor VIII Demand Estimates dated 1 March 2022 paragraph [90] at [46] **[INQY0000336]** Although whether this is self-sufficiency depends on the definition taken

[191] Jenni Richards QC, Matthew Hill; Chronological Presentation on Domestic Production and Self-Sufficiency (England and Wales dated 1 January 2022 **[INQY0000333]**

[192] In our view, it is this point that Dr Lane was making in his HIV litigation statement at paragraph 63 [**CBLA0000005_002**]: *'[i]n the 1970's, self-sufficiency was considered desirable but it was not seen as an imperative in that external alternative sources of supply were available'.* As supply was available elsewhere, it was not imperative that self-sufficiency be sufficiently funded because RHAs could pay to obtain supplies from elsewhere. If that alternative source were not available, it would have entirely changed the dynamic behind funding for self-sufficiency

[193] Draft Proof of Evidence of Dr Lane re HIV Haemophilia Litigation dated 10 December 1990 paragraph [99] at [38] **[CBLA0000005_002]**

> *'4. Mr Parrott explained the Department's thinking on future planning for BPL. It was clear that the current constraints on expenditure and the relationship existing between the Department and NHS field authorities were not conducive to the successful implementation of radical, expensive solutions to blood products production problems. Although the Department fully accepted the desirability of having the activities of RTCs coordinated among themselves and with the central laboratories, it would not be possible to instruct RHAs how to develop their RTCs. However, it was agreed that whatever happened at BPL would tend to influence RHA planning of their own services. Progress would most probably be achieved by concentrating on what needed to be done at BPL and a phased redevelopment solution, such as that put forward by Dr Lane, seemed to be worthy of further examination. The need to expand blood products production, provided this was done on the basis of low-cost, selective development, has now been accepted by the Department, and the importance of maintaining a separate production unit for England and Wales and of not relying194 on the Scottish PFC at Liberton had recently been affirmed. The Department would therefore welcome further development of these ideas by BPL leading to the preparation of realistic development plans, based on agreed production targets.*
>
> *5. The meeting agreed that planning would have to be based on the assumption that the RTCs would be able to deliver the plasma required to meet further demand. […]'*[195]

6.24 Funding was clearly an important issue for many aspects of blood service supply. Plasmapheresis, which was successful in those areas where funding was provided (for example, Dr Robinson [**WITN6926001**][196] and Dr Martlew were both great proponents of the procedure), it was hampered by upfront cost elsewhere.[203] As a result the contribution of plasmapheresis to the plasma supply was more limited than initially envisaged.

(2) Central coordination and control

6.25 The second issue is one which is also identified in the above minutes of the BPL/DHSS meeting. There was no coordinated executive control over RTCs, nor such coordinated executive control over the blood service and the fractionation laboratories. Thus, as is described above, BPL had to be expanded on the assumption that the RTCs would increase supply in response. Further, RTCs would not move as a block, but instead individual RHAs would

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[194] A manuscript change to this document has crossed out '*relying*' and replaced it with '*being totally reliant*'. It is unclear who made this change

[195] Minutes of a meeting held at BPL on 25 October 1977 with annex re: blood products production at paragraph [4] and [5] at [2] [**CBLA0000682]**

[196] Dr Robinson's statement explores plasmapheresis in some detail. See [**WITN6926001**] generally, and particularly from question 147

have to decide to increase supply. And, because BPL was hoping to influence RHA planning rather than directing increased plasma supplies, there was a lag when BPL production came online (as is seen below, RHAs would tend to wait until BPL capacity became available before they acted) [**CBLA0000998**].[197] These issues could have been avoided with coordinated executive control (as NBTS had been asking for – see Section 5(A) above).

(3) Connection between plasma provision and supply of products

6.26 Third, and linked to these first two issues in respect of funding from RHAs to RTCs, was the lack of connection between supply of plasma to the fractionation laboratories on the one hand and provision of Factor VIII concentrate back to the regions on the other. In much of this period increased supply of plasma did not lead to a proportional increase in supply to a region of Factor VIII concentrate. There were two critical phases for this: (1) prior to the pro-rata system being implemented in 1981, when Factor VIII concentrate was not returned to regions in proportion to plasma supplied; and (2) in the period 1983 to 1987 when BPL were stockpiling plasma, so that increasing plasma provision did not immediately lead to the provision of more Factor VIII concentrate back to regions. This issue was a matter Dr Lane regularly commented on, which led to the pro-rata system discussed below [**INQY0000330**].[198]

6.27 It is worth noting why the stockpile was regarded at the time as important. As part of the development plans agreed with the DHSS for BPL it was decided that a stockpile of plasma would be produced so that (once commissioned) the plasma could be fractionated alongside the general supply while RTCs reached sufficient capacity [**NHBT0071562_002**].[199] In addition, for purposes of safety, BPL moved towards a quarantine system whereby plasma provided to BPL was held for 13 weeks to allow reports of infections to filter through the system [**LDOW0000247**].[200] The net result of this was that, for the period 1983-1987, demand for plasma for fractionation continued to increase notwithstanding there was no capacity to fractionate the excess plasma.

D. Self-sufficiency and the plasma supply: a timeline

(1) Introductory

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[197] In a report dated 17 September 1979 Dr Lane said the *'[i]nability to co-ordinate the plasma programme is a central defect of the NBTS organisation*' [**CBLA0000998**]

[198] See for example the presentation on pro rata distribution [**INQY0000330**]

[199] The stockpile, and consistent pressure on the blood service to achieve it, is considered from paragraph 58 of [**INQY0000337**]

[200] Dr Lane produced a report for the House of Commons Social Services Committee which sat on 25 March 1987 [**LDOW0000247**]. In that he described the '*quarantine storage period of thirteen weeks which permits late reports on donors from the Transfusion Service to reach BPL before implicated plasma donations are entered into fractionation*'. On 19 December 1988 the stockpile minimum to allow for quarantine was 100 tonnes [**NHBT0071562_002**]

6.28 As the final part of this section, it is important actually to consider plasma demand and supply over the 1970s and 1980s. This requires a close-grained analysis which assesses the complex picture of competing pressures on RTCs.

6.29 In summary, before giving the detailed history, the high-level conclusions are these:

a) 1973-1975: in this period fractionation capacity exceeded supply. The evidence suggests that lack of funding was critical to the slow increase in available plasma.

b) 1975-1977: in this period the allocation of £500,000 pushed forwards by Dr Owen led to a significant increase in the supply of plasma.

c) 1977-1980: in this period fractionation capacity increased as a result of technological developments at BPL. A lack of coordination between BPL and RTCs, coupled with the disconnect between plasma supply and concentrate provision back to the regions (which dissuaded RHAs increasing funding), hampered an increase in the plasma supply.

d) 1980-1981/1982: Plasma supply increased significantly. Crucial was the introduction of the pro-rata system whereby the provision of plasma to BPL would result in a proportionate supply of concentrates back to the region.

e) 1982/1983: Plasma supply and fractionation capacity were broadly in accordance; the MARP01 works at BPL concluded.

f) 1983-1987/1988: Over this period the new BPL was under construction. Plasma targets continued to increase as BPL was stockpiling plasma, although concentrate provision did not increase. Plasma provision increased over the period primarily as a result of technological advances (notably SAG-M); funding increases from RHAs were more limited.

g) 1987/1988-1990: the new BPL came on-line and fractionation capacity was massively increased. Plasma production also increased and by 1990 the UK Government concluded that self-sufficiency had been reached.

(2) 1973-1975

Supply and fractionation capacity

6.30 Over this period there was a significant increase in the fractionation capacity at BPL owing to revised production processes at BPL [**INQY0000337**].[201] Over

[201] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2 BPL/PFL capacity, production and plasma supply dated 1 March 2022 at Graph 1a paragraph [19] [**INQY0000337**]

that same period the provision of FFP to BPL remained broadly static [**INQY0000337**].[202]

Events

6.31 This period begins with the determination of the Expert Group on Haemophilia dated 20 March 1973, and particularly recommendations 3 and 4 of that group [**PRSE0004706**]:

> *'3. At the same time the U.K. should aim to become self-sufficient as soon as possible by increasing home production of freeze-dried AHG concentrate.*
>
> *4. The Regional Transfusion Directors should be consulted about the consequences of Recommendation 3 in terms of increased demands upon the Blood Transfusion Services throughout the U.K. […]'*[203]

6.32 On 20 July 1973 there was a special meeting of the RTDs where plasma production was discussed [**CBLA0000153**][204], with regional targets set [**CBLA0000154**] (see [**INQY0000333**] paragraph 60 *et seq*).[205] It was suggested that red cell concentrates could be used to produce the plasma equivalent of 100,000 donations, and RTDs were asked to inform Dr Maycock of requirements for staff and equipment.

Factors relevant to the supply of plasma

6.33 Of those features that hampered an increase in the production of plasma over the period, the most significant appears to be a lack of funding **[INQY0000333]**.[206] The net result was that the estimated requirement for funds was not less than £1 million, but that no central funding to support RTCs or BPL would be provided by DHSS. The letter of JA Scott of the Trent RHA to Dr Maycock dated 16 May 1974 [**DHSC0100005_094**] is telling; he wrote that there was a '*national edict*' for self-sufficiency which was not matched with national money.[207] Similarly, at the RTD meeting on 9 October 1974 it was noted '*[p]rogress is likely to continue to be slow until money was provided by one means or another*' [**NHBT0016494**].[208] Indeed, the immediate and

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[202] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2 BPL/PFL capacity, production and plasma supply dated 1 March 2022 at Graph 1b paragraph [20] [**INQY0000337**]

[203] Meeting minutes of the Expert Group on the Treatment of Haemophilia dated 20 March 1973 at [4] **[PRSE0004706];** also explored in detail in [**INQY0000333**] from paragraph 23 *et seq;*

[204] Minutes of a special meeting of Regional Transfusion Directors held on 29 July 1973 **[CBLA0000153]**

[205] Document entitled, 'Plasma needed for the preparation of anti-haemophilic concentrate' dated 20 July 1973 **[CBLA0000154]**

[206] This issue is explored at **[INQY0000333]** at [73-75]

[207] Letter from Dr. Scott to Dr. Maycock regarding the provision of plasma for Factor VIII concentrate dated 16 May 1974 [**DHSC0100005_094]**

[208] Minutes of the 153rd Regional Transfusion Directors' Meeting dated 9 October 1974 at [3] **[NHBT0016494]**

significant increase in plasma production following the investment of £500,000 following Dr Owen's initiative indicates funding was the critical factor in restricting plasma production.

6.34 Aside from funding, it would appear that there was little if any success in England and Wales in moving to an increased use of red cell concentrates (RCCs), albeit Dr Maycock did encourage such a move [**CBLA0000211**].[209] Pages 3-4 of [**INQY0000339**] indicate that from 1974 to 1976 the percentage of RCC use moved from 8% to 12.6%.[210] It is unclear why such difficulty was experienced in moving to more RCCs, although the following appear to be contributing factors:

a) The control of demand for components lay primarily with treating clinicians **[SCGV0000075_042]**.[211] Dr Maycock noted at the RTD meeting on 9 October 1974 that Glasgow had succeeded in moving to 40% issue of RCCs through:

> *'… seminars, […] talks to hospital medical staff and by using every opportunity to persuade clinicians to use concentrated red cells. It has required intensive and persistent effort by the medical staff of the RTC.'* [**NHBT0016494**].[212]

b) The staffing requirements for arranging separation. At the special RTD meeting held on 27 September 1973 it was noted that there was: '*great doubt, however, about getting staff to work evenings to separate plasma, at the present overtime rate*' [**CBLA0000160**].[213]. In essence, this was again a funding issue.

c) Around this time there was a worldwide shortage of plastic. As a result, obtaining plastic for donation collection (rather than glass bottles) was an added difficulty. This is explored in the CTI presentation at paragraph 63 [**INQY0000333**].[214]

(3) 1975-1977

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[209] Circular letter to all Regional Transfusion Directors from the Department of Health and Social Security dated 12 June 1974 **[CBLA0000211]**

[210] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 7, Statistics on Red Cell Concentrate Collections dated 1 March 2022 **[INQY0000339]**

[211] A report from 8 August 1975 of the European Public Health Committee Sub-Committee of Specialists on Blood Products **[SCGV0000075_042]** noted that red cell concentrated had '*been adopted by most persons working in the blood transfusion field it has not yet been fully accepted by many dinicians*'. It was suggested that '*at least up to 40-50% of all transfusions could be given in this form, if only the information and education of clinicians were activated*

[212] Minutes of the 153rd Regional Transfusion Directors' Meeting dated 9 October 1974 at [3] **[NHBT0016494]**

[213] Minutes of the 2nd Special Meeting of the Regional Transfusion Directors held on 27 September 1973 at [2] **[CBLA0000160]**

[214] Chronological Presentation on Domestic Production and Self-Sufficiency dated 1 January 2022 **[INQY0000333]**

6.35 This period was marked by significant investment from the DHSS following Dr Owen's initiative to pursue self-sufficiency. Over this period there was a significant increase in the production of plasma: see paragraph 24 of [**INQY0000337**].[215] Of particular note at the end of this period is the comment from Dr Maycock at a meeting of the RTDs, HCDs, and Regional Scientific Advisors on 26 July 1976 that '*large increases in the supply of plasma would not be helpful*' [**CBLA0000391**].[216] This was because the fractionation capacity in England did not exceed 15 million i.u. of Factor VIII.

6.36 However, the difficulties that would arise in the future were identified in a September 1976 paper of Mr Dutton and Dr Waiter [**DHSC0002181_045**].[217] In a paper set out in detail in [**INQY0000333**] at paragraph 150, the position facing increased provision of Factor VIII protein was discussed. They particularly noted that the current approach to funding the NBTS did not lend itself to a '*production partnership*' with BPL, and recognised that there '*may, however, be some aspects of component production that could with advantage be organised on a supra-national basis*'.

(4) 1977-1980

Supply and fractionation capacity

6.37 The relationship between fractionation capacity and plasma supply over this period is addressed in [**INQY0000337**] at paragraph 33 *et seq*.[218] In respect of plasma for fractionation, the period was marked by a more modest increase from 1977 to 1978 (around 18.5%), being flat from 1978 to 1979, and then a further modest increase from 1979 to 1980 (around 11.2%) **[INQY0000339]**[219]. Over the same period, the CTI have calculated that plasma capacity at BPL/PFL fell in 1978 (by around 14%) before increasing in 1979 (by around 117%). A figure for 1980 is not available (although a further increase may be interpolated). This is shown in Graph 2a of [**INQY0000337**].[220]

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[215] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply at paragraph [24] **[INQY0000337]**

[216] Minutes of meeting of Haemophilia Centre Directors, Regional Transfusion Directors and Regional Scientific advisors from the Supra regional Territory held at the Regional Health Authority dated 26 July 1976 [**CBLA0000391]**

[217] Letter from T. E. Dutton and Sheila L. Waiter, Department of Health and Social Security dated September 1976 **[DHSC0002181_045]**

[218] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply at paragraph [33] **[INQY0000337]**

[219] These more modest increases may in part be related to an approximate 12% growth in the use of RCCs over the period [**INQY0000339**]

[220] The reason why Graph 2b does not reflect an increase in concentrate capacity is unclear. It may be explicable because the source figure for capacity in Graph 2b takes into account actual plamsa provision to BPL, or the findings of the Medicines Inspectorate inspection meant BPL must"..*under no circumstances should production of any product be increased under the existing manufacturing conditions*'. The report is explored in detail at [INQY0000333] from paragraph 197

Events

6.38 At an RTD meeting on 14 December 1977 Dr Maycock noted that BPL could fractionate more FFP and '*asked those RTCs who could possibly do so to increase the amounts of plasma sent to BPL*' [**NHBT0016469_001**].[221] The context of this call is unclear as a BPL report earlier in that year indicated the '*stretched*' capacity of BPL would be reached at the end of the year **[CBLA0000664]**.[222] Given the 18.5% increase from 1977 to 1978, it would appear that at least some RTCs were able to respond to this request. It is unclear from the documentary evidence whether the increase in capacity which became available in 1979 was foreseen or notified to the RTDs at this point.

6.39 That significant increase in plasma capacity in 1979 appears to have been related to research and development improvements at BPL providing for improved filtration and handling procedures, leading to an increase in the pool size from 360-400 litres to 600-650 litres [**CBLA0000840**].[223] These improvements were reported in Dr Maycock's report for the year ending July 1978 (dated 8 September 1978). Significantly increased provision of FFP to BPL to utilise this capacity did not occur until 1981.

Factors relevant to the supply of plasma – funding

6.40 Of those features that hampered an increase in the production of plasma to meet the increased capacity at BPL in 1979, the most significant again appears to be funding. On 26 April 1978 Mr Dutton of the DHSS noted that '*most centres appear to be approaching maximum capacity with present resources*' [**DHSC0002325_013**].[224] On 7 June 1979 Dr Tovey noted that Regions had an '*urgent need* to know where they stood on BPL capacity in the short and long term. He noted that '*many regions would be unable to produce the plasma required to support even the "stop gap" proposals without significant additional investment*' [**CBLA0000952**].[225]

6.41 At the time, funding could be secured in two ways. The first was to seek a further allocation from the DHSS and central government. Funding in this manner was resisted and did not arrive. There were various strands to the position.

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[221] Meeting Minutes of 169th Regional Transfusion Directors' Meeting Minutes dated 14 December 1977 at [8] **[NHBT0016469_001]**

[222] [**CBLA0000664**]. The section of the report drafted by Dr Lane is dated September 1977. This would accord with the concerns about lack of capacity to fractionate more plasma expressed by Dr Maycock on 25 October 1977 [**CBLA0000682**]

[223] Report to Advisory Sub-Committee on Blood Products and Blood Group Reference Laboratories of the Central Committee of National Blood Transfusion dated 8 September 1978 **[CBLA0000840].**

[224] Minutes of Meeting on Handling of the Trends Working Party Report dated 13 February 1978 **[DHSC0002325_013]**

[225] Meeting minutes from Scientific and Technical Committee for the Central Blood Laboratories National Blood Transfusion Service, dated 7 June, 1979 **[CBLA0000952]**

a) That funds arranged by Dr Owen were to encourage investment rather than be the first in a run of direct DHSS investments in RTCs. In a letter of 21 June 1976 Mr Dutton describes the intention of the Department that the scheme was a '*pump-priming*' operation to start the production of plasma; he noted that RHAs were expected to continue the programme from their normal allocation [**DHSC0103283_102**].[226]

b) The structure of healthcare in England and Wales was not, in principle, conducive to this approach. It was inappropriate for the DHSS to provide directed spending through RHAs. An example of this reasoning is quoted above, in the minutes of the meeting of BPL and DHSS on 25 October 1977 [**CBLA0000682**].[227]

c) The cost of procuring more plasma could be offset by RHAs against their current spend for commercial Factor VIII concentrate. For the reasons below, this had the difficulty that the pro-rata system was not in place, so there was no incentive of increased supply of NHS Factor VIII concentrate.

6.42 Mr Dutton on 26 April 1978 provided a paper considering future provision of plasma by RTCs [**DHSC0002325_013**].[228] In that report he considered the countervailing arguments against such funding, before reaching a conclusion which (based on past experience) considered a directed approach where RTCs had an obligation to provide necessary source agreement with the price provided by special allocation. However, this funding did not become available. To borrow the words of Mr Scott in his letter to Dr Maycock (discussed above), once again there was a national edict without the national money.

6.43 The other way for funding was through requiring RHAs to spend sums from their normal allocation. The difficulty of this was that fractionated products were not returned to regions in proportion to their provision of plasma (instead being based on numbers of patients). This is addressed in detail in [**INQY0000330**].[229] An ad hoc meeting of RTDs on 25 July 1979 recognised the current approach to distribution was '*a great disincentive to Regions to produce more plasma and therefore should be changed*' [**DHSC0002193_094**].[230] Similarly at another ad hoc meeting of RTDs on 26 September 1979 it was agreed that**:**

> *'Regional Health Authorities were not sympathetic to requests by Directors for money to finance plasma collection if they were not to*

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[226] Letter T E Dutton, General Administration North West Thames RHA dated 21 June 1976 **[DHSC0103283_102**

[227] Meeting Note held at BPL dated 25 October 1977 **[CBLA0000682]**

[228] Handling of the Trends Working Party Report: Minutes of meeting dated 13 February 1978 **[DHSC0002325_013]**

[229] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 4, Pro-rata Distribution of Blood Products **[INQY0000330]**

[230] Minutes of the meeting of ad hoc group of Regional Transfusion Directors dated 25 July 1979 paragraph [4] at [1] **[DHSC0002193_094]**

receive a proportional part of the finished factor VIII or PPF in return.' [**DHSC0002195_044**][231]

6.44 Thus, when demands for increases in plasma supply came over this period, individual RTCs were asked to increase production without necessary funds. That this position was the critical limiting factor is corroborated by the significant subsequent increase in plasma production achieved following the introduction of the pro rata system.

Factors relevant to the supply of plasma – other

6.45 However, aside from the key issue of funding, there were other factors which NHSBT identifies as relevant to the question of why plasma supply did not increase over this period:

a) **The lack of coordination between BPL and RTCs**. This was a significant problem in that the former could not direct the latter (or, more properly, the individual RHAs) to increase the supply of plasma. This has already been referenced in the general section above in the minutes of the meeting of BPL and DHSS on 25 October 1977 [**CBLA0000682**].[232] This was an issue that Dr Lane recognised in his report on the function of stopgap dated 31 May 1979. He identified a third causal factor in the static situation of production as:

'(3) Lack of a contractual arrangement for plasma supply. The supply of raw material to BPL from RTCs has remained a matter of 'grace and favour' and has never established a regularized contractual supply. The reason for this past failure has stemmed from weak central policy for the transfusion service and anomalous financial arrangements.

Here, a fundamental defect in the NBTS system is apparent: collection and distribution of whole blood and red cells have remained within the RTCs and their regional administrations, yet plasma collection, fractionation, distribution and financing have remained with BPL and the DHSS system of administration and financing. This anomaly has been clearly recognised but remained uncorrected while the increasing growth in requirement for plasma products has accentuated the defect and forced the regional and central issues wider apart.

Within the regional transfusion centres, comparable with BPL, there exists an incapacity to raise plasma production. Inadequate forecasting, deficient forward planning and absence

[231] Minutes of meeting of an ad hoc group of Regional Transfusion Directors dated 26 September 1979 at [1] **[DHSC0002195_044]**
[232] Note of meeting held at BPL dated 25 October 1977 **[CBLA0000682]]**

of a secure financial investment programme are the causes. Like BPL, regional centres have reached an unacceptably high level of occupancy of production capacity and cannot respond to new requirements without further money being spent **[CBLA0000948]**.*'*[233]

b) **The apparent lack of notice about the increase in capacity in 1979.** This was an aspect of the lack of coordination; the increase in capacity was an internal development at BPL rather than an event arising from development agreed with DHSS. Significant increases in production of plasma would take significant time to arrange the necessary donors, staff and equipment. Work was ongoing, including a campaign with the British Safety Council, to recruit more donors [**SBTS0000089_101**].[234]

c) **The precarious position of BPL in respect of its redevelopment**. The CTI presentation maps the development of the stop gap programme and MARP01 **[INQY0000333]**.[235] Indeed, the time from (i) the initial decision of the Joint Management Committee to advance stop gap on 13 June 1979, to (ii) agreement from NW Thames RHA to proceed to tender on MARP01 on 2 February 1981, was over 1.5 years ([**INQY0000333**] paragraph 203).[236] From that first agreement completion of the works took over 3 years ([**INQY0000337**] paragraph 47).[237] Over this period the long-term position for BPL was also in doubt ([**INQY0000333**] paragraph 208).[238] Considering Dr Lane [**CBLA0000005_002**][239] and Dr Maycock's [**CBLA0000840**] [240] view of the amount of time building a new laboratory would take (four to five years) this posed a significant issue for confidence in a route to fractionation [**DHSC0002201_006**].[241]

d) **The precarious position of BPL in respect of the use of capacity at PFC Liberton.** Whether there was such capacity was a technical matter between PFC and BPL; both in his HIV litigation statement

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[233] Report from Dr Lane re: function of the Stop-Gap programme and phased redevelopment of the Blood Products Laboratory **[CBLA0000948]**

[234] This particular campaign was aimed to recruit 21,000 new donors for NBTS. See the minutes of the RTD meeting on 7 February 1979 [**SBTS0000089_101**]

[235] Chronological Presentation on Domestic Production and Self-Sufficiency (England and Wales) dated 1 January 2022 **[INQY0000333]**

[236] Chronological Presentation on Domestic Production and Self-Sufficiency (England and Wales) dated 1 January 2022 paragraph [203] **[INQY0000333]**

[237] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply dated 1 March 2022 at paragraph [47] **[INQY0000337]**

[238] Chronological Presentation on Domestic Production and Self-Sufficiency (England and Wales) dated 1 January 2022 paragraph [208] **[INQY0000333]**

[239] Dr Lane's HIV litigation proof [**CBLA0000005_002**] **paragraph** 187

[240] Annual Report to the Advisory Sub-Committee on Blood Products and Blood Group Reference Laboratories of the Central Committee of the National Blood Transfusion Service dated 8 September 1978 [**CBLA0000840**]

[241] These concerns were also present in the early 1980s also. See, for example, the letter of Mr McKee, RMO for the Wessex RHA letter to DHSS on 8 October 1990 [**DHSC0002201_006**]

[**CBLA0000005_002**] [242] and in contemporaneous meetings [**CBLA0000682**].[243] Dr Lane indicated he did not think capacity in Scotland was available. Whether such capacity should be made available across the border was a matter for DHSS **DHSC0002309_018**]. [244] We do not comment on this more generally; the events are set out in the CTI presentation on Scotland and Northern Ireland [**INQY0000343**].[245] However, a lack of a defined route to fractionation put any investment by RHAs in doubt, as it made it possible that investment in plasma fractionation would not result in a proportional return of Factor VIII concentrate.

e) **The precarious position of BPL in respect of the Medicines Inspectorate.** Dr Lane appears to have been aware at the time of the inspections in April 1979 that the report would be negative for BPL. This information was disseminated and, from that date, put the position on fractionation capacity in doubt [**CBLA0000938**].[246] The report was eventually produced in August 1979 and directed that there should be no increase in capacity under existing manufacturing conditions [**DHSC0001812**].[247]

6.46 Many of these concerns were not discrete to this period; concern about capacity at BPL continued into the 1980s. However, taken with the overall difficulty of funding increased plasma production, they represent various structural issues which impeded any increase in plasma production by RTC.

(5) 1980-1981/1982[248]

6.47 Plasma supplied to BPL from 1980 to 1981/1982 increased substantially (by around 35.2%) [**CBLA0001207**].[249] Over that same year it is unclear whether fractionation capacity increased in 1980 or 1981: no figure for FPP is available for 1980 [**CBLA0001068**].[250] In any event the i.u. capacity does not appear to

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[242] See, for example, Dr Lane's HIV litigation statement [**CBLA0000005_002**] at paragraphs 229, 264 and 291-292

[243] See, for example, meeting of BPL and DHSS on 25 October 1977 [**CBLA0000682**] and the RTD meeting on 18 June 1980

[244] See again meeting of BPL and DHSS on 25 October 1977 [**CBLA0000682**] and the final decision on PFC on basis of (among other things) cost on 30 September 1982 [**DHSC0002309_018**]

[245] Presentation on self-sufficiency and domestic production of blood products in Scotland and for Northern Ireland dated 1 March 2022 **[INQY0000343]**

[246] E.g. letter from Dr Lane to Mr Dutton copied to Mr Smart dated 2 May 1979 [**CBLA0000938**]

[247] Conclusions and Recommendations of Medicines Division re Blood Products Laboratory **[DHSC0001812]**

[248] Note the footnote to page 40 of [**INQY0000337**]. The use of 1981/1982 is because the available data switches to using the BPL annual reports which appear to run by financial year

[249] It is unclear whether any of this increase arises as a result in any change of accounting practice going to the financial year approach in the annual reports. At this time there was also work to improve the quality of the plasma sent to BPL, which may have also increased provision (see minutes of the first meeting of the Advisory Committee on the NBTS on 1 December 1980 [**CBLA0001207**])

[250] At a meeting of the Joint Management Committee for the Central Blood Laboratories on 18 February 1990 Dr Tovey noted that RMOs and RTDs would require about 12 months to respond to the decision

have increased. Also of note is that actual Factor VIII concentrate issued was 43.5% higher than the stated i.u. capacity [**INQY0000337**].[251] These significant increases indicate the success of the pro-rata system introduced on 1 April 1981. The introduction of that approach is described in [**INQY0000330**].[252] It would appear this was the main driver for the increase in provision over this period; although RCCs also had a significant increase in use [**INQY0000339**],[253] and single donor plasma packs were in a trial phase [**INQY0000338**] from paragraph 15 *et seq.*[254] In the BPL Annual Report for 1981/1982 Dr Lane noted [**CBLA0001570**]:[255]

> *'From April 1981, the system of distribution of Blood Products has been one of pro-rata returns to the RTCs relative to plasma received from each. This has had the effect of stimulating regions to supply fresh frozen plasma, and in increasing quantities.'*

6.48 In the words of Mr Dutton when exploring the issue of pro-rata distribution with Dr Lane, in essence the scheme introduced '*a contract fractionating service for the Regions*' [**CBLA0000915**].[256] With some exceptions for special cases (e.g. provision for Lord Mayor Treloar's School), this is essentially what the pro-rata scheme produced. For the first time it directly connected satisfaction of clinical need for Factor VIII concentrate with provision of plasma to BPL.

6.49 In the Annual Report, Dr Lane also noted that BPL was now approaching capacity or above capacity in all mainstream activities. The initial redevelopment of BPL as part of the MARP01 is set out in a chronology from page 79 of [**INQY0000333**].[257] The works were approved by Dr Vaughan at the DHSS on 29 July 1980, and by NW Thames RHA on 2 February 1981. The works were completed in November 1982 [**DHSC0002239_003**].[258] Also, around this time, some RTDs expressed concern about reaching the 435,000kg target due to the availability of funding; a gradual and staged approach to increasing the plasma supply was suggested (see paras 347-349 of Dr Miflin's statement [**WITN0672006**]) [259].

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to introduce the pro-rata scheme [**CBLA0001068**]. This would suggest most of the plasma uplift came in the latter year

[251] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply **[INQY0000337]**

[252] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 4, Pro-rata Distribution of Blood Products **[INQY0000330]**

[253] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 7, Statistics on Red Cell Concentrate Collections **[INQY0000339]**

[254] They appear to have been used significantly more starting in late 1981 and early 1982 considering the 1981/1982 BPL report [**CBLA00001570**]

[255] See, similarly, Dr Gunson in NBTS Joint Management Committee Meeting on 24 April 1982 where the same point is made [**DHSC0002217_011**]

[256] [**CBLA0000915**] Letter from Mr Dutton at the DHSS to Dr Lane on the 26 February 1979

[257] Chronological Presentation on Domestic Production and Self-Sufficiency (England and Wales) dated 1 January 2022 at [79] **[INQY0000333]**

[258] Report from R. S. Lane, Blood Products Laboratory dated 16 January 1984 **[DHSC0002239_003]**

[259] Written Statement of Dr Gail Miflinat at [122] **[WITN0672006]**

(6) 1982/1983

6.50 This year again saw a significant increase in plasma provision to BPL/PFL in the order of 27.5%. With the conclusion of the MARP01 works in November 1982, the i.u. production capacity doubled to 30 million. Again, the relationship with the plasma fractionation capacity (which did not rise at the same time) is unclear. There were interruptions in processing at BPL as a result of the upgrade works (see [**INQY0000337**] at paragraph 46) which led to an excess of FFP input over processing.[260] By the end of the year, BPL was at capacity and the stockpiling of FFP began to assist in the commissioning of the new BPL building [**INQY0000337**] paragraph 49.[261]

6.51 Over this period there does appear to have been some difficulty arising from industrial action. It was thought that 150,000kg would have been achieved over the financial year without this action [**DHSC0002239_003**].[262]

(7) 1983-1987/1988

Supply and fractionation capacity

6.52 From 1983 demand for plasma became a function of FFP for fractionation plus FFP for stockpiling (to assist in the commissioning of the new BPL). Capacity for plasma at BPL/PFC remained at 150,000kg until the 1987/1988 year. Capacity for Factor VIII concentrate remained at 30 million i.u. until 1985/1986, when it reduced to 24 million i.u. (which appears to be connected to the commencement of the heat treatment of products). Plasma provision by NBTS continued to substantially increase as each year went on [**INQY0000337**].[263] Put another way, targets for plasma production by NBTS became a matter of aiming to meet the requirements of BPL when commissioned (and the 435,000 kg of plasma requirement for self-sufficiency).

Events

6.53 While the immediate requirement for plasma to BPL had ceased, pressure remained to increase the plasma supply in line with the targets that had been set. This is explored in **[INQY0000337]** from paragraph 59[264] (and Dr Miflin's statement from paragraph 979 [**WITN0672006**]).[265] Pressure both from the DHSS and BPL to meet targets to ensure proper utilisation of BPL when the

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[260] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply paragraph [46] **[INQY0000337]**
[261] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply paragraph [49] **[INQY0000337]**
[262] Report from R. S. Lane, Blood Products Laboratory, April 1982 - April 1983, April 1983 - December 1983, dated 16 January 1984 **[DHSC0002239_003]**
[263] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply **[INQY0000337]**
[264] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply paragraph [59] **[INQY0000337]**
[265] Written Statement of Dr Gail Miflin dated 19 October 2021 at paragraph [979] at [336] [**WITN0672006**]

redevelopment was complete was consistent. However, it is important to recognise that in this period RTCs did not receive an increase in Factor VIII concentrate provision in line with additional plasma (which was stockpiled). While in the end the delay in increasing product was significantly higher, on 27 April 1983 Dr Lane thought the delay in increased products would be 2 years [**BPLL0003987_002**]:

> *Dr Lane then went on to explain that in order to build up a sufficient supply of plasma for the new factory, the RTD's would need to start working on their budgets from September. However, there would be a two year delay before they received any increased return in products.*[266]

Factors relevant to supply – funding

6.54 Financial concerns remained. In January 1984 Dr Gunson produced a paper for the CBLA following a survey of the RTDs [**CBLA0001800.**][267] He noted that only three RTDs were confident that their RHAs would support the programme of increasing the plasma supply. Two factors Dr Gunson thought significant were that :

> *(1) Many R.H.A.'s are not willing to consider proposals on more than a year by year basis. Plans for the plasma supply require a programme based on a three to five year period.*
>
> *(2) Several regions are finding that with the current national plasma supply of 150,000 Kg per year the demand for P.P.F. is satisfied…*[268]*. This conclusion, however, has led to the view that the most economical way to achieve self-sufficiency is to purchase the additional quantity of Factor VIII required.*
>
> *It is doubtful whether the quantity of plasma in 1984/1985 will exceed that of the current year. The most convenient way in which such an increase could have been achieved is by using the SAG(M) system and it is significant that several RTD's have cancelled orders for these new packs which has caused embarrassment to one supplier…'*[269]

6.55 In respect of point (2), in essence, RHAs were being asked to fund RTCs to produce plasma in circumstances where no increase in concentrates would be supplied. Thus, if concentrates were still needed, the additional cost of purchase of other such products was required to be met. This was a significant

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[266] Minutes for the Central Blood Laboratories Authority meeting dated 27th April 1983 paragraph [54.4] at [4]

[267] Discussed at the meeting of the CBLA on 25 January 1984 [**CBLA0005002**]. Dr Harris of the DHSS at that meeting stressed the need to pressure RMOs and Regional Treasurers.

[268] In the next sentence Dr Gunson disagrees with this because insufficient time has passed. The text in the Relativity document is slightly corrupted.

[269] Dr Gunson, 'Report to the CBLA' dated 1 January 1984 at [1] **[CBLA0001800]**

factor dissuading investment; once again, plasma supply and Factor VIII concentrate returned to regions was decoupled.

6.56 Funding issues remained for much of this period, although they varied over time. Again, this is explored in [**INQY0000337**] from paragraph 59[270] (and Dr Miflin's statement from paragraph 979 [**WITN0672006**]).[271] However, the following give a flavour of these concerns:

a) On 28 November 1984 it was noted at a meeting of the CBLA that three to four regions had been '*unable to give any commitment either in finance or time to plasma supply*' [**DHSC0001101**].[272]

b) On 18 September 1985 it was noted at a meeting of the CBLA that DHSS was still pursuing RHAs on this issue and had written to those regions that had not agreed to meet target requirements [**CBLA0004979**].[273]

c) On 20 November 1985 it was noted at a meeting of the CBLA a concern was rather that the '*problem Regions, in terms of supply, remained a concern*'. It was thought that DHSS would have to '*continue to exert as much pressure as possible on them*' [**BPLL0011017**].[274]

6.57 It is clear that the delays in the commissioning of BPL were of concern to RTDs (not least as they were not yet receiving an increased level of concentrates to reflect the work done on plasma provision). Some of the minutes of this period are discussed in the statement of Dr Miflin at paras 351 to 361 [**WITN0672006**].[275] It is clear that some RTDs were concerned that their RHAs would seek to recoup some of the money that had been provided for plasma procurement (see, for example, the RTD meeting on 9 July 1986 [**CBLA0002312**]).[276]

Factors relevant to supply – SAG-M

6.58 Over the period the number of donations remained static; in both 1983 and 1988 there were approximately 2,140,000 donations in England and Wales [**EXPG0000049**] page 67. This is consistent with the concerns expressed that RHAs would not get value for money in increasing supply of plasma. Thus the continued increase in plasma provision to BPL appears to be a result of the

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[270] See, for example, the views expressed by Mr Winstanley and Dr Lane in the meeting of the Advisory Committee on the NBTS on 17 October 1983 [**CBLA0001763**]. The Advisory Committee recommended support be given to the CBLA and agreed DHSS should discuss the matter with RHAs.
[271] Written Statement of Dr Gail Miflin dated 19 October 2021 at paragraph [979] at [336] **[WITN0672006]**
[272] Dr H Gunson, 'Report to the CBLA' dated 1 April 1984 **[CBLA0001800]**
[273] Dr Gunson, 'Report to the CBLA' dated 1 January 1984 [**CBLA0004979**]
[274] Minutes of Central Blood Laboratories Authority twenty-first meeting dated 28 November 1985 **[BPLL0011017]**
[275] Written Statement of Dr Gail Miflin dated 19 October 2021 paragraphs [351-361] at [123-126] **[WITN0672006]**
[276] Minutes of the 200th Regional Transfusion Directors meeting dated 9 July 1986 **[CBLA0002312]**

way in which the available whole blood was managed rather than an increase in donors.

6.59 The crucial feature that increased plasma supply over the period appears to be the adoption of SAG-M (a solution of Saline, Adenine, Glucose and Mannitol) and the associated blood pack using that solution. In September 1984 50% of plasma was supplied to BPL in single plasma packs. However, this fell to 16% in the same quarter the following year following the introduction of SAG-M packs. SAG-M broadly eclipsed the use of single plasma packs because a larger volume was required to accommodate the additional plasma that could be removed from whole blood [**INQY0000338**].[277] Also by this period the use of RCCs had slowed in its increases, resting at around 56.3% by 1985 [**INQY0000339**].[278]

6.60 SAG-M was the single most significant contributor to the increase in plasma supply over the period. Its use began in mid-1984, with the single largest uptake in the plasma arriving at BPL in SAG-M separation occurring between 1984 (8%) to 1985 (55%[279]). By 1989 the provision at BPL reached 75% [**INQY0000335**].[280] The large uptake from 1984 to 1985 may well be the factor that led to the striking increase of 44% in plasma provided to BPL. At a meeting of the CBLA on 25 March 1986 Dr Lane noted that '*the effectiveness of the SAG programme was particularly relevant*' in achieving a satisfactory supply of plasma [**BPLL0011012**].[281] In the 1986/1987 financial year SAG-M plasma accounted for 65.8% of provision to BPL [**CBLA0002371**][282].

6.61 However, the introduction of SAG-M appears to have faced some delay. While its introduction appears to have been postulated in 1982, its use only began in mid-1984. Funding difficulties persisted, and it was unclear how much the use of this additive cost over older formulations. The details of these funding difficulties, and their resolution over 1985 and beyond, are dealt with in the CTI paper on SAG-M at [**INQY0000335**] and not repeated here.[283]

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[277] Chronological Presentation on the Domestic Supply of Blood Products in England & Wales Appendix 5, The Role of the Single Donor Plasma Pack in Plasma Supply in the 1970s and 1980s 1 March 2022 **[INQY0000338]**

[278] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 7, Statistics on Red Cell Concentrate Collections **[INQY0000339]**

[279] This figure is for July to September 1985. Paragraph 26 of the presentation appears to indicate a drop off back to 30.4% by the end of the year.

[280] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales. Appendix 6: The Role of SAG-M in the Plasma Supply in the 1980s paragraph [34] at [13] **[INQY0000335]**

[281] Minutes of CBLA 23rd meeting on 25 March 1986 at [3] **[BPLL0011012]**

[282] BPL and PFL Annual Report, Manufacturing and Research Development, April 1986 to March 1987 **[CBLA0002371]**

[283] Chronological Presentation on the Domestic Supply of Blood Products in England and Wales. Appendix 6: The Role of SAG-M in the Plasma Supply in the 1980s **[INQY0000335]**

6.62 From early 1986 delays in commissioning of BPL led to a pushing back of plasma targets[284]. A summary of a number of minutes over the period is provided in the statement of Dr Miflin at paragraph 995 [**WITN0672006**].[285] The extent to which this impacted on procurement is unclear.

(8) 1987/1988-1990

6.63 On 29 April 1987 the new production unit at BPL was opened. This meant a jump in the 1987/1988 financial year to a fractionation capacity of 450,000kg, albeit BPL fractionated only 258,629kg of the 374,069kg supplied to it. Of an available 60 million i.u., 24,696,760 i.u. was issued. In the year 1988/1989 BPL fractionated far in excess of the supplied plasma (and, indeed, in excess of its stated capacity for plasma). It produced 57 million i.u. of its 60 million i.u. capacity [**INQY0000337**].[286] The move to the new production facility, which took place across two fiscal years, appears to explain the failure to use capacity in the 1987/1988 financial year (see [**INQY0000337**] at paragraph 73-75).[287]

6.64 1988/1989 represented the first year for many in which actual fractionation capacity at BPL exceeded FFP provided. Thus, the stockpile of FPP was significant in utilising the spare capacity. This fell at a point in time where there was an impending world shortage of Factor VIII ([**INQY0000337**] **paragraph** 79).[288] It also fell at a point in time when cross-charging was introduced (April 1989). This marked a significant change in the approach to plasma provision in the UK, and was important in ensuring sufficient plasma supply going into the 1990s.

6.65 By October 1990 the Government position was that clinical demand for home produced Factor VIII had been reached [**INQY0000336**] paragraph 90.[289] Plasma supply from 1988 onwards is explored in the witness statement of Dr Miflin from paragraph 362, 936 and 1000 [**WITN0672006**].[290]

E. Conclusion

6.66 Taken in the round, the blood service made significant efforts to increase plasma supply over the period in pursuit of self-sufficiency. However, many

[284] See Dr Moore in the RTD meeting of 24 and 25 April 1986 [**CBLA0002307**]
[285] Written Statement of Dr Gail Miflin dated 19 October 2021 paragraph [995] at]341]
[286] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply paragraph dated 1 March 2022 [80] at [36] [**INQY0000337**]
[287] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply paragraph dated 1 March 2022 paragraph [73-75] at [34-35] [**INQY0000337**]
[288] Chronological presentation on the Domestic Supply of Blood Products in England and Wales, Appendix 2, BPL/PFL capacity, production and plasma supply paragraph dated 1 March 2022 paragraph [79] at [36] **[INQY0000337]**
[289] Chronological Presentation on the Domestic Supply of Blood Products inEngland and Wales Appendix 1 Factor VIII Demand Estimates dated 1 March 2022 paragraph [90] at [46] **[INQY0000336]**
[290] Written Statement of Dr Gail Miflin dated 19 October 2021 paragraphs [362, 936, 1000] at [126, 324, 344]

factors outside of its control (most notably funding and structural difficulties) impeded it in its goal. It is important to recognise that the blood service is only the first stage in the process to achieving sufficiency; demand for products and capacity to fractionate are factors that are crucial in whether this goal is attained or not. It is unfortunate that the blood service was not provided with the tools it required to provide a consistently increasing amount of plasma to match the increasing estimates of demand. Were its structure and funding secured at an early stage in the 1970s, the story of plasma supply in England and Wales is likely to have been significantly different.

7. SECTION 7: HEPATITIS GENERALLY

A. Introduction

7.1 In this section NHSBT considers Hepatitis, with a focus on Hepatitis B. Hepatitis is an inflammation of the liver. It has a wide range of causes, including infection and high alcohol intake. The Hepatitis B virus (HBV) and Hepatitis C virus (HCV) are the main causes of viral hepatitis globally. A full description of these viruses including a helpful chronology is set out in the Expert Report to the Infected Blood Inquiry: Hepatitis and is not repeated here [**INQY0000006**].[291]

7.2 This section of these submissions considers blood-borne viral hepatitis as a whole. HCV, initially known as Non-A Non-B Hepatitis (NANBH) is then considered separately in section 10. These submissions do not consider Hepatitis A virus, which is a self-limiting infection that only lasts a few weeks for most patients, with no ongoing carrier state, as it is rare that blood transfusion and factor concentrates have ever transmitted hepatitis A.[292]

B. History of Hepatitis and Homologous Serum Jaundice

7.3 Since the 19th century a connection had been made between human serum and jaundice. From the 1940s, there was a recognition that blood transfusion might result in '*delayed jaundice*' [**DHSC0100008_024**].[293] Systemic study of virus transmission began during this period. In 1942, the Chief Medical Officer published a memorandum in *The Lancet* to stress the importance of recording the batch number of materials used in transfusion and reporting cases of jaundice following blood transfusion [**NHBT0000091_011**].[294]

7.4 By 1944 it was confirmed '*beyond doubt*' that '*hepatitis may result from injection of homologous serum*' [**DHSC0100008_051**].[295] This triggered within the blood services a series of administrative preventative measures to reduce the incidence of jaundice, including the '*deliberate and purposeful*' collection of information to track infections.

7.5 In 1947, an American article identified homologous serum jaundice in recipients of pooled plasma [**RLIT0000054**].[296] This led to action in the blood services. In 1950, Dr Drummond of the Cardiff RTC wrote to Dr Maycock at the DH to state:

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[291] Expert Report to the Infected Blood Inquiry: Hepatitis [**INQY0000006**] at [pg 3-4]: see also paragraph [15.3]
[292] Expert Report to the Infected Blood Inquiry: Hepatitis [**INQY0000006**] [pg 50]
[293] Internal DHSS document titled *'Emergency Blood Transfusion Services delayed jaundice'*. Note of a discussion held in Dr Taylor's room [**DHSC0100008_024**] dated 01.12.1942
[294] Ministry of Health, *Homologous serum jaundice*, Memorandum published in *The Lancet* [**NHBT0000091_011**] dated 16.01.1943
[295] Dr Bradley, Ministry of Health, '*Prevention of Homologous Serum Jaundice: Memorandum to MRC Jaundice Committee on Administrative and Field Aspects'* [**DHSC0100008_051**] dated 20.06.1944
[296] I Brightman and R Korns, *Homologous Serum Jaundice in Recipients of Pooled Plasma* (October 1947) [**RLIT0000054**]

> *'I have decided to abandon large pool plasma filtration. I do not feel I can justifiably continue to issue large pool plasma which has an incidence of homologous serum jaundice of 10 per cent, as opposed to 1 per cent for small pool plasma'* [**DHSC0100010_405**][297].

7.6 A full outline of the actions taken by the blood services to reduce the risk of jaundice is set out in Dr Hewitt's witness statement [**WITN3101006**].[298]

7.7 By the 1950s the blood services had identified that patients responded differently to hepatitis. A report authored by Dr Grant of the Oxford RTC stated that *'it [jaundice] is caused by the transmission of a virus from a carrier donor to a susceptible patient. The donor is probably not aware that he is a carrier,'* it then goes onto describe how recipients vary in their susceptibility and how *'some patients suffer no upset'* [**PRSE0003897**].[299] The report concluded that precautions should be taken before transfusion and that any practitioner should '*satisfy himself that it is really necessary to give blood and that no other treatment would be equally efficacious*.'

7.8 This demonstrates from the 1950s a growing institutional response to the risk of hepatitis. From this point, the directions given by blood service senior management was to limit the use of transfusion, and of the need to convince others to '*occasionally hav[e] the strength of mind to make the unfashionable decision not to transfuse*' [**PRSE0003897**][300].

C. Hepatitis B surface antigen (HBsAg)

7.9 Hepatitis B surface antigen (HBsAg) was discovered in 1965 [**PRSE0001518**][301]. It was named the *'Australia antigen'* (HAA) as it was discovered in Australia. A positive HBsAg test result means a person is infected with HBV as it detects the presence of HBV in blood[302].

7.10 By 1966 a publication in America identified that '*the risk of serum hepatitis from transfusions derived from prison and skid row populations is at least ten times that from the use of volunteer donors*' [**RLIT0000217**][303]. Further details on the blood services and prison, military and workplace donations are contained in Section 6, Running the Blood Service (above). The issue was raised in the BMJ

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[297] Letter from Dr Drummond of the Regional Transfusion Centre in Cardiff to Dr Maycock at the Ministry of Health dated 06.01.1950
[298] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [33-56].
[299] Jean Grant (then Director of the Oxford RTC), *Complications of Blood Transfusion* (The Practitioner, August 1965, Vol 195) [**PRSE0003897**]
[300] Jean Grant then Director of the Oxford RTC Oxford), *Complications of Blood Transfusion* (The Practitioner, August 1965, Vol 195) [**PRSE0003897**]
[301]B Blumberg, H Aller and S Visuich, *A "New" Antigen in Leukemia Sera* (February 1965) [**PRSE0001518**]. This article describes the emerging knowledge of the Australia surface antigen
[302] Expert Report to the Infected Blood Inquiry: Statistics by the Statistics Expert Group [**EXPG0000049**] at [pg95]
[303] J Garrott, Post-Transfusion Hepatitis: A Serious Clinical Problem, (California Medicine, Vol. 104, Issue 4) [**RLIT0000217**]

the same year in the context of the UK [**RLIT0001219**][304], and a letter from Professor Zuckerman to *The Lancet* again raised the issue that larger pool sizes increased the risk of hepatitis, and that one of the reasons that the problem of hepatitis was not as widely appreciated as it could be, was because of its '*comparatively long incubation period*' [**PRSE0000821**][305]. Each of these factors increased the risk of infected blood where pooled products were still used.

D. Measures to remove infected blood

7.11 The need for systemic measures to remove infected blood from the system was developing by the early 1960s. Specifically, the fact that '*in some places the number of deaths from hepatitis after cardiac surgery in some centres exceeds the mortality from surgery*' led to the recommendation by Professor Zuckerman that the NHS should establish a '*follow-up system for all patients who have received blood transfusion*' [**PRSC0000821**][306] with the aim of reducing the amount of infected blood in circulation.

7.12 Not all products carried the same risk of infection. In 1969 researchers identified that a patient had contracted serum hepatitis after '*use of a cryoprecipitated antihaemophilia globulin*': however, it was noted that this '*was unusual*', and the report concluded that '*Cryo represents a considerable advance in the management of the severe haemophiliac*' [**PRSE0003714**][307].

E. Australia Antigen Testing

7.13 In September 1970, the government established a group for the testing of the Australia Antigen [**PRSE0000190**][308]. That group included RTDs. The summary of the report produced by the group states that the RTCs '*should begin at the earliest possible date to test all blood donations for the presence of Australia-hepatitis-associated antigen and its antibody*.' It was estimated that testing would reduce serum hepatitis by 25-30%.

7.14 Testing for the Australia Antigen was introduced in some parts of the blood services by 1971[309]. A 1972 article by Dr Maycock recognised that '*the incidence of serum hepatitis will diminish as transfusion services adopt the practice of excluding all donations of blood in which the Australia antigen is*

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[304] Transmission of disease by blood transfusion (Publication in the British Medical Journal 5 November 1966, Vol. 2 Issue 426)
[305] Letter from Professor Zuckerman to The Lancet [**PRSE0000821**] dated 05.11.1966
[306] Letter from Professor Zuckerman to The Lancet [**PRSE0000821**] dated 05.11.1966
[307] J Whitaker and M Brown, *Serum Hepatitis in a Haemophiliac* (British Medical Journal) [**PRSE0003714**] dated 06.09.1969
[308] First report of The Advisory Group on Testing for the Presence of Australia (hepatitis-associated) Antigen and its Antibody [**PRSE0000190**]. The group was formed under the chairmanship of Dr Maycock.
[309] Written statement of Dr Angela Robinson [**WITN6926001**] at [Paragraph 143]

detected'. However, it went on to emphasise that treatment of blood and blood products will always carry risk, even if screening does take place and that they should be '*administered only when the benefits they are likely to confer upon the patient outweigh the risk to which their use exposes [the patient]* [**RLIT0000169**][310].

7.15 Testing of blood donations for HBsAg was introduced for all blood from December 1972. A study by Alter et al (1972) demonstrated that the exclusion of HBsAg positive blood donors and paid blood donors reduced transfusion associated hepatitis by 85% [**NHBT0000025_006**][311]. The Statement of Dr Gunson in A and Others [**NHBT0000026_009**][312] described how the tests for HBsAg had poor sensitivity, but even as the sensitivity improved hepatitis still occurred in some 7-12% of blood transfusion recipients in the US. In almost all instances this did not appear to be due to type A or type B or previously unrecognized hepatitis due to cytomegalovirus or Epstein-Barr virus, and therefore it was termed Non-A, Non-B Hepatitis (NANBH).

7.16 The experience with the introduction of HBsAg testing clearly influenced the subsequent approach towards the introduction of new tests by the blood services. When HBsAg testing was introduced in the early 1970s, there was a period of one year before all RTCs were testing all donations leading to a situation where some patients had the advantage of receiving tested blood whilst others did not. This was considered unacceptable and when the next test was introduced (for HIV) considerable efforts were made to ensure that tests was introduced simultaneously throughout the UK[313] [**NHBT0000026_009**][314].

7.17 Over the course of the early 1970s the risk of transmission of viral hepatitis was thought to be significantly mitigated by the introduction of increasingly sophisticated screening tests for HBV. The methodology of HBsAg testing improved in the late 1970s, with the tests improving in reliability – or the capability to identify donors who could transmit hepatitis. However, throughout the 1970s, the evidence was that the quality of the tests was not particularly good, requiring tests to be duplicated (as confirmed by Professor Barbara [**INQY1000176**][315]). These tests increased in sensitivity all the way until the 1990s.

7.18 From 1972 onwards there began to appear, in various medical and scientific publications, incidences of post-transfusion hepatitis even after the exclusion

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[310] W Maycock, Hepatitis in Transfusion Services (British Medical Bulletin, 1972, Vol.28 Issue 2) [**RLIT0000169**]
[311] H Alter et al, Post Transfusion Hepatitis After Exclusion of Commercial and Hepatitis-B Antigen-Positive Donors (Annais of Internal Medicine 1972, Vol.77 Issue 5) **[NHBT0000025_006]**
[312] Written Statement of Dr Harold Gunson in A and Others [**NHBT0000026_009**] at [12]
[313] This point is also relevant in the context of the blood services' concern about asymmetric introduction of HCV testing – see Section 9
[314] Written Statement of Dr Harold Gunson in A and Others [**NHBT0000026_009**] at [80]
[315] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [12/3]

of donors found to be positive for HBsAg. This was the basis of what subsequently came to be known as NAN, which we consider in more detail in Section 9.

7.19 An example of the spectre of NANBH is the publication in *The Lancet* in 1974 by Price et al called '*Long-incubation post-transfusion hepatitis without serological evidence of exposure to hepatitis B virus*' [**PRSE0001431**][316]. Clinicians working in the 1970s and 1980s gave evidence that as students when they were taught about the existence of serum homologous hepatitis, they were made aware of both HBV and NANBH.

F. Tail End Hepatitis B Carriers

7.20 Hepatitis B carriers are individuals who have HBV in their blood but do not feel sick. These individuals appear to be 'tolerant' of infection, insofar as they are infectious to others, but not directly harmed by the virus. Tail-end carriers are those who are at the end of carriage but might have some residual infectivity, especially in a large volume of a donation.

7.21 The blood services spent a long time considering whether to introduce anti-HBc testing in respect of these carriers. The anti-HBc test would be a way to determine whether a person is protected against HBV, because of having received the hepatitis B vaccine or successfully recovering from a past hepatitis B infection. Such a test was considered useful in the context of HIV as a potential surrogate test.

7.22 Professor Barbara described how this issue was considered by the blood services:

> *'in the context of a phrase that virologists use about viruses running in packs, a common source of infection for various agents, like intravenous drug use. And my feeling was that there was some possible merit, certainly worth considering, of anti-HBc as an indication of past or present infection with an agent that could, as it were co-infect with HIV'* [**INQY1000176**][317].

7.23 In Professor Barbara's witness statement [**WITN6989001**] he explained the uses further in the context of his comment at the meeting of the UK Working Party on Transfusion-Associated Hepatitis [**PRSE0001299**][318], that the anti-HBc test '*had the value of association with hepatitis B and non-A, non-B hepatitis as well as AIDS.*' However, he also commented that '*it was not clear cut whether the advantages of introducing anti-HBc testing outweighed the*

[316] Prince et al, *Long-incubation post-transfusion hepatitis without serological evidence of exposure to hepatitis B* virus (The Lancet) [**PRSE0001431**] dated 03.08.1974
[317] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [40/17]
[318] Minutes of fourth UK Working Party on Transfusion-Associated Hepatitis meeting [**PRSE0001299**] dated 27.09.1983

disadvantages, and this remained a big grey area. This was why it was discussed so often and wasn't introduced' [**WITN6989001**][319].

7.24 Professor Barbara then explained in oral evidence that *'if we were going to introduce anti-HBc testing it would be in support of the HBsAg testing to detect what I used to describe as 'tail-end carriers'.* These were carriers of the virus where the:

> *'HBsAg level had dipped to just below detectability but where there was still virus there and anti-HBc would have remained positive. Because there would have been continual (albeit low level) viral replication the anti-core would have been at quite a high level. We would have to decide on what the cut-off would be i.e. what was going to be reliable, and these were the logistical problems. Paradoxically I felt that anti HBc would be of most value in making HBsAg testing and hepatitis B safety better. This was prior to the availability of HBV DNA testing'* [**INQY1000176**][320].

7.25 Dr Flanagan agreed with the position put forward by Professor Barbara that the main benefit of anti-HBc testing would be to reduce the likelihood of 'tail-end' carriage: '*In most instances HBsAg will be detectable prior to anti-HBc and so anti-HBc will not significantly contribute to reducing the risk of early window transmission*' [**WITN6933001**][321].

7.26 While Professor Barbara acknowledged that it could have been a useful test, he stated that '*I don't think I ever formulated it in my own head as something that I would definitely want to press ahead with*' [**INQY1000176**][322]. That is, because the benefit of the test was limited: it would '*have detected people who had been infected at birth, early in life, or soon after, maybe because they were in areas of high hepatitis*' [**INQY1000176**][323].

7.27 Further, UK data was limited in relation to studies on anti-HBc [**WITN6989001**][324]. The decision was taken, following the study into the introduction of anti-HBc screening of blood donations [**NHBT0000014_015**][325], and another study into acute NANBH [**NHBT0000030_027**][326] that there was no case for using surrogate testing for NANBH which covered ALT and anti-

[319] Written statement of Professor John Barbara [**WITN6989001**]
[320] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022
[321] Written Statement of Dr Peter Flanagan [**WITN6933001**] at [386]
[322] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [42/11]
[323] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [42/25]
[324] Written Statement of Professor John Barbara [**WITN6989001**] at [480]
[325] Minutes of the Steering Committee meeting on Multi-centre study of ALT and anti-HBc screening of blood donations [**NHBT0000014_015**] dated 08.06.1988
[326] J. Barbara, M. Contreras et al., Lack of Evidence for Post-Transfusion NANB Hepatitis (Abstract from BBTS/ISBT, 1988)

HBc testing [**NHBT0005043**][327]. We consider ALT testing in more detail at Section 9 below.

G. NANBH

7.28 These submissions consider NANBH in detail in Section 9, after HIV in Section 8. This sequence is because during the early 1980s the primary focus within the blood service shifted to HIV as the biggest threat to patient safety.

[327] Minutes of Advisory Committee meeting on the Virological Safety of Blood Minutes of the 4th Meeting Held dated [**NHBT0005043**] 06.11.1989

8. SECTION 8: HIV

A. Terminology

8.1 Throughout these submissions, AIDS will be used to describe the illness caused by the virus HIV. Various historic names exist for both the virus and the disease; those historic names will only be used in the context of evidence which departs from the terminology of HIV and AIDS. The various historic names and their sources are set out in the Expert Report on HIV and are not repeated here [**EXPG0000004**][328]. Unless specified, HIV will refer to HIV-1 only and not HIV-2 (which will be instead referred to using that specific name).

8.2 In respect of the categories of person at risk of HIV, there was a significant focus on men who have sex with men ('**MSM'**). Over the period, the term '*homosexual men*' was commonly used. As the distinction between the terms 'MSM' and 'homosexual men' is important to whether exclusion was successful, we have used the term 'homosexual men' to mirror language contemporary to the period concerned.

B. Emergence and knowledge

(1) Background

8.3 Before identifying what steps should have been taken in response to HIV, it is necessary to determine when relevant clinicians became aware of the illness and the real risk it posed to the recipients of blood and blood products. Because much turns on this issue, this section makes submissions in detail on the chronology of events.

8.4 The difficulties of recall were explored in section 2 above on contextual factors. Without wishing to repeat those submissions, two further things are important to note about the emergence of HIV. First, the crucial period is short (around 1.5 years); asking a person to precisely place their knowledge after 40 years with any degree of accuracy is a difficult task. Second, for HIV, it is hard to separate the knowledge that we now have about the severity of AIDS and its outcomes from contemporaneous memories, and to avoid a retrospective analysis of information using current knowledge. We say this here as it provides some explanation of the variation in the quality of the evidence produced by the clinical witnesses, and indeed the variance in suggested dates of knowledge. This is unsurprising in the context of recalling events from many years ago.

(2) The initial emergence of AIDS in the USA – 1981

8.5 The first reports of the new illness that became known as AIDS were made on or shortly after 5 June 1981 in the *Mortality and Morbidity Weekly Report*

[328] Expert Report to the Infected Blood Inquiry: HIV with Addendum [**EXPG0000004**] at [4]

('**MMWR**') [**CGRA0000242**].[329]. This was shortly followed by further reports on 3 July 1981 [**PRSE0002598**] and 28 August 1981 [**CGRA0000424**]. There were common themes in these reports which continued to appear in the early articles on AIDS: that the illness arose in homosexual men; that the illness may be related to cytomegalovirus ('**CMV'**) infection; and that the illness might be related to inhalant drug use.

8.6 These early reports were pertinent to specific medicine specialists: respiratory physicians, oncologists, and those whose disciplines included the treatment of homosexual men. The disease, particularly at this early stage, was characterised primarily by pneumocystis carinii pneumonia ('**PCP'**) and Karposi's sarcoma ('**KS**') seen in homosexual men. In addition, at this early stage the illness was localised to the US. Thus, both knowledge and deployment of these reports would have been primarily confined to these specialist clinicians and scientists operating in the US. Clinicians outside of these specialisms should not have been expected to have known of the emerging illness.

8.7 There was some change in the position in December 1981 for two reasons. First, the consistency of reporting in the MMWR indicated a developing trend that clinicians could identify and follow. Secondly, there were three reports in the *New England Journal of Medicine* ('**NEJM**') on 10 December 1981, which shed light on the disease. This was striking reporting, all concerning PCP and KS in homosexual men [**CGRA0000243**][330], [**PRSE0004831**], [**PRSE0000746**].

8.8 Letters in the *Lancet,* a UK publication, on 12 December 1981 commented on the NEJM reports. One such article, '*Gay Compromise Syndrome*', commented on the connection with homosexual men and the first UK case reported. The article by Du Bois et al noted a limited number of heterosexuals who had shown evidence of the disease [**PRSE0004476**]. The articles focused on the context of homosexual men suffering from a distinct illness causing immunosuppression. Suggestions of a connection to CMV persisted.

Conclusions

8.9 The evidence suggests that by the end of 1981 there was some reporting of AIDS which would have been circulating in the UK (that from the *Lancet*). However, such circulation would have been limited to specialists dealing with homosexual men, respiratory physicians, and oncologists. Save for the sole AIDS patient in the UK (who travelled to Miami annually), the illness appeared

[329] While it became subsequently known that AIDS may have been an extant illness in the USA from, at latest, late 1978 [**RLIT0000200**], such occurrences of illness related to the disease were apparently not reported in medical literature until 1981. The early history of AIDS is set out in the Inquiry's Chronology at [**INQY0000006**] and is not repeated here.
[330] Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men (The New England Journal of Medicine, 1981, Vol. 305) [**CGRA0000243**]

to be confined to the US. Insofar as such knowledge extended outside of this narrow group of clinicians (which should not at that time have been expected), it is likely to have been non-specific and transient.

8.10 The evidence of clinicians working in this period is consistent with this assessment. Dr Foster, in his evidence to the Penrose Inquiry, reflected that his original knowledge of the disease came in late-1981 as GRID - a strange illness among homosexual men in the US whose cause was not known (with recreational drugs thought to be the most likely cause).[331] Similarly, in his evidence to the Infected Blood Inquiry, Dr Giangrande recollected coming across AIDS, and a person dying from AIDS at the Brompton Hospital, in December 1981. His recollection was that AIDS was '*the subject, particularly based in West London, of educational materials and talks*' and described Dr Pinching (who had been at the renal unit at the Hammersmith Hospital) giving a talk on AIDS when it was '*completely unknown*'[332]. Dr Walford also described AIDS as not relevant to her at this time[333]. This is all indicative of the domain specificity of AIDS at this time with regard to homosexuals.

(3) The emergence of AIDS – January to June 1982

8.11 The presentation of AIDS as an illness primarily localised to homosexual men in the US continued in the first half of 1982. The NJEM reported that the CDC had established a task force in respect of the illness affecting homosexuals on 28 January 1982 [**OXUH0002850**]. The MMWR reported on other sequelae in homosexual men: persistent, generalized lymphadenopathy on 21 May 1982 [**OXUH0002851**] and diffuse, undifferentiated Non-Hodgkins Lymphoma on 4 June 1982 [**CGRA0000289**].[334] Again, while of note to those focused on the treatment of homosexual men with this developing illness, the evidence was limited in respect of what subsequently became recognised as the other AIDS risk groups.

8.12 In mid-1982 MMWR reports continued to paint the developing picture in the US. On 11 June 1982 a report said in respect of AIDS sufferers that the '*proportion of heterosexuals (16%) is higher than previously described*' [**PRSE0000431**]. Reports continued to inform of the increasing number of homosexual men suffering from the disease in the US. On 18 June 1982 a further *MMWR* report included information concerning PCP in California [**RLIT0001690**], and notably referred to one of the sufferers with PCP having anonymous encounters in bathhouses in Los Angeles where other persons had attended with KS and

[331] Oral Evidence of Dr Peter Foster [**INQY1000197**] dated 24.03.2022 [157/19]
[332] Oral Evidence Dr Paul Giangrande [**INQY1000138**] dated 19.11.2020 [5/2]
[333] In her Written statement [**WITN4461001**] at paragraph 70.5 she notes that she became aware of the July 1981 MMWR at some stage, but went on to say that '*since the report did not refer to haemophiliacs or recipients of blood transfusion there was no reason why it should have been sent to me*'.
[334] Reports on AIDS published in the Morbidity and Mortality Weekly Report June 1981 through January 1985 [**CGRA0000289**] at [10]

PCP. In his written statement, Professor Tedder ties his first awareness of the disease to the facts reported in this *MMWR* report [**WITN3436003**].[335]

Conclusions

8.13 By June 1982 the evidence was still broadly confined to AIDS being a new illness primarily contracted by homosexual men. There was also some evidence accumulating that it extended to heterosexual drug users, although the evidence was less clear. The connection with living or visiting the USA remained. Again, there is little if anything to suggest that AIDS should have become common clinical knowledge outside of clinicians working with patients in these specific risk groups exhibiting the specific sequelae of AIDS. Any such knowledge outside of the area was likely to be non-specific and transient.

(4) The relevance of the US position – June 1982

8.14 Before continuing, in this period steps were being taken in the US to address AIDS. This is explored in the Krever Inquiry report [**KREV0000001**] and the Inquiry Knowledge timeline [**INQY0000006**] and not discussed further here. It is possible, although there is little witness evidence to support this, that some clinicians in the UK were aware of the various interagency meetings and conferences on AIDS occurring in the US around this time, although most attendees at these meetings appear to have been American. Such knowledge would not be inconsistent with the view that AIDS was an epidemic confined to the USA based on the evidence available at the time.

(5) AIDS appears in haemophiliacs – July 1982

8.15 Many clinicians who have given evidence to the Inquiry have given evidence that their knowledge of the disease '*developed*'. Save for those with a specific interest in the healthcare of homosexual men, respiratory clinicians, or oncologists in the US, July 1982 has been the common date between many clinicians for such development. This is because three crucial clinical reports were published, each of which expanded the understanding of those at risk of the disease.

8.16 First, the *British Medical Journal* reported on severe acquired immunodeficiency in four previously healthy Danish homosexual men, three of whom had never been to the USA. Three of the four had used nitrites [**PRSE0002691**]. This indicated that transmission was no longer confined to the US. Secondly, on 9 July 1982 the MMWR reported an outbreak of KS and opportunistic infections in 34 Haitians in the USA [**PRSE0003880**]. This indicated that transmission was no longer confined to those traditional routes

[335] Written Statement of Professor Richard Tedder [**WITN3436003**] at [34]

and at-risk groups seen earlier in the AIDS epidemic: sexual (homosexual men) and intravenous (intravenous drug users).

8.17 Thirdly, and most crucially, on 16 July 1982 the MMWR reported three cases of PCP among patients in the USA with haemophilia A with no evidence of homosexuality or intravenous drug use [**PRSE0000523**]. The editorial comment to the MMWR suggested that '*the occurrence among the three hemophiliac cases suggests the possible transmission of an agent through blood products*'. Haemophilia centres in the USA were notified about the cases by the CDC, and a surveillance scheme was established with the National Hemophilia Foundation. A US public health service advisory committee was formed to explore the implications of the findings.

8.18 This report was distributed within the haemophilia treating community, and more broadly in the transfusion community. On 16 July 1982, internal correspondence at the DHSS between Mr Godfrey and Dr Holgate indicates that the MMWR report of the same date came immediately to the attention of Dr Gunson, staff at the DHSS, and Dr Holgate. Mr Godfrey's memorandum notes that:

> *'…some research is about to be published showing fairly conclusively that plasma taken from homosexual drug-takers contains a sort of virus which goes undetected when the plasma is tested…*[336] *it seems that 400 haemophiliacs in the USA have exhibited signs of the virus'.* [**DHSC0002219_009**][337]

8.19 This document indicates that: (1) at least Dr Gunson in the blood service was aware of the recent MMWR report; and (2) the DHSS was similarly aware. The reference to 400 haemophiliacs is difficult to understand; at the time only three haemophiliacs were reported as exhibiting AIDS symptoms. By the end of the year (see below) MMWR had reached a total of 7 (with one added highly suspect case).

8.20 Dr Holgate replied on 20 July 1982 (emphasis in original):

> *'…I was aware of the potential adverse publicity concerning the safety of Factor VIII in the USA (and certain other blood products, in my opinion) where the original donation was obtained from the homosexual community. […].*
>
> *The element of doubt I have in your thesis is that the drug taking may <u>not</u> be an essential feature of the affair – but I am open to correction on this; if it is solely the curious activities of the homosexual male which*

[336] We have omitted an erroneous explanation of the scientific mechanism.
[337] Memorandum from Mr Godfrey to Dr Holgate [**DHSC0002219_009**] dated 16.07.1982

> *lead to the infection, without superadded drugs, then our own blood production system may not be exempt.'* [**WITN4461115**][338]

8.21 Dr Wagstaff dates his first knowledge of AIDS to the MMWR report of 16 July 1982 [**WITN6988001**].[339]. In his oral evidence, Dr Boulton recognised that MMWR reports would take '*a little time to reach us*', expressing the view it might take '*a few weeks*'.[340] He said that this report was known about in the UK by the time of the Edinburgh Fringe Festival.[341] In his witness statement Dr Barbara also connects his knowledge to a call he received from Dr Roger Dodds about the first AIDS cases in two male haemophilia patients [**WITN6989001**].[342] Professor Barbara dated this call to '*in or around 1983*'. However, it is likely this is linked to the first three cases reported in MMWR, which would indicate Professor Barbara is mistaken and the call happened in July 1982.[343]

8.22 A number of HCDs also gave evidence that this MMWR report would have come to their attention.[344] Professor Tuddenham gave evidence he would have been aware of the July MMWR immediately following its publication;[345] Dr Colvin suspected in the weeks that followed;[346] and Professor Ludlam thought he became aware of it between August and October.[347] Professor Ludlam noted that the MMWR was a specialist journal that took time to come to the UK; Professor Franklin gave similar evidence while accepting he would have read it at the time:

> *'…I started looking at them. They weren't easy to find but yes, I did, because that was where – I think I mentioned in my report that the pre-internet era, the – actually knowledge was quite powerful, when I think about it, because not everybody had it. Now everybody has knowledge.*
>
> *So we all knew AIDS was happening in the gay men in America. The journals were months out of date, so you really relied on things like MMWR, because it was a weekly report, and also word of mouth by*

[338] Memorandum from Dr Holgate to Mr Godfrey [**WITN4461115**] dated 20.07.1982
[339] Written Statement of Dr William Wagstaff [**WITN6988001**] at [423]
[340] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [113/4]. Dr Foster gave similar evidence in respect of the knowledge of fractionators: Oral Evidence of Dr Peter Foster [**INQY1000197**] dated 24.03.2022 at [158/9]
[341] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 [112/23]
[342] Written Statement of Professor John Barbara [**WITN6989001**] at [199]
[343] His statement goes on to say, '*following this I realised that HIV (HTLV-III) and AIDS was very likely to have a viral aetiology*'. Consistently with the other witnesses, it is likely this was incremental in the period immediately following this call.
[344] Oral Evidence of Professor Iann Hann [**INQY1000082**] dated 08.12.2020 at [60/6]. Professor Hann also recollected the matter of the three haemophiliacs came up in a discussion of GRID at a conference called the Second International Symposium on the Immunocompromised Host
[345] Oral Evidence of Professor Edward Tuddenham [**INQY1000067**] 22.10.2020 at [62/14]
[346] Oral Evidence of Dr Brian Colvin [**INQY1000061**] dated 06.10.2020 at [163/12]
[347] Oral Evidence of Professor Christopher Ludlam [**INQY1000078**] dated 02.12.2020 at [3/12]

experts. Reading journals was – you had to read the journals but it was insufficient…' [**INQY1000068**][348]

8.23 The events of July 1982 mark a significant departure from all of the evidence that came before. It seems clear that it was in this month that the apparent categories of risk for AIDS became significantly wider. The MMWR reports suggested an expansion of the territorial remit of AIDS, and of the categories of person at risk of AIDS. While confined to a very small number of patients (three), the report indicated a possibility that some feature common to haemophiliacs may put them at risk of developing AIDS. From this point, it was possible for a person to conclude that haemophilia put someone at risk of developing AIDS. It was also possible, not least as the MMWR suggested it (and Mr Godfrey wrote such a suggestion in his memo), for a person to conclude that it could be related to illness through treatment. However, such conclusion required considerable extrapolation from the available evidence. All in all, the appropriate action in the face of these possibilities seems to have been to undertake investigation and research into the disease and these new risk categories. This is what occurred over the remainder of 1982.

(6) Events immediately following the July MMWR reports – July to September 1982

8.24 Between 1 and 7 August 1982, Dr Aledort discussed AIDS at the 19th Congress of the International Society of Haematology and 17th Congress of the International Society of Blood Transfusion in Budapest [**PRSE0003247**]. He noted in discussion of '*future problems in the treatment of haemophilia*' that the most recent problem to surface in the USA was three deaths from respiratory infections which had been linked to the development of AIDS. In his oral evidence, Dr Foster commented that he had attended this meeting alone (which he thought preceded or just coincided with the MMWR report). He explained:

'…I was expecting a discussion, and I was quite taken aback when everyone stood up and left the room. And that seemed to me to indicate that there must have been a belief that these men were gay, and people didn't want to talk about it because homosexuality in those days wasn't considered in the same way as it is today.' [**INQY1000197**] [349]

8.25 On 13 August 1982 an article by Jean Marx was published in *Science* titled New Disease Baffles Medical Community. It stated:

'Although other explanations have not been ruled out, most investigators currently think that the disease is caused by an infectious

[348] Oral Evidence of Professor Franklin [**INQY1000068**] dated 27.10.2020 at [160/25]
[349] Oral Evidence of Dr Peter Foster [**INQY1000197**] dated 24.03.2022 at [159/1]

agent, possibly a new virus or a new variant of an existing virus. The spread of AIDS resembles that of hepatitis B virus.' [**RLIT0000200**]

8.26 The article went on to note the possible connection to blood products, and the lack of evidence linking to ordinary transfusion. It also considered potential other causes which had consistently appeared in past journal articles, dismissing nitrites as connected only to the homosexual community, CMV (an immunosuppressive virus, supported by Gottleib) as not a new virus, and homosexual men being particularly at risk of AIDS on the basis that they were more immunosuppressed than members of the public. The article concluded that '*identification of the cause and then prevention are the major goals*'.

Conclusions

8.27 The evidence suggests that the development of knowledge following July 1982 was an organic process, informed by individual experience and hampered by the comparative lack of connectivity (due to technology and the lack of cross-fertilisation between clinical specialities). The lack of an apparently transfusion-related transmission was a factor obscuring the route towards a blood-borne aetiology. In circumstances where evidence was sparse and varying interpretations of that evidence plentiful, it is unsurprising that different clinicians approached the correct interpretation of the evidence at varying speeds.

8.28 It is risky to suggest, on the basis that some clinicians reached the correct conclusion in mid-1982, that clinicians as a whole, or some critical mass of clinicians, should have reached such a conclusion. We submit that this would be an impermissible use of hindsight which disregards the confused picture that all those operating in the field faced. Clinicians in this period should have broadly become aware of the disease and the threat it might pose as:

a) the MMWR reports of July 1982 were precisely within or close to their expertise

b) *Science* magazine was a pre-eminent clinical journal; and

c) the CDC released a case definition for AIDS on 24 September 1982 [**OXUH0002484**]. However, recognition of the disease should not be conflated with understanding its aetiology nor indeed its nature and progression.

(7) The emergence of information about AIDS – September 1982 to December 1982

8.29 The remainder of the year is marked by clinicians and scientists in the UK making inquiries to obtain more information about the disease, in line with the development of knowledge described by the oral witnesses. This position is consistent with the documents. In September 1982, the HCDs were aware of

the new disease. The disease is commented on at the 15th meeting of the Reference Centre Directors on 6 September 1982, when Dr Craske was asked to investigate the matter further [**HCDO0000410**]. On 13 September Dr Craske reported to the HCDs that there was a '*remote possibility the commercial blood products had been involved*' and asked to be updated on any cases arising [**CBLA0001619**].[350] The UKHCDO Hepatitis Working party on the same date also noted that AIDS had '*similarities in its epidemiology to that of hepatitis B virus infection*' and inquiries would be made to '*ascertain the likelihood of transmission of the disease by blood or blood products*' [**CBLA0001618**].[351]

8.30 Dr Craske went on to produce a report on AIDS on 5 November 1982 [**CBLA0001653_003**],[352] in which he noted and rejected the suggestion that the aetiology of AIDS was related to amyl nitrates and other drugs. He also suggested it seemed 'unlikely' that the disease was related to the immunosuppressive effects of cytomegalovirus. The third option (of three suggested) was that AIDS was an infectious agent with a similar epidemiology to that of hepatitis B. Dr Craske went on to note:

> *'…if (3) is the most likely cause, then it seems possible that such an agent might be present in the plasma of hepatitis B carriers used to prepare hepatitis B vaccines...'* [**CBLA0001653_003**][353]

8.31 Professor Tedder notes in his written statement that it was the parallel with hepatitis B which indicated to him that the most likely aetiology was a virus [**WITN3436003**].[354]

8.32 Also on 5 November 1982 the MMWR issued guidance on '*precautions for clinical and laboratory staffs*' in respect of AIDS [**RLIT0000231**].[355] This noted that the aetiology remained unknown, but suggested precaution on the basis that *'one hypothesis consistent with current observations is that a transmissible agent may be involved*'. The parallel with hepatitis B was noted. On 14 November 1982, *The Observer* reported that '*a consensus seems to be forming that the disorder is caused either by a deadly virus, or by a dangerous variant of an existing one*' [**MDIA0000010**].[356] That article went on to comment that a '*major speculation*' was whether the virus was carried in the blood (with a link to hepatitis, injecting drug users, and heterosexual haemophiliacs noted).

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[350] Minutes of the thirteenth Meeting of UK Haemophilia Centre Directors [**CBLA0001619**] dated 13.09.1982
[351] Minutes of the tenth Meeting of the UK Haemophilia Centre Directors Hepatitis Working Party [**CBLA0001618**] dated 13.09.1982
[352] J Craske, The Acquired Immune Deficiency Syndrome (AIDS) [**CBLA0001653_003**] dated 5.11.1982
[353] J Craske, The Acquired Immune Deficiency Syndrome (AIDS) [**CBLA0001653_003**] dated 5.11.1982
[354] Written Statement of Professor Richard Tedder [**WITN3436003**] at [37 and 40]
[355] CDC, Current Trends Acquired Immune Deficiency Syndrome (AIDS): Precautions for Clinical and Laboratory Staffs (MMWR, 1982, Vol. 31, Issue. 43) [**RLIT0000231**]
[356] C Doyle, No Defence Against Gay Disease (The Observer) dated 14.11.1982 at [pg25]

Genetic susceptibility, inhalant drugs, and the homosexual male lifestyle were also identified as possibly relevant.

8.33 The evidence indicates that the response of clinicians directly involved in treating haemophiliacs was to undertake further research into the disease and the information available. This is an unsurprising result in the context of haemophiliacs being identified as a further possible risk group for the disease for the first time. That it was haemophilia clinicians first undertaking these investigations is consistent with the direct relationship they had with the patients in the risk group. In circumstances where little was known, such research appears to have been an appropriate first step.

(8) The San Francisco baby case – December 1982

8.34 Matters developed significantly in December 1982. On 9 December 1982 the National Hemophilia Foundation in the USA wrote an advisory in its *Hemophilia Newsnotes* which concluded:

> *'..it is NHF's point of view that patients and parents should be aware of the potential risks. If you have any questions regarding this matter, they should be directed to your treating physician and/or NHF.'* [**BAYP0000018_119**]

8.35 On 10 December 1982 the MMWR reported on possible transfusion-associated AIDS in a 20-month-old infant [**PRSE0003276**] (the San Francisco baby case). This was crucial as it suggested that transfusion of blood or blood components were sufficient to transmit the disease. The editorial note included:

> *'The etiology of AIDS remains unknown, but its reported occurrence among homosexual men, intravenous drug abusers, and persons with hemophilia A (1) suggests it may be caused by an infectious agent transmitted sexually or through exposure to blood or blood products. If the infant's illness described in this report is AIDS, its occurrence following receipt of blood products from a known AIDS case adds support to the infectious-agent hypothesis.'* [**PRSE0003276**]

8.36 This view of the San Francisco baby case was expressed by some clinicians. Dr Walford described it as a '*watershed*' moment that '*rang all sorts of alarm bells*', although she noted that '*you could not* actually *conclude from one case*'.[357] In her written statement Professor Contreras describes the case as '*pivotal in my view shifting*' [**WITN5711001**].[358] In his oral evidence, Dr Wagstaff took the report of haemophilia A patients in July 1982 with the San Francisco

[357] Oral Evidence Dr Diana Walford [**INQY1000137**] dated 19.07.2021 at [122/18]. She went on to say '*But I think that gradually the feeling in the wider department, if you like, was that: actually, this is looking more and more likely that blood and blood products are certainly capable of transmitting this agent. Not necessarily we conclude that they have but they are capable of doing it.*'
[358] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [251]

baby case to indicate that a virus transmissible by blood '*seemed the most likely explanation*'.[359]

8.37 In her statement, Dr Walford also describes the view of the San Francisco baby case within the DHSS more broadly In particular, she says that the Department's '*awareness of the potential transmission of AIDS through blood and blood products grew incrementally*' from January 1983. However, while there was '*mainstream*' acceptance that the agent was a virus, '*even by the middle of 1983, not all doctors in the DHSS were necessarily persuaded by this*' [**WITN4461001**].[360] For example, Dr Keith Fowler (a medical assessor to the CSM) preferred the view of Sonnabend et al published on 6 May 1983 in *The Journal of the American Medical Association* linking the disease to immunosuppressive effects of allogeneic sperm [**OXUH0002239_005**].[361] Dr Walford's written statement suggests that Dr Fowler extrapolated from this view to suggest that AIDS may be a function of the concentrates itself, rather than being a viral agent [**WITN4461001**].

8.38 Also on 10 December 1982, there were updates in the MMWR on the three haemophilia A patients identified in July 1982. The report explained that those three patients had since died, and a further four additional heterosexual haemophilia patients had been identified as AIDS cases (alongside a further highly suspect case). The report noted a lack of commonality in the brands and lot numbers of the Factor VIII concentrates that they had received [**PRSE0003276**].[362]

8.39 There followed on 17 December 1982 a report in the MMWR on unexplained immunodeficiency and opportunistic infections in infants. The editorial note identified that the infants' mothers appeared to fall into AIDS risk categories and suggested '*it is possible that these infants had the acquired immune deficiency syndrome*'. While other routes were considered, the note suggests that the transmission of an AIDS agent could have happened '*either in utero or shortly after birth*' [**CGRA0000289**].[363]

Conclusions

8.40 In our submission, December 1982 is a crucial point in time for the knowledge of AIDS and its risks in the UK. By this date, we submit that clinicians and

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[359] Oral Evidence Dr William Wagstaff [**INQY1000175**] dated 25.01.2022 at [52/17]
[360] Written Statement of Dr Diana Walford [**WITN4461001**] at [71.1-71.5]
[361] J Sonnabend at al., Acquired immunodeficiency Syndrome, Opportunistic Infections, and Malignancies in Male Homosexuals (The Journal of the American Medical Association, 1983, Vol.249 Issue17) [**OXUH0002239_005**]
[362] Update on Acquired Immune Deficiency Syndrome (AIDS) among Patients with Hemophilia A. Reports case studies of patients in the US (MMWR) [**PRSE0003276**] dated 10.12.1982
[363] This article from MMWR does not appear in disclosure. A reference to the existence of the article appears in [**CGRA0000289**] at [pg2] but this does not include the full article. The article is available on the CDC website here. The article is also described in [**JREE0000019**].

scientists working in haemophilia and blood transfusion spheres were (or, if not, probably should have been) aware of AIDS. With the addition of the first evidence suggesting a connection to transfusion of blood components (rather than blood products), an aetiology including blood-borne transmission gained evidential foundation. At this time, or in the month that followed, there was an accumulation of evidence sufficient that clinicians and scientists working in the field could identify (as many did) a real risk of a viral aetiology for a disease transmissible by blood and blood products. However, a significant portion of medical opinion still considered that other aetiologies better suited the presentation of the disease, and knowledge of the transmission routes continued to develop. Furthermore, that real risk was understood, based on the evidence available at the time, as being connected to commercially obtained blood and blood products sourced from the USA. There was an absence of evidence in respect of UK-produced blood products.

8.41 This real risk of AIDS through blood and blood products was recognised in the evidence of some haemophilia centre clinicians. Dr Winter expressed the view that by the end of the period July 1982 to December 1982, haemophilia doctors should have had real concerns that the cause of AIDS was something in the blood, and that this '*must be a virus or something like that*'.[364] He saw it as the '*only clinical interpretation of data that was available. There was no other way that this child could have acquired this very unusual condition*'.[365] Professor Franklin stated in his oral evidence, in respect of when it became reasonably clear that AIDS was probably being transmitted by blood and blood products, that: '*…by the time that – the case of the baby came out, then that was pretty clear. There were still other theories around but I think they began to fall away*'[366]. Professor Hay considered that he would certainly have heard of the three US cases by 1983, but could not be more specific as to the precise date of his knowledge.[367] Dr Bevan recollected seeing the MMWR published as a supplement to *The Journal of American Medical Association*, and was of the view that the association of AIDS to blood products seemed '*quite likely*'.[368]

(9) Haemophiliacs and commercial products – January 1983

8.42 January 1983 saw the publication of a significant amount of evidence on haemophiliacs. On 7 January 1983, various relevant papers were published. First, Marx followed up on his earlier AIDS article in *Science* with 'Spread of AIDS sparks new health concern' [**RLIT0000233**].[369] He reported that Harold Jaffe of the CDC said '*…the problem in hemophiliacs is real…it isn't going to*

[364] Oral Evidence of Dr Mark Winter [**INQY1000059**] dated 01.10.2020 at [75/13]
[365] Oral Evidence of Dr Mark Winter [**INQY1000059**] dated 01.10.2020 at [76/21]
[366] Oral Evidence Professor Franklin [**INQY1000068**] dated 27.10.2020 at [163/21]
[367] Oral evidence of Professor Charles Hay [**INQY1000072**] dated 04.11.2020 [56/1
[368] Written Statement of Dr David Bevan [**WITN4106001**] at [pg17-18]
[369] J Marx, Spread of AIDS Sparks New Health Concern (Science, 1983, Vol. 219, Issue 4580) [**RLIT0000233**]

go away'. The CDC was also reported as saying that evidence of transmission to haemophiliacs is '*clear-cut*'. In addition, MMWR reported on the apparent transmission of AIDS from male sufferers to female sexual partners [**RLIT0000232**][370] and of prison inmates in New York and New Jersey suffering from the disease [**CGRA0000332**].[371] In his written statement, Professor Tedder notes his recollection of that latter MMWR report and said that it '*helped to reinforce my view of AIDS being caused by a virus*' [**WITN3436003**].[372]

8.43 A run of clinical literature in January 1983 indicates findings of T-cell imbalances in the US possibly associated with concentrates (similarly produced in the US). There were three pertinent reports in the NEJM on 13 January 1983. First, a Menitove et al., article that reported T4/T8 ratios in haemophilia patients. It noted that '*…caution must be exercised in interpreting the meaning of these laboratory findings*'. The discussion concludes:

> '*…The proposed explanations for AIDS include infections (cytomegalovirus), drug use (inhaled nitrites) and exposure to foreign antigens (spermatozoa). Our data are consistently with the possibility that commercially prepared lyophilized factor VIII concentrates can induce an AIDS-like picture, but a large number of patients must be studied before a definite conclusion can be drawn. In addition, we cannot hypothesize about the emergence of this apparently new syndrome at this time. Whether the abnormalities found in our patients will evolve into clinical disorders remains to be determined, but we urge those involved in the care of patients who use factor VIII concentrate to follow them carefully for stigmata of AIDS and changes in immunological state.'* [**PRSE0001320**][373]

8.44 Second, there was a report of Lederman et al. This article compared lyophilized and cryoprecipitate users against controls. The article concluded:

> '*A more likely possibility is that the immune dysfunction is acquired. Active infection with hepatitis B virus is probably not responsible, since none of the 11 patients in the LYOPH group had demonstrable hepatitis B surface antigenemia. The cause of the immunosuppression in this population is not known; among patients with AIDS, however, epidemiologic evidence would implicate a blood-borne pathogen. Whether or not this putative immunosuppressive agent is responsible*

[370] CDC, Epidemiologic Notes and Reports Immunodeficiency among Female Sexual Partners of Males with Acquired Immune Deficiency Syndrome (AIDS) -- New York (MMWR, 1983, Vol.31, Issue 52) [**RLIT0000232**]
[371] CDC, Acquired Immune Deficiency Syndrome (AIDS) in prison Inmates -- New York, New Jersey (MMWR, 1983, Vol.31 Issue 52) [**CGRA0000332**]
[372] Written Statement of Professor Richard Tedder [**WITN3436003**] at [40]
[373] J Menitove et al., T-Lymphocyte Subpopulations in Patients with Classic Haemophilia Treated with Cryoprecipitate and Lyophilized Concentrates (The New England Journal of Medicine), dated January 13th 1983. [**PRSE0001320**]

> *for the abnormalities in cell-mediated immunity that we have observed in healthy hemophiliacs and for the opportunistic infections recently described in this population remains to be determined.'* [**PRSE0004470**].[374]

8.45 Third, there was the issue's editorial by Desforges. That article commented on these two articles, and concluded that '*…preventing the complications of the present treatment may have to take precedence over preventing the complications of hemophilia itself*'. It should be noted that Desforges was writing in the context of the treatment position in the USA [**PRSE0002410**].[375]

8.46 With respect to the haemophilia directors, Dr Colvin thought he was made aware of the risk by the publications in the NEJM. He was of the view that the articles of this date indicated a risk to haemophiliacs of AIDS, and that the '*most likely route of transmission of AIDS for haemophiliacs was blood and blood products*'.[376]

8.47 A few days after this run of articles in the NEJM, *The Lancet* published a letter from Jones et al on 15 January 1983. In that article the authors commented on alteration in T cell subsets:

> *'…the alterations in T cell subsets in our survey may simply reflect temporary altered immune status in multitransfused individuals. But half our patients without T cell ratio reversal had been exposed to equally large quantities of blood. It could be that T cell ratio reversal is a normal defence mechanism to antigenic load, and that patients without reversal show an abnormal lack of response.*
>
> *None of our patients, whom have been exposed to commercial blood products of American origin, shows features of AIDS, but our findings do highlight the need for continued, careful surveillance of the severely affected haemophilic community.'* [**DHSC0002351_004**][377]

8.48 An Observer article published on 16 January 1983 focused on the commercial import of blood products from the US and the threat posed to haemophiliacs [**DHSC0002223_085**].[378] The article references the viral aetiology hypothesis but notes that '*the cause remains baffling*'.

8.49 On 18 January 1983, a meeting of the UK Working Party on Transfusion Associated Hepatitis was held, chaired by Dr Gunson [**NHBT0000056_012**]. At that meeting Dr Craske commented on AIDS and mentioned '*in the USA it is*

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[374] M Lenderman et al., Impaired Cell-Mediated Immunity in Patients with Classic Haemophilia (The New England Journal of Medicine, 1983, Vol.308 Issue 2) [**PRSE0004470**]
[375] J Deforges et al., AIDS and Preventive Treatment in Haemophilia (New England Journal of Medicine, 1983, Vol.308 Issue 2) [**PRSE0002410**]
[376] Oral Evidence of Dr Brian Colvin [**INQY1000061**] dated 06.10.2020 at [169/16]
[377] P Jones et al., Altered immunology in haemophilia (The Lancet) [**DHSC0002351_004**] dated 15.01.1983
[378] C Doyle, Mystery Disease Threat (The Observer) [**DHSC0002223_085**] dated 16.01.1983

recommended that homosexuals with AIDs [sic] be deferred from donating blood or organs'. Dr Craske noted that he would be studying the effects of American Factor VIII on UK recipients and examining immunological markers, though he noted that the field was currently very confused.

8.50 In our submission, the position in January 1983 was a mixed one. First, there was the further expansion of the risk categories for AIDS consistent with a viral aetiology (per Professor Tedder, because of the parallel to HBV). There was also the growing identification of factor concentrates, and particularly commercial factor concentrates sourced from at-risk groups in the USA, as a significant vector for infection. These factors all supported the conclusion that haemophiliacs were at a real risk of AIDS, albeit without describing the nature and extent of that risk. They also provided supporting evidence indicating a viral aetiology transmissible through blood and blood products.

8.51 However, the evidence in respect of T-cell imbalance was complex. While with hindsight it appears that Menitove, Lederman and Jones were describing the early indicia of HIV infection and progression to AIDS, this was not clear at the time. Indeed, at the time of these reports the CDC had reported seven haemophiliacs[379] in the USA suffering with AIDS (and none were reported in the UK). This was in stark contrast to the high number of haemophiliacs demonstrating a T-cell imbalance. It is unsurprising in the context of that disparity that clinicians had not broadly accepted that such an imbalance indicated AIDS, nor indeed that the cause of such an imbalance was a virus. This is apparent in the range of causes discussed by all three sets of authors.

8.52 Thus, even though it had been recognised that AIDS posed a real risk to haemophiliacs, it remained unclear what the nature and extent of that risk was. While some (such as Desforges) had reached the correct conclusion, that does not mean such conclusions were the only appropriate ones to draw from the evidence available at the time.

(10) The run-up to the first identified case of AIDS in a haemophilia patient in the UK – February to April 1983

8.53 In early 1983 articles on AIDS continued to be published. These remained of the view that the aetiology was unknown, although some foregrounded a viral aetiology. These included an article in *The Lancet* on 22 January 1983, which commented '*if the syndrome does prove to be transmissible, this will strengthen the suspicion that the immunodepression is due to an infective agent*' [**SBTS0000315_021**],[380] and an article in *The New Scientist* which noted the hunt for the aetiology which the author thought had '*labelled as prime suspect*

[379] As of January 1983, the number is not precisely clear, although 7 was reported in the *MMWR* by December 1982 [**PRSE0003276**]. By 24 June 1983, of the 1,641 AIDS cases in the USA, 16 were in haemophiliacs (with a further 98 of unknown risk) [**JREE0000019**] (internal page 63).
[380] Acquired Immunodeficiency Syndrome (The Lancet) [**SBTS0000315_021**] dated 22.01.1983

some unknown blood-borne virus' [**PRSE0000726**].[381] A further article in *The Lancet* on 5 March 1983 referenced the postulation of a viral aetiology and noted that reports of AIDS in haemophiliacs might support this hypothesis. That article concluded by noting *'prolonged exposure to factor concentrate might present an age-dependent risk of AIDS*' [**PRSE0001330**].[382]

8.54 In March 1983, Drs Curran Evatt and Lawrence of the CDC published an editorial in *The Annals of Internal Medicine* maintaining the view that a viral aetiology was likely. The article concluded:

> *'Even in the absence of certainty about the cause of acquired immune deficiency syndrome, there are opportunities for prevention. Because sexual transmission of a causal agent appears likely, sexual contact with known or suspected patients should be avoided. Because the syndrome (and presumably the "agent") is more prevalent among sexually active homosexual men, persons in this group could further reduce their risk by minimizing the number of sexual contacts, specifically avoiding all casual and anonymous contacts. Prevention of the syndrome in recipients of blood and blood products may call for restricting use of blood from high-risk donors, improving preparation and processing of these products, and disseminating guidelines for their use.'* [**PRSE0001163**][383]

8.55 On 7 March 1983, Dr Evatt wrote to Dr Bloom regarding the AIDS pandemic in the USA [**DHSC0001175**]. The letter provides the details of the increasing number of infections noted in haemophiliacs, with 13 confirmed patients at the time of writing and 5 highly suspect cases. Dr Evatt noted that '*AIDS syndrome was the second cause of death among haemophiliacs in 1982 in the U.S. (hemorrhage was the largest cause of death)*'. Dr Evatt went on to refer to 12 patients developing AIDS following blood transfusions. He said '*I suspect it is a matter of time before you begin to see cases in the United Kingdom*'.

8.56 In March 1983, the evidence suggests that the UK blood service began to take steps to protect the safety of the blood supply from AIDS. By this stage, some RTDs were responding at a local level: Dr Ala's letter to Dr Gunson on 17 October 1989 illustrates this [**NHBT0020751**][384]. Dr Ala reported that he had participated in two or three local radio programmes in Birmingham '*aimed*

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[381] O Sattaur, AIDS - Transfusion Patients May Be At Risk (The Scientist) [**PRSE0000726**] dated 03.02.1983

[382] N Luban et al., Altered Distribution Of T-Lymphocyte Subpopulations In Children And Adolescents With Haemophoilia (The Lancet) [**PRSE0001330**] dated 5.03.1983

[383] J Curran et al., Acquired Immunodeficiency Syndrome - The Past as Prologue (Annals of Internal Medicine,1983, Vol.98 Issue 3) [**PRSE0001163**]

[384] While this document dates from the HIV litigation, it gives useful background as to what was happening at a local level at one RTC prior to a decision being reached on a combined approach. The evidence from individual RTCs is less complete than the national picture, which makes it difficult for the Inquiry to understand the local picture. As this document indicates, there were local responses before the national level steps taken beginning April/May 1983.

towards deterring "at risk" donors, in February and March 1983'. At a CBLA meeting on 23 March 1983, Professor Bloom suggested that AIDS should be discussed at a further meeting, and Dr Gunson said it would be discussed at the Council of Europe's Committee [**CBLA0001690**]. A meeting of Scottish RTDs and HCDs also discussed AIDS and asked for the matter to be kept for review at the next meeting [**PRSE0000728**].

8.57 On 28 March 1983, correspondence from the DHSS medicines division suggested that the issue of licensed blood products be considered at a meeting of the Committee on Safety of Medicines (Biologics). The letter noted the steps being taken in the US to avoid the use of blood from certain high-risk groups in the preparation of certain products [**PRSE0004683**].

8.58 As at 1 April 1983, some scientific literature remained of the view that the link to a viral agent was not sufficiently established to act upon. An editorial in *The Lancet* stated that '*…whilst careful surveillance must continue, the reported cases do not constitute a strong argument for a change in treatment policy*' [**PRSE0002723**].[385] However, at the end of the month several letters also in *The Lancet* expressed support for the virological agent hypothesis [**PRSE0000317**][386], [**CBLA0000059_031**].[387]In her written statement, Professor Lee identified these articles as the first indication of transmission by blood transfusion. She did not think she was aware of the MMWR report of 10 December 1982.[388]

8.59 Evidence of a viral aetiology continued to grow over the early part of 1983, with clinicians beginning to suggest ways of managing the spread of the disease based on that assumption. Certainly, the position changed in the USA with a move towards the introduction of donor exclusion which exerted some influence in the UK. Thus, the evidence suggests that it was reasonable at this stage to take steps to explore limiting assumed routes of transmission into the blood supply.

8.60 However, it also seems unsurprising (and indeed appropriate) that the UK should have followed – and have been to some extent behind – the USA in its approach, since: (1) the epidemic was far more advanced in the USA, and the UK could learn from the USA's initial experiences of donor exclusion; (2) there was not yet any evidence of an infection of a recipient of blood or blood

[385] Acquired Immunodeficiency in Haemophilia (The Lancet) [**PRSE0002723**] dated 02.04.1983. It would appear that this editorial was written by Dr Peter Jones

[386]A Ammann et al., Acquired Immunodeficiency in an Infant: Possible Transmission By Means of Blood Product (The Lancet) [**PRSE0000317**] dated 30.04.1983

[387] R Gordon, Factor VIII Products and Disordered Immune Regulation; C Kessler, et al., Abnormal T-Lymphocyte Sub Populations Associated With Transmissions Of Blood-Derived Products (The Lancet) [**CBLA0000059_031**] dated 30.04.1983. Other letters did not comment on the source see [**PRSE0002321**]

[388] Written Statement of Professor Christine Lee [**WITN0644058**] at question 37. Note, however, that Professor Lee became a consultant in 1987.

products in the UK (or, if there was such evidence, it was not widely distributed); and (3) the ongoing discussion in the DHSS and between clinicians had some focus on the risk of imported factor concentrates (rather than domestic blood, blood components, and derived blood products). However, as can be seen in this section and below on the progression of the AIDS leaflet, tentative steps were being taken to respond to AIDS.

(11) The identification of AIDS by Montagnier and the first haemophiliac in the UK with AIDS – May 1983

8.61 For the understanding of AIDS in the UK, and the threat posed to the recipients of domestically derived blood and blood products, the evidence suggests that May 1983 was the turning point. On 1 May 1983 there was a spate of articles on the AIDS crisis and its link to haemophiliacs. This included reporting in *The Observer* that a haemophiliac patient in Cardiff was suspected of having AIDS [**MDIA0000016**].[389] Such coverage continued on 4 May 1983 with *The Guardian* reporting Dr Craske's statement that reports of two haemophiliacs in London and Cardiff contracting AIDS from US Factor VIII had not been confirmed [**MDIA0000023**].[390] Note, however, that articles were still being published which indicated against a viral agent (most notably, Sonnabend et al [**OXUH0002239_005**],[391] discussed above, which suggested that AIDS in homosexuals was '*probably*' related to multiple factors including CMV and allogeneic semen).

8.62 On 6 May 1983, an internal minute from Mary Sibellas to Dr Oliver reported the diagnosis of a patient at Cardiff with AIDS [**DHSC0002227_021**]. It was noted that Dr Galbraith wished the matter to be considered by the Department as a priority, with any top-level meeting to include the CDSC. It was also reported that Dr Gunson was aware of this issue and that alternative supplies of Factor VIII were being considered, although these would not be easy to come by.

8.63 Dr Gunson did raise the issue of obtaining supplies of plasma for Factor VIII from Switzerland with Dr Alfred Hassig (Director of the Swiss Red Cross) on 15 May 1983 [**DHSC0000716**].[392] Dr Hassig was '*mystified*' by reports in England of Switzerland providing plasma as the supplies were barely sufficient to meet self-sufficiency in his country, and '*there would be no question of supplying any*

[389] A Ferriman, Killer disease alert over gay blood donors (The Observer) [**MDIA0000016**] dated 01.05.1983
[390] A Veitch, Warning Against AIDS "Panic" (The Guardian) [**MDIA0000023**] dated 4.05.1983
[391] J Sonnabend at al., Acquired immunodeficiency Syndrome, Opportunistic Infections, and Malignancies in Male Homosexuals (The Journal of the American Medical Association, 1983, Vol.249 Issue17) [**OXUH0002239_005**]
[392] Letter from Dr Gunson to Dr Walford [**DHSC0000716**] dated 16.05.1983. He spoke to Dr Hassig the day previous to the letter.

plasma for the UK'. Dr Hassig himself was not aware of anyone at his institute speaking to the British press.[393]

8.64 On 9 May 1983, Dr Galbraith wrote to Dr Field at the DHSS advising that he had concluded:

> *'…all blood products made from blood donated in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission by these products has been clarified'.* [**CBLA0000043_040**]

A paper attached to his letter provided his reasons, and noted that the AIDS epidemic in the USA was '*probably due to a transmissible agent*'.

8.65 On 13 May 1983, there was a special meeting of the haemophilia reference centre directors to discuss AIDS [**BPLL0001351_024**]. It was noted that there was a suspected case within UK haemophilia patients, and 10 cases of confirmed AIDS in homosexual males in London. It was agreed that any patient suspected to be suffering from AIDS should be reported. In respect of the use of concentrates from the USA, it was:

> *'…agreed that there was insufficient information available from the U.S. experience to warrant changing the type of concentrate used in any particular patient'*

8.66 It was thought directors retaining a supply of NHS product for children and the mildly affected was '*circumspect*'. The paper went on note:

> *'It was also agreed that there was, as yet, insufficient evidence to warrant restrictions of the use of imported concentrates in other patients in view of the immense benefits of therapy. The situation shall be kept under constant review.'*

Finally, the meeting noted and welcomed the news that the RTDs were to discuss donor screening.

8.67 On 20 May 1983, the isolation of HIV was first announced by Dr Montagnier [**PRSE0004469**]. The article was published in *Science* along with a paper from Dr Gallo on his work connecting AIDS to HTLV viruses [**RLIT0000115**][394] and an article by Jean Marx explaining the discovery [**RLIT0001205**].[395]

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[393] In Susan Douglas' article in The Mail on Sunday [**PRSE0000199**] it was suggested that the Swiss Red Cross would '*welcome requests from Britain for "clean" plasma*'. This was discussed further in the Oral Evidence of Ms Douglas [**INQY1000242**] dated 15.09.2022 at [17/11] and [52/2]. This memo from Dr Gunson to Dr Walford indicates no such capacity existed. Indeed, as the memo notes, Switzerland was producing around 2 million i.u. at the time. The UK was using more than ten times this amount in both domestically produced Factor VIII concentrate and imported concentrate. Thus, the implication that Switzerland could be used in substitution for American Factor VIII appears to be mistaken.

[394] R Gallo, Isolation of human T-cell leukemia virus in acquired immune deficiency syndrome (AIDS) (Science, 1983, Vol.220 Issue4599) [**RLIT0000115**]

[395] J Marx, Human T-Cell Leukemia Virus Linked to AIDS (Science, 1983, Vol.220 Issue 4599) [**RLIT0001205**]

8.68 The same day, Professor Tedder wrote to Dr Walford following a meeting of the previous week in which research into AIDS had been discussed [**DHSC0003824_164**].[396] While there was some dispute between Dr Walford[397] and Professor Tedder[398] as to the tone of the meeting, the net result appears to be that Professor Tedder was advised to seek funding from the Office of the Chief Scientist rather than through the DHSS. In the letter, Professor Tedder refers to undertaking further research into AIDS, including research on virology, to consider:

a) the increased microbiological load of these patients; and

b) the possible identification of a single novel aetiological agent

8.69 In his oral evidence explaining seeking the funding, Professor Tedder explained that he sought this funding because '*the pattern of this… transmission events and who it affected and who it didn't, you'd say, that's a transmissible agent*'. [**INQY1000256**][399]. In written evidence, Professor Tedder said that '*by early 1983, we knew that we needed to do something quickly. I think this is why I found the response from the DHSS particularly difficult*' [**WITN3436003**].[400]

8.70 While it would be another year until Dr Gallo's own announcement of the isolation of HIV, by this point most clinicians and scientists recognised (or, probably, should have recognised) the real risk that AIDS was caused by a viral agent transmissible in blood and blood products. While the matter was not determined, the evidence was sufficiently strong to proceed as a precaution with steps to reduce the risk. In addition, evidence at this stage supported the conclusion that, for those who developed AIDS, the disease was incredibly serious with a high mortality rate.

8.71 However, in May 1983 much about AIDS remained unknown. Most notably, it remained unclear whether all infections with HIV led to AIDS, or whether individuals could clear the virus or otherwise the virus could manifest sequelae less serious than AIDS. Various clinicians recognised this difficulty, including Dr Walford[401] ('*nor, indeed, how many people who had become infected, if they had become infected, would ultimately go on to develop AIDS*'). The minutes of the meeting of the Medical Research Council ('**MRC**') Working Party on AIDS on 10 October 1983 are instructive on this point, in particular:

> *'The possibility that AIDS as currently defined was the tip of an iceberg in terms of a range of clinical or subclinical responses to infection with a putative AIDS agent was mentioned; it was recognised that the*

[396] Letter from Professor Tedder to Dr Walford [**DHSC0003824_164**] dated 20.05.1983
[397] Oral Evidence Dr Diana Walford [**INQY1000137**] dated 20.07.2021 at [147/13]
[398] Oral Evidence of Professor Richard Tedder [**INQY1000256**] dated 13.10.2022 at [47/12]
[399] Oral Evidence of Professor Richard Tedder [**INQY1000256**] dated 13.10.2022 at [56/23]
[400] Written Statement of Professor Richard Tedder [**WITN3436003**] at [70]
[401] Oral Evidence Dr Diana Walford [**INQY1000138**] dated 21.07.2021 at [86/4]. See also at [88/14].

existence of milder forms would be hard to establish without a marker for such an agent.' [**PRSE0000389**]

8.72 Similarly, Professor Tedder in his letter to Dr Walford on 20 May 1983 considered research into outcomes for the disease in his letter to Dr Walford on 20 May 1983 [**DHSC0003824_164**]: '*the natural history of the patient with AIDS or pre-AIDS is not known. We do not know the long term outcome of patients with abnormal lymphocyte function.*' This can also be seen in Professor Tedder and Dr Barbara's later article '*Viral Infections Transmitted by Blood and Its Products* in *Clinics in Haematology'* dated 3 October 1984 [**NHBT0000030_009**]: '*What is not known at present is the proportion of anti-HLTV III-positive persons who will subsequently develop* AIDS''.

8.73 It is possible now to see that the reports of significant T-cell imbalances (among a range of other reports) indicated a more widespread issue with AIDS in the blood and blood product recipient community. However, this is to use hindsight in a way which does not reflect the difficulty in interpreting such results at the time. Other serious reasons for that imbalance and response remained advanced by many (including leading) clinicians. For example, a letter in *The Lancet* on 28 May 1983 from Professor Ludlam and others remained of the view that '*it seems likely that the immunosuppression observed in haemophiliacs… results from infusion of foreign protein or a ubiquitous virus rather than a specific AIDS virus*' [**PRSE0001303**].

8.74 The figures for identified AIDS cases remained low even into late 1984 (on 14 December 1984, UKHCDO was reporting three cases of haemophiliacs with AIDS[402]). Even with the growing knowledge of the latency period of the development of AIDS from infection, statistically the risk was not understood (not least as it was unclear when infections would have occurred). Thus, in our submission, while the risk of AIDS was real for those receiving blood and blood products, it remained unclear what the scale of the risk was to the community of such patients at large. This was a feature of subsequent discussions which, it seems, obscured what we now see as clear and obvious symptoms evidencing transmissions of HIV through blood and blood products.

C. Donor selection and the AIDS leaflet

(1) Donor exclusion in the US

8.75 Once it became apparent that AIDS exclusion guidance was required, the UK response to AIDS was informed to some extent by the donor exclusion steps taken in the US. Such steps began in the US in late 1982. The fact that there was limited oral evidence from witnesses to the Inquiry in respect of the steps taken in 1982 and early 1983 appears to reflect a limited cross-fertilisation of information across the Atlantic before the epidemic became established (and,

[402] HCDs' AIDS Advisory Document [**HCDO0000270_007**] 14.12.1984

indeed, reflects the lack of modes of communicating information in contrast to today).

8.76 On 3 October 1982, the US National Hemophilia Foundation endorsed a resolution seeking to exclude groups with high incidence of AIDS from plasma donation. This was reported in the November/December 1982 edition of the American Association of Blood Banks' ('**AABB**') *News Briefs* [**CBLA0000056_102**].[403] Some pharmaceutical companies took steps to implement exclusions in late 1982 (e.g. Travenol on 9 December 1982 [**CGRA0000655**][404]).

8.77 In his article titled, 'The Tragic History of AIDS in the Hemophilia Population 1982-1984' (published in December 2007) [**PRSE0000831**], Dr Evatt recounts the steps towards exclusion. In particular, he noted a meeting of an advisory committee on AIDS in Atlanta on 4 January 1983. Dr Evatt described that event as '*possibly the most discouraging and frustrating day of the epidemic for CDC staff*'. His recollection is not recounted here, although he notes the difficulty experienced in the USA in moving towards a process of donor exclusion.[405]

8.78 On 13 January 1983 the AABB, American Red Cross and Council of Community Blood Centres published guidance [**CBLA0000064_020**].[406] Among other things, the document encourages questioning about AIDS indicia. However, the paper is against direct or indirect questions about a donor's sexual preferences. The document also appears in the March-April 1983 edition of *Transfusion* [**OXUH0000824**].[407]

8.79 On 4 March 1983, the Public Health Service in the USA recommended interim measures in respect of AIDS [**BAYP0004470**].[408] While the measures included donor exclusion, they did not include the questioning of donors:

> *'As a temporary measure, members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, even though many individuals may be at little risk of AIDS. Centres collecting plasma and/or blood should inform potential donors of this recommendation.*

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[403] Haemophilia Foundation Passes AIDS Resolution (America Association of Blood Banks, 1982, Vol.5 Issue11) [**CBLA0000056_102**]

[404] Letter from Michael Rodell (Vice President, Hyland) to Charles Carman and Louis Aledort (National Haemophilia Foundation) [**CGRA0000655**] dated 09.12.1982

[405] Note that a more positive outlook on the meeting appeared in Article by J Marx, Health Officials seek ways to halt AIDS, (*Science*) [**PRSE0001370**] dated 21.01.1983

[406] Joint Statement on Acquired Immune Deficiency Syndrome [**CBLA0000064_020**] dated 13.01.1983

[407] J Lippincott Co, Report on the Joint Statement on Acquired Immune Deficiency Syndrome (AIDS) (Transfusion, 1983, Vol.23 Issue2) [**OXUH0000824**]

[408] US Department of Health and Human Services News bulletin re AIDS dated 04.03.1983 Also reported in MMWR on the same day. See Current Trends Prevention of AIDS: Report on Inter-Agency Recommendations [**PRSE0000546**] dated 04.03.1983

> **The following groups should be considered at high risk, even though many individuals may be at little risk of developing or transmitting the condition: patients diagnosed with AIDS; sexual partners of AIDS patients; persons with symptoms and signs suggestive of AIDS; sexually active homosexual or bisexual men with multiple partners; Haitian entrants to the U.S.; present or past abusers of intravenous drugs; and sexual partners of individuals at high risk of AIDS.'*

8.80 On 24 March 1983, the Department of Health and Human Services in the USA issued a letter to all licensed manufacturers of plasma derivatives, requiring them not to use plasma taken from donors suspected of being at increased risk of transmitting AIDS for producing fractionated derivatives known to have a risk of transmitting infectious diseases [**DHSC0001203**].

8.81 From a US perspective, it was in March 1983 that the situation moved towards one of avoiding donations from at-risk groups. It is unclear how much of this information was known by clinicians in the UK blood services; or indeed how much of it was deemed relevant when the AIDS epidemic was far less developed in the UK. Further, as has already been noted, it was only in the preceding three months that the risk that AIDS may be transmitted in blood and blood products was identified. Notwithstanding this, it is around the time of these changes in the US that exclusion in the UK began to be considered.

(2) Initial suggestions of a donor selection response in the UK – April 1983

8.82 Following on from preliminary discussions (some of which are noted above) in March 1983, on 1 April 1983 Dr Gunson provided a report for the upcoming Council of Europe meeting on AIDS. In that report he noted the eight possible cases of AIDS in the UK. He also stated that '*a Working Party of the Regional Transfusion Directors is considering action to be taken with respect to selection of donors, but no steps have been initiated at present.*' [**NHBT0017437_002**][409]

8.83 On 18 April 1983, the minutes of a meeting held at BPL noted that Mr Vallet had:

> *'…brought back recommendations from the USA that outlined ways of reducing AIDS in source plasma e.g. by further screening of donors, taking account of their history and background and sexual activities'* [**BPLL0008758**].

8.84 It is likely that this refers to the directions issued by the Department for Health and Human Services in late March 1983. In respect of minutes of NBTS, BPL, and the CBLA, this appears to be the first cross-fertilisation of information on this issue.

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[409] Dr Gunson, Report on AIDS [**NHBT0017437_002**] dated 01.04.1983

8.85 At or around the end of April 1983, the blood service was considering the making of a donor leaflet to encourage exclusion. At a meeting of the UK Working Party on Transfusion-Associated Hepatitis on 20 April 1983, Dr Gunson's attendance at the Council of Europe meeting was noted, as was Dr Craske's report that there were no cases of AIDS in UK haemophiliacs (although 6 likely cases in UK homosexuals). It was also noted that:

> *'Dr Gunson asked members of the working party to bear the topic in mind and consider the possibility of producing a pamphlet for donors illustrating AIDS risk groups'* [**NHBT0000023_003**][410]

That information was reported in the Council of Europe paper dated 28 April 1983 [**DHSC0000717**].[411]

8.86 On 27 April 1983, Dr Gunson reported at a CBLA meeting that:

> *'…the RTD's [sic] had considered all of the American literature on this subject, and at the next meeting of their Committee it would be recommended that no further measures be taken, apart from those already being carried out'* [**CBLA0001702**].[412]

8.87 This decision eventuated in the decision of the Working Party on Transfusion-Associated Hepatitis held on 28 April 1983:

> *'The Working Party has followed carefully the information from the U.S.A on AIDS and has considered the recommendations with respect to donor screening and the use of cryoprecipitates. To date there have been no cases reported following transfusion of blood or blood products. It has been agreed that, until further information is available, the Working Party will not recommend changes to present practices for donor selection or the use of blood products'* [**CBLA0001703**].[413]

8.88 From the available documents, it is unclear whether the reference in the CBLA minutes to '*further measures*' already being carried out included consideration of a pamphlet for donors (as identified at the UK Working Party on Transfusion-Associated Hepatitis meeting on 20 April 1983[414]). Certainly, such letters were progressing to an extent at a local level. In his letter to Dr Gunson dated 17 October 1989 (in respect of the HIV litigation), Dr Ala pointed out that a '*locally-produced leaflet*' was sent to all donors and handed out from donor sessions in

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[410] Minutes of the third meeting of the UK Working Party on Transfusion-Associated Hepatitis [**NHBT0000023_003**] dated 20.04.1983
[411] Minutes of the sixth meeting of the Committee of Experts on Blood Transfusion and Immunohematology [**DHSC0000717**] dated 16-19.05.1983
[412] Minutes of the fifth meeting of the CBLA [**CBLA0001702**] dated 27.04.1983
[413] H Gunson and J Barborough, Working Party on Transfusion-Associated Hepatitis [**CBLA0001703**] dated 27.04.1983
[414] Minutes of the third meeting of the UK Working Party on Transfusion-Associated Hepatitis [**NHBT0000023_003**] dated 20.04.1983

early May 1983 [**NHBT0020751**]. Thus, it appears progress to an exclusion leaflet did continue (at least in some form) over this period.

8.89 It is also unclear whether the reference in the Working Party minutes to '*further information*' in this context was directed towards the knowledge that Dr Gunson would be attending the Council of Europe Committee on Experts on Blood Transfusion and Immunohematology meeting the following month. In circumstances where such a meeting was liable to involve the sharing of considerable amounts of information across Europe, it was reasonable that Dr Gunson and the RTDs considered it prudent to obtain the views of other European experts before progressing an AIDS response. As to the decision not to recommend changes in the use of blood products, it is unclear what if anything the committee could do due to the principle of clinical freedom.[415]

(3) The response to the Council of Europe meeting and the first haemophiliac patient in the UK with AIDS – May 1983

8.90 On 16-19 May 1983, Dr Gunson attended the aforementioned Council of Europe Committee of Experts on Blood Transfusion and Immunohematology meeting.[416] On 16 May 1983, he wrote to Dr Walford and, among other matters, noted that the Council of Europe was going to recommend providing '*information to all donors so that those at risk will abstain from donating*' [**DHSC0000716**].[417] This also appears in the informal and formal reports Dr Gunson produced, and in the eventual recommendation. Thus, it would appear that the determinations reached in Lisbon at the Council of Europe meeting (likely coupled with the news of the first haemophiliac with AIDS at Cardiff) prompted progress on the AIDS leaflet.

8.91 Indeed, by the RTD meeting of 18 May 1983, Dr Gunson had written on the issue of a leaflet [**NHBT0015768**]. It seems likely this must have been sent at or shortly before the Council of Europe meeting In addition, it is likely that the matter was further prompted by the Cardiff patient being identified; the UKHCDO special meeting minutes of 13 May 1983 note that the RTDs were convening a meeting to discuss donor selection [**HCDO0000003_008**].

8.92 Diverting to the recommendation itself, Recommendation No. R (83) 8 was adopted on 23 June 1983 and included, among other things, the requirement to take:

> *'all necessary steps and measures with respect to the Acquired Immune Deficiency Syndrome' and included a requirement 'to provide all blood donors with information on the Acquired Immune Deficiency*

[415] Save, possibly, for referring the matter to the CMO or the CSM.
[416] Minutes of the sixth meeting of the Committee of Experts on Blood Transfusion and Immunohematology [**DHSC0000717**] dated 16-19.05.1983
[417] Letter from Dr Gunson to Dr Walford [**DHSC0000716**] dated 16.05.1983

Syndrome so that those in risk groups will refrain from donating.' [**NHBT0010651_004**]

8.93 An exemplar leaflet, as used by the American Red Cross, was appended to the recommendation. The following were identified in that draft as:

'…ask[ed] to refrain from donating blood at this time:

- persons with symptoms and signs suggestive of AIDS. These include severe night sweats, unexplained fevers, unexpected weight loss, lymphadenopathy (swollen glands) or Kaposi's Sarcoma (a rare cancer);

- sexually active homosexual or bisexual men with multiple partners;

- recent Haitian entrants into the United States;

- present or past abusers of intravenous drugs;

- sexual partners of persons at increased risk of AIDS.'[**NHBT0010651_004**]

8.94 The evidence suggests that the discussions in which Dr Gunson was involved at the Council of Europe meeting, taken with the news of the Cardiff patient, were significant in catalysing the steps that followed and the progression of the AIDS leaflet. In the context of significant changes in the understanding of the risk of AIDS to recipients of blood and blood products in the UK, coupled with the views expressed by other European countries, it is in our submission appropriate that this is the point at which significant steps were taken towards the production of that leaflet.

(4) The drafting of the AIDS leaflet by the RTDs – May to June 1983

8.95 The decision to progress a leaflet was made by the RTDs at the meeting of 18 May 1983 [**NHBT0015768**]. The timeline from that date to the introduction of the first leaflet on 1 September 1983 [**NHBT0001068**] is set out in the written statement of Dr Miflin on behalf of NHSBT and is not repeated here [**WITN0672006**].[418] In addition, various relevant documents are set out in Dr Hewitt's written statement responding to the institutional R9 request [**WITN3101006**].[419]

8.96 At the meeting of 18 May 1983, the RTDs considered a leaflet produced by Dr DBL McClelland for SNBTS [**NHBT0015768**]. Drs Davis and Barbara appear to have been tasked with producing a draft leaflet for NBTS. The suggested time for progressing the leaflet to the printing stage was six weeks.

[418] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1156-1165]
[419] Written Statement of Dr Patricia Hewitt [**WITN3101006**] from [118]

8.97 Dr Walford's evidence was that the original draft produced was inadequate as it was too ambiguous.[420] She recalled that Dr Gunson rewrote the document and it was produced in a new form [**WITN4461132**].[421] There was some input on the wording from DH at this stage, as demonstrated in a memo between Mr Windsor and Mr Winstanley dated 8 June 1983 [**DHSC0002321_018**]. Mr Winstanley also noted the need for expedition, and commented that it was '*essential to act without delay*' and that '*the time for printing and distribution seems painfully slow*'.

8.98 On 14 June 1983, Dr Gunson reported at a meeting of the SNBTS directors that a draft had been circulated and revised, with discussions regarding distribution to take place [**MACK0001960_001**]. At this time, Dr Gunson made amendments (to include changes as suggested at the SNBTS meeting) [**PRSE0002473**].[422] Correspondence between Dr Gunson and Dr Wagstaff on 15 June 1983 (including Dr Gunson's proposal of putting the distribution issue to Dr Walford) indicates ongoing discussions as to the form and content of the leaflet [**NHBT0039762_044**].

8.99 In the context of a new leaflet that needed to balance the competing needs of exclusion without risking a catastrophic drop in the number of donors (which would be a serious risk to the reliability of the blood supply), in our submission the leaflet was progressed in good time. This is particularly so considering that the nature and aetiology of the disease remained unknown. The wording of this initial draft was subsequently changed by the DHSS, but in our submission the original version bore a close resemblance to the leaflet utilised in the USA and capitalised on the experiences and knowledge developed there. The precise wording of the leaflet is discussed further below.

(5) Progress of the AIDS leaflet at the DHSS – June to August 1983

8.100 Dr Walford submitted the draft internally on 17 June 1983 [**WITN4461131**].[423] A further DH draft with changes was produced on 24 June 1983 [**DHSC0002309_122**]. Dr Walford identifies those changes in her statement [**WITN4461001**].[424] A memo of 6 July 1983 indicates that Mr Fowler thought the terms of the leaflet too strong [**PRSE0000049**].[425] On 6 July 1983, Dr Wagstaff sent a final copy of the leaflet and indicated that it was going to print. That leaflet also included proposed changes to the illness notice to include unexpected

[420] Oral Evidence Dr Diana Walford [**INQY1000138**] dated 21.07.2021 at [167/1]
[421] Leaflet answering questions on AIDS [**WITN4461132**]
[422] Letter from Dr Bell to Dr McIntyre [**PRSE0002473**] dated 15.06.1983
[423] Memo from Dr Walford to Mr Winstanley attaching revised AIDS leaflet and asking that itis forwarded to ID [**WITN4461131**] dated 17.06.1983
[424] Written Statement of Dr Diana Walford [**WITN4461001**] at [86.1]
[425] Memorandum from Dr Bell to Dr Scott [**PRSE0000049**] dated 06.07.1983

weight loss and whether the person was in good health or had needed to see the doctor recently [**PRSE0000161**].[426]

8.101 Internally at the DHSS there were discussions about the form, content, and distribution of the leaflet. The Minister for State for Health ('**MS(H)**') accepted the principle of the leaflet on 6 July 1983 [**PRSE0004727**].[427] It would appear Dr Gunson attended at the DHSS on 13 July 1983 to discuss the leaflet and the Government's line [**DHSC0002321_024**];[428] [**DHSC0002484_030**].[429] There followed a run of correspondence concerning distribution of the leaflet, with some indication that ministers did not want it distributing with donor cards, and wanted to keep the leaflet operation low key: [**PRSE0004308**][430] [**PRSE0002193**][431] [**PRSE0000646**].[432] On 25 July 1983, one such memo indicated that

> *'On purely medical grounds I am convinced that sending out the leaflet with the call-up cards is the only sensible thing to do and indeed this is the independent advice we have received from our consultant advisor whose opinion I respect.'* [**PRSE0003725**][433]

8.102 On 29 July 1983 there was a formal submission to ministers for printing, distribution arrangements and publicity for the leaflet [**DHSC0002327_016**]. That paper considered the options for distribution and recommended a six-month trial period for RTDs to take their chosen approach for the most effective means of distribution in their own region. In the draft leaflet at this time, the words '*donors are requested not to give blood*' had changed to '*donors are asked not to give blood*'.

8.103 Ministers approved the submission on 2 August 1983. PS(H) asked that the arrangements go ahead as soon as possible with low-key publicity as suggested [**DHSC0002327_118**].[434] MS(H) also approved the submission, although indicated that RTDs should not handle queries which should go through the DHSS press office [**DHSC0002327_119**].[435] On 3 August 1983, Lord Glenarthur also approved the leaflet and suggested use of both methods of distribution. He added:

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[426] Memorandum from Dr Wagstaff to his colleagues re: AIDS Leaflet [**PRSE0000161**] dated 06.07.1983. It would appear that this change was made in the course of 1983 to the illness notice see leaflet [**PRSE0003547**]
[427] Minutes of the meeting between Minister for the State for Health and Lord Glenarthur [**PRSE0004727**] dated 06.07.1983
[428] Letter from Dr Gunson to Dr Oliver [**DHSC0002321_024**] dated 14.07.1983
[429] Minute from Dr Oliver to Dr Walford [**DHSC0002484_030**] dated 18.07.1983
[430] Memorandum dated 19.07.1983 [**PRSE0004308**]
[431] Memorandum dated 20.07.1983 [**PRSE0002193**]
[432] Memorandum dated 21.07.1983 [**PRSE0000646**]
[433] Memorandum (recipients redacted) [**PRSE0003725**] dated 25.07.1983
[434] Memorandum from Mrs Walden to Mr Alcock [**DHSC0002327_118**] dated 02.08.1983
[435] Memorandum from Mr Alcock to Mrs Walden [**DHSC0002327_119**] dated 02.08.1983

> *'We may be at the tip of an iceberg with AIDS and find ourselves in trouble in 18 months' time unless we are really positive in our approach – even if it does embarrass a few 'gay' people.'* [**DHSC0002327_120**][436]

8.104 On 5 August 1983 it was indicated that it would take about three weeks for the leaflet to be printed by DHSS [**DHSC0002309_033**].[437] On or around 12 August 1983 news of the leaflet leaked: [**PRSE0004587**][438] and [**PRSE0004017**].[439] Correspondence in the DHSS followed, including MS(H) asking whether he could insist on a national method for distribution of the leaflet [**DHSC0002309_034**].[440] Such direction did not come, although Lord Glenarthur made the trial period three months rather than six: [**DHSC0002309_035**][441] [**DHSC0002321_034**][442] [**DHSC0002309_036**].[443] The final form of the leaflet is here [**PRSE0004076**].[444]

8.105 At the RTDs meeting on 22 September 1983 it was noted that the leaflet had been issued, and RTCs had been encouraged to use different methods of distribution. It was further recorded that the DHSS wished to receive feedback on the leaflets within three months [**CBLA0001742**].[445]

8.106 Clearly, the AIDS leaflet was the subject of a two-stage approach. It was first considered and written up by the RTDs (led by Dr Gunson and, to a lesser extent, Dr Walford). For the reasons expressed above, this appears to have been timely. However, with the benefit of hindsight, it appears that this second stage, in which the leaflet progressed through the DHSS and proceeded to printing, took longer than was necessary.

(6) The text of the original AIDS leaflet

8.107 The paper drafted by Dr Gunson used forthright and firm language (including on the risk that AIDS was in fact transmitted by blood). As the UK was taking advice from the US, the parallels to the wording used in the American Red Cross leaflet (which was attached to the Council of Europe recommendation) are understandable. NHSBT suggests that this was a sensible approach, relying on the skill and knowledge of those in the US acquired from dealing with the more developed progress of the AIDS epidemic. As to the steps taken by the DHSS, there appears to have been a process of review by the Department's civil servants and ministers.

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[436] Memorandum from Mr Joyce to Mr Parker [**DHSC0002327_120**] dated 03.08.1983
[437] Memorandum from Mr Parker to Mr Joyce [**DHSC0002309_033**] dated 05.08.1983
[438] AIDS Circular (The Scientist) [**PRSE0004587**] dated 11.08.1983
[439] Docs Ban Gays' Blood (The Sun) [**PRSE0004017**] dated 12.08.1983
[440] Memorandum from Mr Naysmith to Mr Winstanley [**DHSC0002309_034**] dated 26.08.1983
[441] Memorandum from Mr Naysmith to Mr Ghagan [**DHSC0002309_035**] dated 31.08.1983
[442] Memorandum from Mr Naysmith to Mr Winstanley [**DHSC0002321_034**] dated 26.08.1983
[443] Memorandum from Mr Ghagan to Mr Naysmith [**DHSC0002309_036**] dated 01.09.1983
[444] Guidance on AIDS and how it concerns blood donors [**PRSE0004076**]
[445] Minutes of the meeting of Regional Transfusion Directors [**CBLA0001742**] dated 22.09.1983

8.108 Further, of those descriptors for the exclusion criteria which have been particularly focused on in the Inquiry, it is of note that '*multiple partners*' and *drug abusers*' were both used as part of the USA exclusion leaflet and the leaflet attached to the Council of Europe recommendation. While this language could have been clearer, blood services across the world were balancing exclusion against the real risk of alienating donors (and thus risking catastrophic shortages of blood and blood components). Even in September 1983 the aetiology and interaction between the risk groups was not clear (albeit that evidence was increasing). In a field where matters were new and moving quickly, it was appropriate that the UK would take input and advice from the experiences of exclusion leaflets in the US and the recommendations of the Council of Europe.

8.109 It is also of note that the leaflet went further than the US and the Council of Europe examples in including, in the section '*who is at risk from AIDS',* a section noting that patients suffering from AIDS are also more likely to have had hepatitis, syphilis, and other venereal diseases. Between Dr Gunson's version and the final published version his text '*hepatitis (an infection of the liver causing jaundice)*' was modified to hepatitis B. This is indicative of the fact that these leaflets were the first of their kind, excluding for a disease for which there was still limited information.

8.110 It must also be borne in mind that the AIDS exclusion leaflet was not the only mechanism through which exclusion was achieved. For decades the blood service had operated a broader donor health notice (under the heading NBTS 110A) which was explored in Section 5 of these submissions. The provisions of that notice were also relevant to exclusion. Indeed, as Dr Wagstaff indicated in his letter of 6 July 1983 ([**PRSE0000161**],[446] discussed above) changes were also to be made to that notice because of AIDS. In addition, in the highest risk area of North London, additional steps including the donor questionnaire and confidential exclusion were implemented to further successfully manifest donor exclusion.

8.111 However, it was an important feature of deliberations around this time that there was a balance to be struck in drafting the leaflet: this is apparent in respect of the section addressing homosexual men. At the time of the leaflet's drafting there were questions about the involvement of the gay community in distribution [**PRSE0002473**].[447] There were significant and valid concerns about causing offence; this issue had been significant in the introduction of donor exclusion in the US, and both Professor Tedder and Professor Contreras spoke to the initial defensive reception that they received on speaking to the London Gay Representatives group.[448] Further, Dr Wagstaff recognised that

[446] Memorandum from Dr Wagstaff to his colleagues re: AIDS Leaflet [**PRSE0000161**] dated 06.07.1983.
[447] Letter from Dr Bell to Dr McIntyre [**PRSE0002473**] dated 15.06.1983
[448] Written Statement of Professor Richard Tedder [**WITN3436003**] at [114]

RTDs were concerned about deterring donors and the loss of donor numbers because of the leaflet. The concern was loss

> *'…at a higher rate, which was a possibility if the questions were not phrased in such a way as to be acceptable to the donors being presented with them in an open forum.'*[449]

Such an exclusion effort was beyond anything previously attempted by the blood service, and the risk of a catastrophic shortage of blood and blood components was a real one.

8.112 The text of the first leaflet reflected a compromise. First, it compromised between the need to exclude donors who were at a real risk of AIDS on the one hand, and the real risk that the leaflet might cause offense and a significant drop in donors, endangering the blood supply. Secondly, it was a compromise between the firmer version of the leaflet drafted by Dr Gunson and Dr Walford on the one hand, and the modifications made by the DHSS on the other. The leaflet also sat alongside the other exclusion material that the blood service used to ensure the reliability of the blood supply. With the benefit of hindsight, it does appear that the wording of the leaflet could have been more stringent.

8.113 However, considering the competing risks involved, and the climate in which the leaflet was written, we can see why at the time the final version of the leaflet was thought to strike the appropriate balance. However, with the benefit of hindsight it seems unfortunate that the stronger wording produced by Dr Gunson and Dr Walford was not advanced as the final version of the leaflet.

(7) Distribution of the first AIDS leaflet

8.114 While the DHSS eventually considered directing that the leaflet be distributed directly to donors with their call-up cards, this policy was not implemented. The decision was left to individual RTCs. Following the three-month introduction period, Dr Wagstaff wrote to the DHSS on 3 January 1984 with details of the methods of distribution adopted by the RTCs [**PRSE0000387**]. He noted that '*physically handing a leaflet to each donor at the session was the only method of distribution which caused offence*'. A table of information at the three-month stage is at [**PRSE0000249**][450] while the six-month stage is at [**CBLA0001820**].[451]

8.115 These tables both indicate the variance in how the RTDs approached distribution. As some recognised in oral evidence, decisions as to distribution could be determined by practical issues (e.g. whether a document could be

[449] Oral Evidence Dr William Wagstaff [**INQY1000175**] dated 25.01.2022 at [60/2]
[450] Letter from Dr Wagstaff to Dr McClelland [**PRSE0000249**] dated 03.01.1984
[451] Leaflet from the Advisory Committee on the NBTS titled: The First Six Months Experience of AIDS [**CBLA0001820**]

sent out with a call-up card which was in the form of a postcard[452]). Given that this was a new activity that RTCs had not previously had to undertake, such variance and searching for the most appropriate approach was understandable.

8.116 The six-month analysis at [**CBLA0001820**][453] includes a column headed '*donor response, effect on attendance*'. In our submission, this column is primarily directed to identifying whether donors expressed comments (and, particularly, adverse comments). This is because a significant concern of the RTDs at the time was negative impact on donors (which today we may interpret as a harm to donor goodwill). This broadly mirrors the use of the column in the three-month stage report [**PRSE0000249**].[454] In our submission, it is unlikely RTCs would have been able to quantify the number of donors lost through the leaflet; there is no direction that a donor must notify an RTC, and given the societal context it seems unlikely a donor would give notice of exclusion for being a homosexual man or an injecting drug user in any event. This broadly mirrors the view that Dr Martlew had of the table, which was that recording discussions at the RTC was unlikely to accurately reflect the number of successful exclusions.[455]

8.117 Following this initial cycle of issuing the leaflets, the approach was modified such that the leaflet was sent out with donor call-up cards. This was agreed at a meeting of the Advisory Committee on the NBTS on 10 April 1984 [**CBLA0001835**].

8.118 As with the text of the leaflet, the issue of how to provide the leaflet to donors again raised issues of practicality and a balanced approach to encouraging donor exclusion without causing significant harm to donor goodwill. Considering the overall context of AIDS at this time in the UK (and, particularly, the apparently low prevalence) the approach adopted was an appropriate one. This was a new approach to excluding donors that RTCs had not had to adopt before. However, once it was realised that the use of the leaflet was not a real risk in the way initially thought, it was appropriate to take the firmer approach and send the leaflet out with call-up cards.

(8) The first revised AIDS leaflet – 1984 to 1985

8.119 The events leading to the revised AIDS leaflet being published in England are included in Dr Miflin's written statement [**WITN0672006**][456]. That revised leaflet

[452] This was the case in North London. See Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [177/14]
[453] Leaflet from the Advisory Committee on the NBTS titled: The First Six Months Experience of AIDS [**CBLA0001820**]
[454] Letter from Dr Wagstaff to Dr McClelland [**PRSE0000249**] dated 03.09.1984
[455] Oral Evidence of Dr Vanessa Martlew [**INQY1000174**] dated 20.01.2022 at [21/21]
[456]Written Statement of Dr Gail Miflin [**WITN0672006**] at [1166-1195]

was introduced at the end of January 1985 [**NHBT0096480_022**]. A memo from Dr Smithies dated 19 July 1985 recorded:

> *'Just to put the record straight about the last leaflet. It was revised within the Department by MED SEB and agreed with HS1 and the RTDs in April 1984. Because of delay within the Department for one reason or another it was not issued until January 1985. The information finally issued was virtually the same to that agreed in April 1984 although ID division suggested alternative methods of presentation.*
>
> *The delay between drafting and issue caused considerable concern amongst RTDs. In view of the need to issue a further redraft I suggest that before it goes to RTDs we should ensure that there will be a smooth uninterrupted path to issue.'* [**DHSC0002273_002**]

8.120 The text of that leaflet is at [**NHBT0096480_022**] and includes two major modifications on the risk categories:

a) it now identifies *'practising homosexual and bisexual men'*; and

b) it now identifies *'sexual contacts of people in these groups'*. The *'drug abuser'* text remained the same.

8.121 The leaflet states that *'donors in the risk groups must **not** give blood'* (emphasis in the original). The requirements for the distribution of this leaflet were set out in a DHSS Health Circular [**DHSC0002159**].

8.122 In our submission, the language used in the leaflet was appropriate (mirroring the US approach) at the time it was drafted by the RTDs in April 1984. It reflected the incremental approach required to avoid deterring donors and risking the blood supply (as described above). However, by the time the leaflet was printed and distributed, there are grounds to doubt whether the language remained sufficiently strong. The delays between April 1984 and January 1985 in the leaflet progressing through the DHSS were unfortunate considering that they appear to have been administrative and to have arisen at a point in time prior to other mechanisms being in place to ensure the reliability of the blood supply (i.e. testing and heat treatment of factor concentrates).

(9) Was donor exclusion successful?

8.123 It is difficult to say whether donor exclusion was successful. Documentary evidence is available of the positivity rate of donors once HIV testing was introduced at the blood service (but prevalence data for HIV in the UK in the general population between 1985 and 1990 is limited). In the report at [**NHBT0015578_001**].[457] Dr Gunson records positivity rates from 1995 onwards in the region of 0.001-0.002%. Whether this was in any way influenced by the

[457] Dr Gunson, Anti-HIV 1 Testing of Blood Donations in the U.K. 1985 - 1989 [**NHBT0015578_001**]

'magnet effect' is unclear. Lacking good prevalence data, the best that can be said is that these figures appear low in the abstract. Certainly, it was noted by blood service witnesses that the success of exclusion made HIV-targeted lookback significantly harder (to which, see the section below on HIV exclusion).

8.124 Today, donor exclusion procedures are a crucial part of ensuring the reliability of the blood supply. As the HIV experts recognise in their paper, prevalence of HIV in first time donors is 0.003% (or '*53 times lower than that estimated in the general population*').[458] While these are figures for 2015, and reflect a time in which (1) attitudes to HIV are considerably different; and (2) exclusion is a longstanding and recognised approach, they are nevertheless indicative of the massive impact on donor positivity that exclusion policies alone can have.

D. Use of cryoprecipitate

(1) The principles of blood product production and use

8.125 Another aspect of the response to HIV is whether appropriate consideration was given to the substitution of treatment with factor concentrates with treatment using cryoprecipitate.

8.126 In the first instance, haemophilia clinicians treating patients had clinical independence. This is an issue explored in Section 3 of these submissions (Reviewing the Past in Context). Such independence was regarded as crucial to the medical profession by both the treating haemophilia clinicians and the Department of Health. In those circumstances, it was not the role of the blood service to intrude and direct a specific mode of treatment to those clinicians. See, for example, the comments in the oral evidence of Dr Walford [**INQY1000136**][459] and Dr Pickles [**INQY1000205**]. [460]

8.127 Secondly, as has also been noted, the period of the emergence of HIV coincided with the period following the implementation of the pro-rata distribution of concentrates produced domestically. This sat alongside plasma targets and the demand for plasma more generally. A move to provide less plasma by a given RTC (so that cryoprecipitate could be produced instead) would both fail in the meeting of these plasma targets, but also deprive treating haemophilia clinicians of access to NHS concentrates. This is because, as noted in Section 6 of these submissions (Self-Sufficiency), such domestically produced concentrates were distributed on a pro-rata basis against the plasma supply. Thus, direction from some centralised body with executive authority would have been required to enact a wholesale change of production practices.

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[458] Expert report to the Infected Blood Inquiry: HIV, January 2020 with addendum [**EXPG0000004**]
[459] Oral Evidence Dr Diana Walford [**INQY1000136**] dated 19.07.2021 at [47/22]
[460] Oral Evidence of Dr Hillary Pickles [**INQY1000205**] dated 12.05.2022 at [62/24]

8.128 Thirdly, the production of cryoprecipitate necessarily excluded the production of factor VIII concentrate and made the production of other products (most notably albumin and factor IX concentrate) much more difficult. As noted below, cryoprecipitate production was historically undertaken in RTCs. The provision of the cryoprecipitate supernatant to BPL in a sterile process (for production of other products) was not an easy circle to square. Such a change, if it were to be made, would take significant planning.

(2) The focus on concentrate production

8.129 Having considered those matters, a chronology of the use of and demand for cryoprecipitate appears in the written statement of Dr Miflin [**WITN0672006**].[461] Without repeating the generality of the documents set out there, it is important to note some of the important events in the period on the selection of treatment method.

8.130 In the second half of the 1970s, the push of treating clinicians was towards the use of factor VIII concentrate only. There was a meeting of the RTDs, HCDs and others at Sheffield on 22 October 1976, where the HCDs indicated that they wished for as much plasma to be put to the production of concentrates as possible (indeed, Professor Bloom asked for '*100% freeze-dried*'). In respect of that request, Dr Bevan thought the phasing out of cryoprecipitate and complete replacement with concentrate would take three years [**CBLA0000473**].[462] The Working Group on Trends in the Demand for Blood Products report of December 1977 maintained this view of a '*complete transfer*' [**DHSC0002189_014**].

8.131 On 15 September 1981 there was a meeting of certain HCDs, RTDs, and DHSS staff to discuss plasma and the redevelopment of BPL [**CBLA0001448**].[463] The view was that 100 million international units would be required of factor VIII by the mid-1980s. In respect of the split of production, the vast majority was in intermediate-purity product. Of the remainder:

> *'Directors agreed that they needed to reconsider their original estimated requirement for 10 million international units of freeze-dried cryoprecipitate and 10 million international units of high-purity concentrate. Dr Walford explained that to produce that amount of high-purity Factor VIII concentrate would require a disproportionate amount of plasma, and the costs of production would be very high. Directors agreed that if freeze-dried cryoprecipitate were not available, then frozen cryoprecipitate would be an acceptable substitute. However, if*

[461] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1366-1408]
[462] Agenda and Minutes of the Exploratory Meeting of Blood Transfusion Directors and Haemophilia Reference Centre Directors [**CBLA0000473**] dated 22.10.1976
[463] Minutes of the Joint Meeting of Representatives of HDCs, RTDs and DHSS [**CBLA0001448**] dated 15.09.1981.

> *more intermediate-purity concentrate was made available, the need for frozen cryoprecipitate would drop even further. At present about 1-2 million international units of frozen cryoprecipitate were used to treat von Willebrands disease. Directors thought that the need for high purity concentrate might be substantially less than 10 million international units, but the requirement and supply would need to be kept under careful review. (In view of the above requirements it is likely that the plasma requirement could be reduced to 435,000kg).'*

8.132 The demand for plasma supply to BPL is discussed in the Self-Sufficiency section of these submissions: the position was that demand for plasma for fractionation was high. The NHS concentrate produced by BPL would then be provided pro-rata to the HCDs for the treatment of their patients. The demand from the treatment side was, again, to maximise the amount of domestic concentrate production. The demand for cryoprecipitate was low, while the demand for BPL concentrate always outstripped supply.

(3) The demand for cryoprecipitate in response to AIDS

8.133 The documentary and oral evidence from witnesses all indicates that treating clinicians did not wish for production to be switched from concentrates to cryoprecipitate. Dr Lane notes as much in his statement in the HIV litigation [**CBLA0000005_002**].[464] The Haemophilia Society maintained its view that there should not be a ban on American products by a letter of 17 May 1983 [**PRSE0003827**]. The World Federation of Haemophilia recommended on 29 June 1983 that there was '*insufficient evidence'* to recommend a change in treatment from current blood product use [**PRSE0001351**].[465] Many of the blood service's witnesses were asked whether requests were made for increased cryoprecipitate production. While most were of the view that such production could have been increased,[466] this demand does not on the whole appear to have come about.[467] See, for example, the oral evidence of Dr Wagstaff [**INQY1000175**][468] and Professor Contreras[469] on this issue.

8.134 Indeed, going further, in mid-1983 the demand for UK-produced factor concentrates remained high because they were regarded as a safe option. Dr Gunson noted in an informal report in May 1983 that the yield from

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[464] Written Statement of Dr Richard Lane (HIV Haemophilia Litigation) [**CBLA0000005_002**] at [633]
[465] Resolutions by the World Federation of Hemophilia General Assembly Regarding Acquire Immune Deficiency Syndrome (AIDS) [**PRSE0001351**] dated 29.06.1983
[466] See for example: Oral evidence of Dr Colin Entwistle [**INQY1000167**] dated 06.12.2021 at [26/6]; Oral Evidence of Dr William Wagstaff [**INQY1000175**] dated 25.01.2022 at [47/17]
[467] Although note Dr Napier who did think there was some increase. Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [179/10]
[468] Oral Evidence Dr William Wagstaff [**INQY1000175**] dated 25.01.2022 at [55/1]
[469] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [149/19

cryoprecipitate could be a significant difficulty[**NHBT0017430**].[470] Further, he recognised that HCDs said they always needed up to 100% more factor VIII [**NHBT0017430**]. This is further mirrored in the letter sent out by Professor Bloom to HCDs on 24 June 1983:

> *'At the above mentioned meeting on May 13th the following general recommendations were agreed.*
>
> *[…]*
>
> *2. For treatment of children and mildly affected patients or patients unexposed to imported concentrates many Directors already reserve supplies of NHS concentrates (cryoprecipitate or freeze-dried) and it would be circumspect to continue this policy.*
>
> *It was agreed that there is as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy but the situation will be constantly reviewed.'* [**HCDO0000270_004**]

8.135 It is an important to note that the demand for concentrates in the UK did not in fact diminish. It was in principle open to the blood service to make this switch from supplying plasma for concentrate production to the production of cryoprecipitate. However, it was not open to the blood service to make this unilateral change in a context where:

a) demand for concentrates, supplied on a pro-rata basis, remained; and

b) plasma targets encouraged externally remained effective.

8.136 Indeed, there may well have been a risk that a unilaterally imposed decrease in the amount of available NHS factor VIII concentrate would encourage HCDs to use more imported product to fill the shortfall. Therefore, the first point, in our submission, is that it was out of NBTS's hands.

8.137 Moreover, and perhaps more importantly, if such a change were indicated, it would have required a fundamental change to the historic direction of travel. It would have required a departure from the pro-rata distribution of the available NHS concentrate (not least in the period where the production of concentrate was declining against production of cryoprecipitate increasing). It would also have required an acceptance that the provision of plasma to BPL, and compliance with the plasma targets imposed on RTCs, would cease.

(4) The prospect of switching to cryoprecipitate in 1983

8.138 Separate to the question of demand remains the issue of whether sufficient amounts of cryoprecipitate could have been produced. The evidence suggests

[470] Dr Gunson, Informal report on the proceedings of the sixth meeting of the Committee of Experts on Blood Transfusion and Immunohaematology held on 16-19.05.1983 [**NHBT0017430**] dated 19.5.83

that the blood service and the fractionators did consider the production of cryoprecipitate in the first half of 1983 as a response to AIDS. By 24 March 1983, Dr Lane was of the view that BPL needed to consider whether it could move to manufacturing small pool freeze dried cryoprecipitate He wrote:

> *'It is necessary for this laboratory to develop a policy, which may only be implemented on a short-term basis, which will allow for the presentation of a large proportion of NHS factor VIII as cryoprecipitate. Staff will be aware that many Regional Transfusion Centres have not made wet cryoprecipitate for some time and would now be both out of practice and in some cases without the facilities to recommence large-scale production. The implications for BPL source material are very real.'* [**CBLA0001691**].[471]

8.139 A further BPL meeting considered these issues and the steps BPL could take in production. This resulted in a position of '*wait and see*'. In his statement for the HIV litigation, Dr Lane noted:

> *'However, to an extent, we were obliged to adopt a policy of "wait and see". We needed direction from haemophilia clinicians and DH before we could react to produce what was needed'* [**CBLA0000005_002**].[472]

8.140 Dr Gunson also addressed the question of cryoprecipitate production in his correspondence with Dr Walford dated 16 May 1983. He noted that:

> *'You can see that what they are leading to is the greater use of cryoprecipitate, […]. Like you, I do not think BPL could change to freeze-dried cryo. rapidly and the logistical problems would be considerable. The CBLA is going to have to consider the interim period before the completion of the new plant very carefully and I am not sure yet, until I can give the matter more thought, what would be the best solution.'* [**DHSC0000716**]

8.141 In his informal report from the Council of Europe meeting on AIDS, Dr Gunson expressed the view that a move away from coagulation factors prepared from large plasma pools

> *'…will in my view cause problems, since this basically means the use of small pools of plasma for coagulation factor production and this will cause logistic problems and possible also practical ones with respect to the capability of the present B.P.L. to produce such material.'* [**NHBT0017430**][473]

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[471] Memorandum Dr Lane to Mr Mallory [CBLA0001691] dated 24.03.1983
[472] Written Statement of Dr Richard Lane (HIV Haemophilia Litigation) [**CBLA0000005_002**]

[473] Dr Gunson, Informal report on the proceedings of the sixth meeting of the Committee of Experts on Blood Transfusion and Immunohaematology held on 16-19.05.1983 [**NHBT0017430**] dated 19.5.83

Conclusions

8.142 In our submission, the focus on the production of concentrates prior to 1983 had left the blood service and fractionators with limited capacity to switch to cryoprecipitate quickly or without an intermediary period where the overall capacity for the production of Factor VIII (in any form) was diminished. It is clear that Dr Gunson had serious concerns about the capacity for such a transfer, which indicated to him against such a switch. However, as a clinician of the blood service rather than a haemophilia treating clinician, there is limited evidence as to the extent to which his concerns about the practicalities of such a change impacted the independent decision of the HCDs. In any event, it was appropriate that Dr Gunson consider these difficulties so that they might be prepared for and responded to. For his part, Dr Lane was prepared for the demand for such a change, and foresaw the considerable difficulties RTCs would face in such a switch. A *'wait and see'* approach was adopted as NBTS and BPL could not choose the treatment for HCDs or their patients. Such an approach was appropriate in the circumstances.

(5) The Committee on Safety of Medicines – July 1983

8.143 The question of whether there should be a move to cryoprecipitate use was eventually considered by the Biological Subcommittee of the Committee on the Safety of Medicine In the suggested agenda for the meeting, it was noted that Professor Bloom would speak to the issue of withdrawal of factor VIII and IX concentrates. The initially proposed summary was:

> *'Conclusion? This step cannot at present be recommended: (a) it is probably impossible to satisfy UK needs in this way; (b) even if needs could be satisfied it would involve a major rethink of UK policy for preparing blood products; (c) the perceived level of risk at present does not justify serious consideration of this conclusion.'* [DHSC0001209][474]

8.144 On 15 July 1983, the Biological Subcommittee met. In respect of the use of cryoprecipitate versus NHS-produced product, the following was recorded:

> *'(3) The possibility was considered of withdrawing clotting factor concentrates from the market and replacing them with cryo-precipitate. It was concluded that this is not feasible in the UK on grounds of supply.*
>
> *(4) The possibility was considered of withdrawing US preparations from the UK. It was concluded that this is not at present feasible on grounds of supply. Moreover, the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to secure UK independence of foreign suppliers of clotting*

[474] Include description

> *factor concentrates. This should reduce markedly, although not eliminate, the risks to recipients of these products, and the Sub-Committee strongly supports this aim. The Sub-Committee was also informed that the UK Haemophilia Centre Directors have adopted a policy for the use of US Factor VIII in order to minimise risks as far as possible.'* [**DHSC0001208**]

8.145 The recommendations of the Subcommittee were endorsed by the full committee at its meeting on 21-22 July 1983 [**DHSC0006259_007**].

8.146 While the shape of demand did change somewhat in the coming months, the determination of the CSM is likely to have been a significant factor indicating against a wholesale shift to cryoprecipitate. Cryoprecipitate would be a move away from the satisfaction of this demand for concentrates, which remained as a result of this determination.

8.147 Taking this section in the round, the evidence suggests:

a) that there was no demand from treating clinicians for a switch of domestic production from factor concentrates to cryoprecipitate

b) that the blood service could not unilaterally switch production in the face of the availability of commercial factor concentrates (and the application of the pro-rata system)); and

c) that there were serious questions about the capacity of the NBTS blood services to quickly switch to cryoprecipitate supply (and, indeed, BPL).

8.148 From the perspective of the blood service, its options were limited as, fundamentally, demand for domestically produced factor concentrates (and demand for the supply of plasma to fractionation laboratories) was not something the service could override.

E. Surrogate testing for HIV

(1) Surrogate testing in the USA

8.149 In the early part of 1983, some American publications suggested an approach of assessing screening procedures for their effectiveness at identifying and excluding blood and plasma with a high probability of transmitting AIDS. The PHS in the USA made such a suggestion in its press release on AIDS of 4 March 1983 [**BAYP0004470**]. Some USA pharmaceutical companies also seem to have considered this: see the Armour letter to HCDs on 19 May 1983 [**BART0000863**] and the proposal (and difficulties involved) in surrogate testing for antibody to hepatitis B core antigen in *The Journal of Anaesthesiology* **BAYP0000028_106**. On 29 June 1983 the World Federation of Haemophilia

noted that '*efforts to develop "surrogate" donor blood tests as highly specific or sensitive markers for AIDS have not been successful*' [**PRSE0001351**].[475]

8.150 The Inquiry has some evidence from American pharmaceutical companies on their consideration of surrogate testing. To properly assess this evidence, it is necessary to remember that the prevalence of HIV in the USA was understood to be considerably higher than in the UK. An internal Hyland Therapeutics memo extensively considers various possible surrogate testing procedures [**CGRA0000324**].[476] In that correspondence anti-HBc testing was identified as '*the best single test system*' with 87.5% sensitivity and a false positive rate of 12.5%.[477] Combined anti-HBc with SBA was rated as 98.4% sensitive with a false positive rate of 15%. Hyland proposed to test all donors for anti-HBc once (with ongoing HBsAg thereafter) and SBA testing on each bleed. In respect of the implementation, the memo records consideration of the time required for the introduction of the tests (8-12 weeks for SBA, 4 weeks for anti-HBc). It also considers the false positive rate:

> *'2) A large enough supply of plasma and donors to accommodate the False positive rate of the test system.*
>
> *[…]*
>
> *Item 2 is very complicated. At present, plasma supply is the major issue in Bioprocurement. Until the plasma supply increases substantially, the AIDS screening would not be feasible. A possible alternative supply of plasma could be the prison system. If the testing could insure "clean" plasma for AIDS, I feel the prison plasma is viable.*' [**CGRA0000324**][478]

8.151 While the American pharmaceutical evidence is not directly relevant to the UK (it concerns a private company operating in a country with paid donations and a much higher HIV prevalence), it is instructive. Hyland report they would test 30,000 donations for the first two months, with 10,000 in the months subsequent. The matter of false positives and the plasma supply was thought '*very complicated*'. In the same year, the Expert Report on Statistics suggests that England took 2,015,297 donations [**EXPG0000049**].[479] If the false positive rate provided for here was anywhere close to correct, the blood service would expect false positives in the region of hundreds of thousands of donors. This is important background to the blood service's evidence on surrogate testing considered below.

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[475] Resolutions by the World Federation of Hemophilia General Assembly Regarding Acquire Immune Deficiency Syndrome (AIDS) [**PRSE0001351**] dated 29.06.1983
[476] Memorandum from Mr Slimak to Mr Bacich [**CGRA0000324**] dated 27.06.1983
[477] Put another way, specificity of 87.5%. To recap, this means that 12.5% of all blood donors would test false positive on the surrogate test for AIDS.
[478] Memorandum from Mr Slimak to Mr Bacich [**CGRA0000324**] dated 27.06.1983
[479] Expert Report to the Infected Blood Inquiry: Statistics by the Statistics Expert Group [**EXPG0000049**]

8.152 This document is also indicative of the relationship between high sensitivity and high specificity. As Professor Tedder explained in his written statement, '*high sensitivity is often associated with a risk of increased prevalence of false positive reactions*' [**WITN3436003**].[480]

(2) Surrogate testing in the UK

8.153 Detail of the history of surrogate testing for AIDS in the UK has been most expansively considered by Professor Tedder [**WITN3436003**].[481] Dr Miflin also addresses some of the documentation [**WITN0672006**].[482] In respect of such surrogate testing, it is important to note the short timeframe involved for the development of this testing before the viral agent HIV was discovered by Dr Gallo. As Professor Tedder noted surrogate testing becomes less valuable in circumstances where the aetiological agent of a disease has been identified [**WITN3436003**].[483]

8.154 The documents suggest that testing for high-risk donors using surrogate markers was first explored as a possibility around 22 September 1983. At an RTD meeting of that date '*early information*' was noted that hepatitis B core antibody and syphilis testing may be suitable (with the former regarded as '*possibly the most valuable marker*') [**CBLA0001742**]. The matter appears to have been further explored at a meeting of the UK Working Party on Transfusion-Associated Hepatitis on 27 September 1983 [**NHBT0000023_004**] and the CBLA working group on AIDS on 14 October 1983 [**CBLA0001754**]. At that latter meeting it was suggested that, if any type of surrogate test was going to be investigated, anti-HBc screening was preferable. That meeting also noted that some research on anti-HBc screening had already been done. At a meeting of the Advisory Committee on the NBTS on 17 October 1983, Dr Gunson noted that studies on surrogate testing were being undertaken and would be available in 1984 [**CBLA0001763**]. Such research continued through 1983 [**SCGV0000052_086**].[484]

8.155 An international view on surrogate testing is provided in the 12 December 1983 draft of a World Health Organisation paper titled 'Acquired Immunodeficiency Syndrome, An Assessment of the Present Situation in the World' [**CBLA0001775**]. One recommendation of that paper was the use of surrogate testing, which '*may theoretically help identify individuals who are at risk of AIDS*'. The report noted:

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[480] Written Statement of Professor Richard Tedder [**WITN3436003**] at [307]
[481] Written Statement of Professor Richard Tedder [**WITN3436003**] at [366-390]
[482] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1223-1229]
[483] Written Statement of Professor Richard Tedder [**WITN3436003**] at [389]
[484] Memorandum from Dr Bell to Dr Scott and Dr McIntyre enclosing the Minutes of meeting of CBLA Central Committee for Research and Development in Blood Transfusion of 07.11.1983 [**SCGV0000052_086**]

> *'Since such tests are not direct measures of AIDS or of susceptibility to AIDS, a certain number of individuals not belonging to a risk group would be excluded from donating blood. This number may vary considerably in different parts of the world, depending on the characteristics of the risk groups. Thus, the specificity and sensitivity of any such test(s) for this purpose must be evaluated in the environment in which it is to be applied, taking into consideration potential effectiveness of the test as well as the impact on the blood supply and the potential alienation of donors.'* [**CBLA0001775**]

8.156 The benefits and difficulties of surrogate testing for HIV were recognised in the UK. On 7 November 1983, at the CBLA Central Committee for Research meeting, the inefficiency of anti-HBc screening and HBs/Ag screening as a surrogate marker was noted. That meeting noted anti-HBc was the only screening seriously considered, as others were '*not at present sufficiently promising*' [**SCGV0000052_086**]. Similar discussions were part of the CBLA Working Group on AIDS meeting on 27 January 1984 [**CBLA0001799**].

8.157 At that meeting it was also proposed that Dr Wallington would draw up a protocol for a prospective study [**CBLA0001799**]. The proposal was advanced at a meeting of the CBLA Central Committee for Research and Development on 28 February 1984 [**CBLA0001806**], where Dr Wallington proposed a screening study of 50,000 blood donor samples for anti-HBc at North London and Bristol RTCs. It was also proposed that other tests would be applied to those testing positive: '*TPHA, Alpha interferon, circulating immune complexes, beta-2 microglobulin, immunoglobulin and HTLV antibody.*' Dr Wallington agreed to formulate a proposal to make a grant application to the MRC. It appears likely that Dr Wallington produced a paper for this meeting which proposed the study would take two years [**CBLA0001973**][485] [**NHBT0004229**].[486]

8.158 Dr Wallington produced a formal paper for submission to the MRC to apply for funding for the surrogate testing study. That paper was dated 17 April 1984 [**CBLA0001837**]. Dr Gunson provided this paper to the DHSS on 19 April 1984 with a brief summary of its contents. Among other things he noted:

> *'I think that it is very important that this study is put into operation since I fear that we may otherwise be forced into anti-HBc screening by events taking place in the U.S.A. We have heard that some commercial operators are considering routine anti-HBc screening on their plasmapheresis donors…. There is also an article on the report of the Study Group on AIDS where there was divided opinion on the value of*

[485] Dr Wallington, The Acquired Immunodeficiency Syndrome (AIDS): Can laboratory screening tests identify blood donors at high risk of transmitting AIDS? [**CBLA0001973**]
[486] Letter from Dr Wallington to Dr Gunson [**NHBT0004229**] dated 23.02.1984

> *anti-HBc screening and there is an interesting comment that pilot studies should be instituted on β2 microglobulin screening, which will constitute part of our proposed study.'* [**DHSC0002241_017**][487]

8.159 On 23 May 1984 Dr Gunson confirmed that Dr Wallington's application had been made. However, by this point '*this had now somewhat been overtaken by events*' following the identification of a viral agent. As such, it was noted that Dr Gunson and Dr Wallington were preparing a paper modifying the proposals with regard to the application [**CBLA0001846**].[488] As Professor Tedder noted, once:

> *'…the virus was out there to be identified, it would then be strange to spend time on using surrogate markers of unknown specificity and sensitivity rather than putting effort into developing [a test for the agent].'* [**WITN3436003**][489]

8.160 Considering the issue of surrogate testing overall, such testing faced significant difficulties with specificity and sensitivity. Such an approach would be liable to threaten the blood supply (risking catastrophic shortages of blood and blood components) and not provide sufficient identification of positive donors. The period available for the introduction of such testing, being short, provided little time to arrange proper studies to resolve these issues, or to arrange the practical aspects of introducing such testing. Finally, once HIV was discovered, the possibility of introducing testing for the specific agent was brought to the forefront. Thus, in our submission it was appropriate that the blood service did not introduce surrogate HIV testing, considering the difficulties of implementation and the speed of progression of science.

F. HIV Screening

(1) The development of the first HIV test in the UK – 1984

8.161 The development of testing in the UK is set out extensively in the written statement of Professor Tedder [**WITN3436003**][490] and Professor Weiss [**WITN6868001**].[491] This maps the work to produce a research assay, relying on their earlier work in developing testing for HTLV-I and HTLV-II. Various difficulties in the progress to a scaled-up domestic test available to the blood service are identified in their evidence.

8.162 First, there was the matter of a suitable sample for the HTLV-III test. Professor Tedder notes that access to cell lines was arranged through Professor Weiss

[487] Letter from Dr Gunson to Dr Harris [**DHSC0002241_017**] dated 19.04.1984
[488] Minutes of the twelfth meeting of the Central Blood Laboratories Authority [**CBLA0001846**] dated 23.05.1984
[489] Written Statement of Professor Richard Tedder [**WITN3436003**] at [387]
[490] Written Statement of Professor Richard Tedder [**WITN3436003**]
[491] Written Statement of Professor Robert Weiss [**WITN6868001**]

and CBL.[492] A first sample came from Dr Montagnier which was either lost due to delays in transit[493] or of a type which was not suitable for propagation.[494] The first tests were instead developed from a sample provided by Dr Gallo, with use of a subsequent cell line from Dr Montagnier occurring in early 1984.

8.163 Secondly, there was the difficulty in scaling up production. Professor Tedder particularly noted the difficulty in producing enough material to properly undertake testing.[495] He explained the difficulty of production of supernatant at MHMS (including the health and safety concerns),[496] and the difficulties that Porton Down initially had in producing the same.[497] Professor Weiss noted the specific requirement for any research on HIV to be done using a HSE-approved Category III containment laboratory.[498] Some of the difficulty of scaling up production is set out in the UKHCDO Reference Centre Director meeting minutes of 3 January 1985 [**CBLA0001948**].

8.164 Thirdly, there was the difficulty in transferring to ELISA typing. Both Professor Tedder[499] and Professor Weiss[500] note the significant benefits of this type of test over RIA. Both also note the move of the industry generally to ELISA. Professor Tedder explains that the team lacked the skill to do the work required to use horseradish peroxidase conjugation and thus the requirement for the input of industry into the production.[501] In respect of Wellcome, who had previously been involved in the HBsAg assay, Professor Tedder notes that '*our concern was to get things done quickly. We knew they could do it; and they did deliver it very quickly*'.[502]

8.165 Fourthly, there were the difficulties in legal permission for the use of the Gallo cell line. Professor Weiss comments on this in his statement and the provisions of the Materials Transfer Agreement which allowed the use of the isolate only for research purposes.[503] For his part, Professor Tedder noted that this would be a matter between Dr Gallo and CBL.[504] In any event, Professor Weiss was eventually successful in developing a cell line CBL 1[505].

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[492] Written Statement of Professor Richard Tedder [**WITN3436003**] at [215]
[493] Written Statement of Professor Richard Tedder [**WITN3436003**] at [179]
[494] Written Statement of Professor Robert Weiss [**WITN6868001**] at [3.20]
[495] Written Statement of Professor Richard Tedder [**WITN3436003**] from [194]
[496] Written Statement of Professor Richard Tedder [**WITN3436003**] at [205]
[497] Written Statement of Professor Richard Tedder [**WITN3436003**] at [187]
[498] Written Statement of Professor Robert Weiss [**WITN6868001**] at [5.33]
[499] Written Statement of Professor Richard Tedder [**WITN3436003**] at [218]
[500] Written Statement of Professor Robert Weiss [**WITN6868001**] at [5.84]
[501] Written Statement of Professor Richard Tedder [**WITN3436003**] at [266]
[502] Written Statement of Professor Richard Tedder [**WITN3436003**] at [225]
[503] Written Statement of Professor Robert Weiss [**WITN6868001**] at [5.44-5.45]
[504] Written Statement of Professor Richard Tedder [**WITN3436003**] at [191] and [203]
[505] Written Statement of Professor Robert Weiss [**WITN6868001**] from [5.49] explores the history of and contamination between the cell lines at this section.

8.166 Evidence from Professor Tedder[506] was that the test was progressed as quickly as was feasible in the above circumstances. Both provide evidence that they were not involved in the commercial work around developing the test with Wellcome. Both had only a consultative role as advisers.[507]

8.167 There is little that NHSBT can in its submissions add to the evidence of Professors Tedder and Professor Weiss on the initial development of the test. Their responses to the written statements of Dr Karpas [**WITN0684001**][508] [**WITN0684019**].[509] also speak for themselves and are not explored here. Save for noting one preliminary point, these submissions pick up on the issue of the introduction of testing generally in the blood service.

8.168 The preliminary point is that, by 16 July 1984, RTDs had already come to realise that screening would soon be available, and that a government committee was required to address the issue. Dr Fraser wrote to Dr Smithies on this point and noted that the RTDs, PHLS and CDSC were:

> *'…unanimous in the view that the D.H.S.S. should set up urgently a working party on AIDS as when the screening test for this disease is generally available there will be numerous problems to sort out'* [**DHSC0000448**].[510]

8.169 EAGA first met on 29 January 1985 (see below).

(2) Progress to the introduction of the HIV test – early 1985

8.170 In mapping the testing and introduction of the HIV test in the UK, the CTI chronology [**INQY0000388**] is of assistance and should be read alongside the remainder of this section. The contents of that chronology are not generally repeated here.

8.171 Following the first meeting of the Advisory Committee on the NBTS Working Group on AIDS on 27 November 1984, Dr Abrams wrote to Dr Harris to confirm the (emphasis in original):

> *'Unanimous strong view that the antibody test for HTLV III must be used for <u>all</u> NBTS donors as soon as possible. They hoped that the Tedder/Weiss test could be scaled up very quickly – Professor Weiss pointed out some of the problems of doing this.'* [**DHSC0002251_011**]

8.172 In the early part of 1985, the RTDs were noting some of the difficulties that needed to be avoided in the introduction of the HIV screening test. This

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[506] Written Statement of Professor Richard Tedder [**WITN3436003**] at [204]
[507] See Written Statement of Professor Richard Tedder [**WITN3436003**] at [227] and Written Statement of Professor Robert Weiss [**WITN6868001**] at [5.79] onwards.
[508] First Written Statement of Dr Abraham Karpas [**WITN0684001**]
[509] Second Written Statement of Dr Abraham Karpas [**WITN0684019**]
[510] Letter from Dr Fraser to Dr Smithies [**DHSC0000448**] dated 16.07.1984

included the issue of funding and providing for tests in the community to avoid a '*magnet effect*'.[511] These matters were referenced in the RTD meeting on 23 January 1985 [**CBLA0001995**]. The first meeting of the Expert Advisory Group on AIDS ('**EAGA'**) held on 29 January 1985 noted the requirement to undertake evaluation of the screening tests. That meeting reaffirmed the view of the Advisory Committee on the NBTS that screening tests should be made available as soon as possible. A screening sub-group of EAGA was established [**PRSE0002734**].[512]

8.173 On 13 February 1985 figures from an FDA trial of HIV tests were available [**PRSE0004653**].[513] The figures contained no analysis of negatives (so did not cover propensity for false negatives), and on a voluntary donor population gave varying levels of positivity from 0.2% to 5.9%[514] with the percentage of the assays matching Western Blot on positivity ranging from 12.5% to 63.6%. The paper concluded that a comparative evaluation must be undertaken in the UK.

8.174 By 11 March 1985 five manufacturers were in place to commence the review of the HIV tests [**PRSE0002672**].[515] This followed the approval of three such kits (Abbott, Electro-Nucleonics, and Litton-Bionetics) by the FDA on 2 March 1985 [**BART0000795**].[516] The proposal for the review was that there would be a two-stage process, commencing with testing at PHLS, followed by field testing by the blood service. At this time there were significant concerns from RTDs across the UK that the commercial kits were insufficiently specific for use in the blood service, which precipitated the need for proper evaluation [**PRSE0004824**].[517] Professor Weiss notes the view that the Abbott test '*yielded some false negative results and far too many false positives*'. Professor Weiss explains that, in respect of Dr Gallo's isolate, this issue arose because of human proteins in the virus preparation [**WITN6868001**].[518]

8.175 Steps to commence review at PHLS were discussed in March 1985 (see e.g. the memo from CMO on 25 March 1985 [**USOT0000016_143**] and [**INQY0000388**][519]). Some delays at PHLS were reportedly due to a move of laboratory on 1 April 1985, although Dr Mortimer expressed a desire to undertake a comparative review of HIV tests as soon as possible

[511] It would appear at this time there was some reluctance from GUM clinicians to introduce the screening because of the social problems created. See the Minutes of the meeting of the HCDs at BPL on 10.10.1984 [**CBLA0001948**].
[512] Minutes of the First Meeting EAGA [**PRSE0002734**] dated 29.01.1985
[513] Results of FDA Evaluation of HTLV III Antibody Screening Tests [**PRSE0004653**] dated 13.02.1985
[514] The tests were not applied to the same samples so there was no comparison of effectiveness.
[515] Letter dated 11.03.1985 [**PRSE0002672**]
[516] Clinical Management Update (AIDS Centre News, 1985 Vol2, Issue2) [**BART0000795**]
[517] J Carlson et al., HTLV-III Antibody Screening of Blood Bank Donors (The Lancet) [**PRSE0004824**] dated 02.03.1985
[518] Written Statement of Professor Robert Weiss [**WITN6868001**] at [5.104-5.107]
[519] Chronology on the Introduction of HIV Screening [**INQY0000388**] from [pg41]

[**HCDO0000273_020**].[520] On 22 April 1985, EAGA was of the view that the tests must have a sufficient degree of specificity, and that there must be proper validation and arrangements for introduction made [**PRSE0001239**][521].

8.176 By 28 May 1985, the meeting of EAGA noted that PHLS had been asked to review the tests [**PRSE0002837**]. Dr Mortimer noted that evaluation would be undertaken on 350 sera, half of which were blood donors. The first two tests would be covered in the next two weeks, with the third in the next four to six weeks. It was suggested the data would be available in mid-July, although EAGA agreed PHLS should obtain further types of sera for testing. The results of PHLS testing became available on or around 15 July 1985 and were submitted to EAGA (see below) [**NHBT0015169**].[522]

8.177 For the reasons already noted above in respect of the FDA testing and expanded upon below in respect of the PHLS results, we submit that it was necessary to undertake testing of the available assays before their introduction. However, it is unclear why it took around 4 months for the work of PHLS reviewing the tests to be completed. Considering PHLS were using a panel of plasma which aimed to capture various cases against which the assays would be tested, the difficulty of obtaining that plasma may have delayed matters.[523] Considering the general agreement that testing be introduced as soon as possible, it is unfortunate that the first stage of the review was not completed at an earlier stage. Indeed, among other people, Professor Bloom did express his concerns about the time that the test was taking to evaluate.[524] Thus, on the evidence currently available there is a case for saying that the first stage of the review of the tests was slower than was necessary.

8.178 Whether this delayed the introduction of the tests overall is a separate question, considering those factors identified below (particularly testing in STD clinics and practical difficulties for introduction in RTCs).

(3) The need to evaluate tests – stage 1 and PHLS

8.179 On 11 July 1985, prior to a meeting of EAGA on 30 July 1985, a committee of the RTDs produced a testing protocol to use for the actual implementation of

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[520] Minutes of the third meeting of the AIDS group of Haemophilia Centre Directors [**HCDO0000273_020**] dated 01.04.1985
[521] Minutes of the third Meeting of the EAGA [**PRSE0001239**] dated 22.04.1985
[522] J R Pattison et al., Draft Preliminary Report to a DHSS Ad Hoc Group On The Evaluation Of Commercial Anti-HTLV 3/LAV Assays [**NHBT0015169**] dated 15.07.1985
[523] Professor Tedder gave this as a possible reason for the time that testing took. Oral Evidence of Professor Richard Tedder [**INQY1000256**] dated 14.10.2022 at [42/14]
[524] He is recorded as flagging his concern at delay and asking for the introduction as soon as possible at the EAGA meeting on 29 May 1985 [**PRSE0002837**]. He repeated this as a representative of the '*users*' at a meeting of the CBLA Central Committee for Research and Development in Blood Transfusion on 9 July 1985 [**BPLL0004117**].

screening and confirmatory testing in NBTS [**PRSE0000832**][525] (and corrigendum dated 30 July 1985 [**PRSE0002402**]:

> *'It was agreed that routine screening tests for anti-HTLV III should not be introduced until the following had taken place:*
>
> *3.1. The proposed evaluation in the N.B.T.S. of different test kits has enabled satisfactory system(s) to be selected.*
>
> *3.2. The establishment of Reference Centres for the purpose of carrying out nationally agreed confirmatory tests on sera giving positive results upon screening.*
>
> *3.3. The establishment of alternative venues for anti-HTLV III tests on members of the General Public who are not blood donors.'*

8.180 At its core there was a requirement to evaluate the screening tests proposed for introduction to the service. For the reasons set out in section 4 of these submissions, it is necessary to do so to ensure the sensitivity *and* specificity of any such test that is introduced. Put another way: the test must be reliable. It was noted, for example, at the EAGA Screening Test Subgroup on 1 March 1985 that there was some concern that the commercial tests were unreliable [**DHSC0000421**]. This concern for reliability was one expressed by a number of RTDs in their letter to *The Lancet* dated 2 March 1985 [**PRSE0004824**]. The requirement to validate was also maintained by EAGA on 22 April 1985 [**PRSE0001239**][526] and Dr Mortimer of the PHLS [**NHBT0000186_032**].[527] The need to assess the false positive rate when the prevalence of antibodies in the donor pool was not known was also flagged by Dr Gunson at a meeting of the Central Committee for Research and Development on 16 July 1985 [**BPLL0004117**].

8.181 In a ministerial statement dated 27 June 1985, Mr Kenneth Clarke similarly made clear that tests should not be introduced until reliability is established, as there is '*no point in introducing a test which often fails to detect antibodies in the blood or detects antibodies where there are none*'.[528] A background note to this statement was provided by the CMO where it was noted that more than two million blood donations were collected each year, and thus on this scale the test introduced must be consistent with good sensitivity and specificity [**DHSC0001501**]. In respect of introducing the tests without such evaluation, the CMO noted:

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[525] Report of the Working Party of the Regional Transfusion Directors' Committee, Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres [**PRSE0000832**] dated 11.07.1985
[526] Minutes of the third Meeting of the EAGA [**PRSE0001239**] dated 22.04.1985
[527] Letter from Dr Mortimer and Dr Harris to Dr Whitehead dated 31.01.1985
[528] Written Answers dated 27.06.1985. Features comments from Kenneth Clarke on the screening of blood donors for Aids [**HSOC0018679_003**]

> *'It has been suggested that testing should be introduced immediately, before the reliability of the tests available has been evaluated. Early experience of other countries and the considerations outlined in this note have led Ministers to decide that it would be wrong to introduce a screening test until the further evaluations mentioned above have been carried out.'*

8.182 The requirement for the first stage of the assessment resulted in two of the five tests being excluded for an unacceptably high number of false positives and as being unreliable [**BART0000778**].[529] This is consistent with the position that approval specifically in the context of the UK required consideration of the different position in respect of positivity in the donor pool. A draft of the report was circulated on 15 July 1985 [**NHBT0015169**].[530] It is not possible to go through the report here, but to take two examples:

a) the high false positive rate of the Abbott test is apparent at internal page 21;[531] and

b) the ease of use of the Abbott, Wellcome and Organon tests is set out on internal page 31.[532]

8.183 In a letter from Dr Barbara and Dr Hewitt in the *New Scientist* dated 29 August 1985, it was again noted that it was not sufficient to simply treat American evaluation of the tests as determinative because of the significant difference in donor demography and parameters for transmission [**NHBT0000030_012**]. As was noted in section 4 of these submissions, the base rate of infection in a population is crucial in determining what the false positive rate of a test is. With the AIDS epidemic at different stages in the US and UK, this was an important factor in understanding the applicability of the screening tests in the UK. This is something that Dr Gunson recognised [**BPLL0004117**][533] and indeed the DHSS recognised [**DHSC0002311_017**].[534]

8.184 The trialling of screening tests is necessary for a few reasons. First, it is necessary that the test be reliable in detecting true positives (that is, sensitive). Trialling is required to ensure that appropriate cut-offs are determined to identify what a true positive is. Without this step, the test would be introduced with the serious risk of giving false negatives which fail to exclude positive

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[529] Letter from Dr Harris, Department of Health and Social Security [BART0000778] dated 01.08.1985
[530] The final version is dated September 1985 and is far easier to read as the tables are converted from freehand to typed [**DHSC0000486**].
[531] On 57 samples labelled '*potentially false positive*' Abbott produced 15 positives compared to Organon producing 1 and Wellcome producing nil. Also its sensitivity was doubtful; repeat testing of positives under the assay saw (among other things) three positives become negative and four more become equivocal.
[532] Respectively they scored 41, 42, and 48 out of 60. ENI scored 32 and Ortho 29.
[533] Minutes of the sixth meeting of the Central Committee for Research and Development in Blood Transfusion [**BPLL0004117**] dated 9.01.1985
[534] Memorandum from Dr Harris to Dr Smithies [**DHSC0002311_017**] dated 05.06.1985

donors (and, indeed, may actively encourage them to continue to donate in the future).

8.185 This is particularly important in relation to the introduction of the HIV test. Even with the introduction of the test at other centres, the risk remained that the test at RTCs would encourage higher risk donors to donate (including those in or close to the window period). An insufficiently sensitive test would risk increasing the number of at-risk donors donating without sufficient detection and exclusion of positive donors. This would have been a considerable safety risk to blood and blood products; indeed, in theory the outcome could have been worse than the continued use of exclusion alone.

8.186 Secondly, it is necessary to ensure that the test is sufficiently specific. As with sensitivity, the specificity of a test is in part determined by the cut-offs chosen for the working of the test. Importantly (and as has already been discussed) specificity is a function of the number of people being tested rather than the number of those infected. The Expert Report on Statistics indicates that, in 1985, the blood service in England and Wales would have taken 1,999,464 donations [**EXPG0000049**].[535]

8.187 If that is correct, a sensitivity of even 95% would still mean 99,973 false positives. A drop of donations in the tens of thousands would have posed a risk to the blood supply such that a catastrophic shortage of blood (and the safety risk to patients that entailed) could have occurred. Further, the risk of a false positive, particularly a false positive for AIDS, would have had a significant deterrent effect to donors and may have made the risk to the supply considerably worse. As to confirmatory testing, such testing of tens (or even hundreds) of thousands of donors would not have been feasible in an acceptable time frame. It would also put intolerable strain on testing laboratories and made the likelihood of a critical safety error more likely. Indeed, under such pressure a critical safety error could have arisen in an entirely unrelated area (e.g. a failure in HBV testing). All these factors underline the significant importance of ensuring that the test was sufficiently specific.

8.188 Thirdly, the value of the test was also dependent on the underlying prevalence of the disease in the local community. As explained above, where the false positive rate is a function of the number of persons tested, the value of a test where only 1 in every 500 is truly positive, compared to 1 in every 5 truly positive, is significantly different. It is necessary to undertake field testing to identify whether the test is reliable, and also fit for the purpose it is intended. From the perspective of managing the blood supply, the ethics of asking donors to undertake reliable testing, and the practicality of managing confirmatory

[535] Expert Report to the Infected Blood Inquiry: Statistics by the Statistics Expert Group [**EXPG0000049**]

testing and counselling, it is necessary to understand the value of a test. Importantly, that value will differ between countries.

8.189 Based on the information in the PHLS review, it is understandable why the conclusion was reached to advance the Organon and Wellcome tests, considering their comparative sensitivity, specificity, and ease of use. The importance of review before introduction is apparent in light of (for example) the sensitivity and specificity of the Abbott test. However, this does not necessarily explain the delay that was experienced waiting for the PHLS study to be completed.

8.190 It is only with the benefit of hindsight that it can be known that the tests used were sufficiently sensitive and specific when introduced in October 1985. Further, this was only the case once sufficient trialling and testing had been undertaken (and, as is noted below, the second stage of the trial was cut short). Looking at the matter prospectively when little was known about the entirely new test, the prevalence in the UK of HIV, or the practicalities of its safe introduction, in our submission the approach adopted on the introduction of HIV testing by the blood service was appropriate and in line with international norms.

(4) The introduction of tests – stage 2 and NBTS

8.191 Shortly after the PHLS draft became available, the RTDs considered the second stage of the testing process (which was to be in blood service hands). In a corrigendum tabled on or around 30 July 1985[536] to the RTD paper of 11 July 1985 (already discussed above) [**PRSE0002402**] the RTDs recognised:

> *'…there was a degree of urgency for the introduction of routine anti-HTLV III screening of blood donations which precluded the completion of N.B.T.S. evaluation of different test kits prior to arrangements being undertaken for the introduction of routine screening. Regional Transfusion Directors are being advised, therefore, to make arrangements with their respective R.H.A.'s for the introduction of routine screening whist the N.B.T.S. evaluation is proceeding, the selection of kits for use being made on the recommendations from the P.H.L.S. study. Long-term contracts with a particular manufacturer should be avoided until the results of the N.B.T.S. evaluation are available.*
>
> *By this means it may be possible to commence screening of blood donations by October, 1985, and it was agreed that the introduction of*

[536] It is unclear whether this is the date that it was tabled for the EAGA meeting. The letter [**PRSE0003215**] notes that EAGA approved the decision on a Tuesday, and 30 July 1985 was a Tuesday.

the tests should take place throughout the U.K. over the shortest period practicable'.

8.192 This decision was approved by EAGA. The DHSS wrote to all RTDs to notify them of the decision to truncate any delay awaiting review by the blood service on 1 August 1985 [**PRSE0003215**]. RTDs were asked to raise if they would be unable to meet the mid-October introduction date. That letter also noted that a formal report would take 2-3 months, and that instead RTDS had decided that over that period steps would be taken to introduce screening on an interim basis by the October date.

8.193 By 7 August 1985[537] NBTS had produced a first draft of its evaluation of the Organon and Wellcome tests [**DHSC0001607**]. The report details that the introduction of these tests was not a simple process, with various possible difficulties arising. The contents of the report are not repeated here. On 1 October 1985 a '*Dear Doctor*' letter was issued by the CMO to prepare clinicians for the introduction of testing [**DHSC0000177**].

8.194 Testing of donations, and availability of testing in the community, commenced from 14 October 1985 [**NHBT0004299**].[538]

8.195 In our submission, the decision to truncate any formal review and introduce the test quickly following the finish of the PHLS review was appropriate. There is nothing to suggest that the introduction over that period could have been done more quickly (considering those factors discussed below). The RTDs balanced the risks and benefits of introducing the test without completing the formal review and decided to introduce it by October 1985. In our submission that was appropriate.

(5) Alternative testing locations and the magnet effect

8.196 Aside from the requirement to evaluate the tests, it was also necessary to have alternative locations for testing outside of the blood service. This was necessary to avoid the *'magnet effect'* of high-risk individuals coming to the blood service for testing. Of particular concern here was the danger that those in the HIV window period would attend and risk donations which would not be captured by the screening test. For the first generation immunoassays we now know that the window period was around 50 days[539]. The danger of this magnet effect was another concern expressed by the RTDs in their letter to *The Lancet* on 2 March 1985 [**PRSE0004824**]. Similar views were expressed by the RTDs at their meeting of 10 July 1985, where Dr Smithies confirmed that this concern

[537] Date of this report taken from the CTI timeline as it is not apparent on the face of the document.
[538] Press release from DHSS : All blood donations now being screened for antibodies to the AIDS virus [**NHBT0004299**] dated 14.10.1985
[539] Expert Report to the Infected Blood Inquiry: HIV with addendum [**EXPG0000004**] at [16]

was also present centrally [**CBLA0002212**], and in the *New Scientist* article already referenced above on 29 August 1985 [**NHBT0000030_012**].

8.197 This concern is also consistently seen in the discussions of EAGA (see for example the minutes of the screening subgroup on 28 March 1985 **DHSC0001571** and the main committee on 30 July 1985 [**NHBT0000186_035**][540]) and CBLA discussions (see for example minutes of the meeting of 2 April 1985 [**CBLA0002113**]). In a paper prepared for a Consultant Advisor meeting dated 14 June 1985, Dr Gunson similarly stressed the need to offer alternative testing sites so as to ensure that the blood supply was not made less safe through the introduction of testing [**NHBT0039762_105**]). In that paper Dr Gunson specifically identified the concern that persons may donate having been infected but without having developed the antibody. On 1 August 1985, Mr Williams of the DHSS wrote to RTDs to confirm that RHAs had been asked to provide alternative site testing [**PRSE0003215**].

8.198 On 1 October 1985, Dr Acheson sent a letter to all doctors in England enclosing information about the HIV test. In that he noted that all blood would be screened at RTCs, and at the same time testing would become available at GUM clinics and with arrangements through GPs. He noted that the synchronous implementation of this testing was to avoid high-risk individuals seeking to be tested through the blood service [**DHSC0000177**].

8.199 In our submission, the magnet effect is an important risk that had to be taken into account in the introduction of the test. The risk was a clear one: with testing not otherwise available and significant national concern about AIDS, it is likely that some individuals would choose to ignore exclusion criteria and get tested. Particularly difficult would be the understanding of some people that, because there was a test, they would be identified if they were positive and thus would pose no threat to the blood supply in any event. This is incorrect for two reasons:

a) it assumes the perfect sensitivity of the test for people with developed AIDS; and

b) it ignores the window period

8.200 Thus, the introduction of testing, without management of the magnet effect, posed a significant risk of increasing the overall risk of HIV to the blood supply. Indeed, as a pressure moving directly contrary to the donor exclusion scheme, such a risk could have outstripped the benefit of the introduction of testing.

(6) Counselling of donors

[540] It was said that it would be *'tragic to expose the BTS to the risk of being the only free access testing point'*.

8.201 A further feature of the introduction of testing was the requirement to offer counselling to those testing positive for AIDS. Mr Clarke's ministerial statement of 27 June 1985 noted the arrangements ongoing for such counselling [**DHSC0001184**]. This issue is discussed further below.

(7) Practical matters

8.202 Once it was known what test would be used, there was also a need to achieve sufficient accommodation, equipment and staff recruitment to introduce testing: this was raised at the RTD meeting on 10 July 1985 [**CBLA0002212**]. There was a parallel requirement for funding: some such funding for assessment appearing to have been confirmed at an EAGA meeting on 30 July 1985 [**NHBT0000186_035**]. Requests for funding from RHAs for testing in NBTS and at STD clinics were also made (see the DHSS letter of Mr Hart to regional general managers on 30 July 1985 [**DHSC0000593**]). Funding to PHLS for a laboratory for confirmation was also confirmed in Dr Harris's letter of 1 August 1985 [**BART0000778**].

8.203 Such practical matters were pressing. As Professor Tedder recognised, if '*you stress the testing laboratories, you make them more likely to make mistakes'.*[541] It would have been a considerable risk to introduce such testing before the practical position was sufficiently managed (even if not completely resolved).

G. Counselling

(1) The general role of the blood service

8.204 In general, the blood service had little role in counselling the recipients of blood and blood products (whether in respect of receipt of the blood or blood product itself, or testing) as blood service clinicians had limited contact with recipients. Going further, the blood service did not have the mandate to undertake such counselling (from treating clinicians, or from DH), nor did it generally have the resources to do so. There were some limited instances in which counselling was given to recipients, albeit not in the context of HIV.

8.205 As a preliminary point, various blood service witnesses have emphasised that the blood service was not trained or set up to offer 'counselling' as such. As Dr Hewitt[542] and Dr Williamson[543] explained, the matter was one of *'post-test discussions'.* This more accurately reflected the role of the blood service; to communicate a test result to the person and the implications of that test. It did not extend to providing psychological support. This point was also noted by Dr Wagstaff

[541] Written Statement of Professor Richard Tedder [**WITN3436003**] at [343]
[542] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 09.12.2021 at [103/3]
[543] Oral Evidence of Dr Loran Williamson [**INQY1000169**] dated 08.12.2021 [60/24]

> *'250. The counselling at the RTC would have been at the level of explaining what the results were, what they meant and arranging for repeat testing to be done. Further follow-up would be done by referral to the donor's General Practitioner, and we would suggest a referral to an interested physician, usually a liver physician for those with hepatitis and a sexually- transmitted disease clinician for those with HIV.*
>
> *251. Once they are referred clinically, it would then be up to their treating clinicians to refer on as appropriate in the circumstances and sometimes this would include psychological treatment.'* [**WITN6988001**][544]

(2) Post-test discussions

8.206 Provision for post-test discussions was an important part of the introduction of screening tests. In respect of HIV, the requirement for counselling on the introduction of screening tests was considered by EAGA at its first meeting on 29 January 1985.[545] At that meeting the requirement for such counselling was generally agreed, and a small working group assessing the issue was established. The minutes record:

> *'Following discussion, the Group concluded that counselling must be available at the point when an individual is first told that he has AIDS, and/or a positive test for HTLV III antibody, and should preferably be provided by the person who imparts this information. The person (or service) which instigates the screening test, and gives out the result – whether this be the NBTS, or STD Clinic, or hospital – must take responsibility for the consequences, including counselling. The provision of effective counselling could, however have significant resource implications.'*

8.207 Shortly following that meeting, a paper dated February 1985 was produced by the DHSS posing questions to the working group on counselling. In that paper itIt was noted that (emphasis in original):

> *'The Blood Transfusion Service deals with volunteers (not patients) and is not usually expected to counsel patients who are found to have a positive blood test (whether hepatitis B or VDRL). Patients who agree are referred to their own general practitioners.'* [**NHBT0015453_001**]

8.208 The approach to donor counselling developed alongside the advancement of HIV testing. Initially it was thought that the blood service was '*working under intense pressure and was not in a position to counsel every individual found to have a positive blood test*' (see minutes of the EAGA sub-group on AIDS

[544] Written Statement of Dr William Wagstaff [**WITN6988001**]
[545] Minutes of the First Meeting EAGA [**PRSE0002734**] dated 29.01.1985

counselling on 13 February 1985 [**DHSC0003711_031**]). However, at subsequent meetings of the EAGA sub-group on AIDS counselling the position changed [**DHSC0003711_027**][546] [**DHSC0002263_051**].[547] Of particular difficulty at these meetings was the question of whether the blood service could collect the GP information from all donors.

8.209 At a meeting of the screening test sub-group of EAGA on 10 June 1985, a procedure for informing donors of testing was discussed [**DHSC0000551**]. It was part of that procedure that, on recall to give a further sample, NBTS staff would give a '*preliminary explanation and advice to donors*'. At that meeting, it was regarded as necessary that a medical practitioner would need to be told of the positive test, and that donors who would not agree to this would be asked not to donate. Also at that meeting, '*…members agreed it was crucial that NBTS staff were suitably trained for this "counselling'' role.*'

8.210 On 10 July 1985, there was a meeting of the RTDs. At that meeting counselling was discussed, and it was said that:

> *'Obviously HTLVIII positive donations would be destroyed. The initial approach to such a donor would be from the NBTS and afterwards counselling would be essential. We look to the Expert Advisory Group for guidelines but GPs should be involved, with the donor's consent.'* [**CBLA0002212**]

8.211 As has already been discussed above, a committee of the RTDs formulated a protocol for the screening of blood in RTCs [**PRSE0000832**][548] and corrigendum [**PRSE0002402**][549]. Section 5 of that paper provides the relevant protocol for informing donors. At the meeting of EAGA on 30 July 1985 the protocol developed by the RTCs was discussed [**PRSE0002628**]. In respect of the protocol, Dr Gunson summarised the counselling provisions:

> *'On receipt of a confirmed positive result for HTLVIII antibody, the donor would be sent a letter by the Centre and an appointment arranged for the donor to be interviewed by a doctor trained in counselling. The donor would be asked for the name and address of his family doctor and efforts made to ensure that the donor received further medical advice and obtaining his consent for the results of the test to be reported to his family doctor.'*

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[546] Minutes of the meeting of the EAGA, sub-group on AIDS Counselling [**DHSC0003711_027**] dated 4.03.1985
[547] Minutes of the meeting of the EAGA sub-group on AIDS Counselling [DHSC0002263_051] dated 25.03.1985
[548] Report of the Working Party of the Regional Transfusion Directors' Committee, Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres [**PRSE0000832**] dated 11.07.1985
[549] Corrigendum tabled on or around 30 July 1985 to the RTD paper of 11 July 1985 [**PRSE0002402**]

8.212 On 9 October 1985, at a further meeting of the RTDs counselling was discussed. It was said that:

> *'Problems were foreseen over counselling of donors found to be HTLV-III antibody positive, and Dr Smithies assured the meeting that the DHSS is interested in hearing these experiences. The initial approach is to be by the Regional Transfusion Service but there must be adequate follow-on support within the community.'* [**CBLA0002266**]

8.213 It should be noted that some RTCs had the resources for counselling broadly available. This appears to have been the case at NLBTC, where a group of clinicians from the blood centre attended the training available at St Mary's Hospital.[550] Others, however, had to seek such resources to employ another consultant. Broadly, the evidence supports the conclusion that many of the RTDs used, either directly or indirectly, the training available at St Mary's Hospital.

8.214 NHSBT submits that, in the circumstances and the contemporary position on pre-test counselling, the approach adopted was a necessary one for the introduction of HIV screening to ensure proper management of the blood supply and ethical management of donors. However, considering the time frames involved, by the introduction of testing in October 1985, counselling does not appear to have been a critical factor in respect of timing.

H. HIV-2

8.215 Details of the introduction of HIV-2 testing are addressed in Dr Miflin's written statement [**WITN0672006**].[551] The content of that written statement is not repeated here.

8.216 The blood service, through Dr Gunson, appears to have first became aware of two English men suffering from HIV-2 following a trip to Africa on 27 November 1986 [**CBLA0002351_002**][552]. It was noted that HIV-2 positivity was unreactive to the current Wellcome test for HIV. Dr Gunson was of the view that this reinforced the need to maintain close questioning and permanent exclusion of donors who had visited or lived in Africa south of the Sahara since 1978 and had sex with men and women living there. That requirement was in the AIDS leaflet for September 1986. This requirement was emphasised by Dr Martlew who sent a letter to all medical officers on this topic on 28 November 1986 [**NHBT0004481**]. Dr Gunson contacted Luc Montagnier to seek samples of HIV-2 [**NHBT0004484**][553] [**NHBT0006731**].[554]

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[550] Oral evidence of Professor Marcela Contreras [**INQY1000166**] dated 03.12.2021 [32/16]
[551] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1339-1365]
[552] Letter from Dr Gunson to Dr Lane [**CBLA0002351_002**] dated 27.11.1986
[553] Letter from Dr Gunson to Dr Montagnier [**NHBT0004484**] dated 28.11.1986
[554] Letter from Dr Montagnier to Dr Gunson [**NHBT0006731**] dated 26.12.1986

8.217 Following research at PHLS, it was agreed at a meeting of the RTD UK AIDS Working Group on 5 May 1987 that the introduction of routine HIV-2 testing would not be recommended as it was not necessary [**CBLA0002373**]. However, a proposal was suggested for testing the blood of donors who had visited Africa (with a particular focus on West Africa). The process would be reviewed after six months and a decision to be made about future action. On 11 June 1987, Dr Gunson wrote to all medical officers and clerks at RTCs with proposals for this procedure [**NHBT0004131**]. A review of the scheme was undertaken at a meeting of Dr Gunson, Dr Smithies, Dr Mortimer, Professor Tedder and Mr Lister on 26 February 1988 [**NHBT0004212**], following which Dr Gunson again wrote to all RTDs asking for them to submit samples (not least as the earlier letter had prompted no such samples) [**NHBT0003698**].

8.218 On 25 March 1988 Dr Gunson wrote to Dr Smithies concerning the news report of a HIV-2 positive donor [**NHBT0003695**]. He noted that the procedure currently adopted meant that cellular products were not being quarantined awaiting the outcome of Dr Mortimer completing the test (he did think plasma could be withdrawn sufficiently). He suggested that Dr Mortimer provide kits to RTCs so they could undertake testing alongside HIV-1 testing. On 12 April 1988 the matter went before EAGA, which concluded that routine testing for HIV-2 was not presently justified and remained of the view that testing at central laboratories remained appropriate [**MRCO0000003_137**].[555] Following this, Dr Gunson wrote again to all RTDs with the procedure for achieving such testing, and included in the protocol provision for the isolation of the blood components while awaiting the results of the test [**NHBT0003691**].

8.219 At the 11th meeting of the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology on 3-6 May 1988, it was noted that no country was conducting routine HIV-2 testing. Five countries (including the UK) had carried out limited testing to the end of December 1987 [**NHBT0000018_019**][556] [**NHBT0004514_001**].[557] At the 12th meeting of the Committee the following year (23-26 May 1989), the situation remained that no routine testing for HIV-2 was being undertaken, but selective screening of donors remained recommended [**NHBT0004027**].

8.220 The matter of HIV-2 testing was raised at various meetings of the ACVSB. At the first meeting on 4 April 1989, Dr Mortimer noted that combined tests from Wellcome and Abbot were due, and that an evaluation was required. The Chairman said they would await the outcome of the evaluation [**PRSE0000416**]. At the fourth meeting of the Committee on 6 November 1989,

[555] Minutes of the twenty-first meeting of the EAGA [**MRCO0000003_137**] dated 12.04.1988
[556] Minutes of the meeting of the Council of Europe's European Health Committee [**NHBT0000018_019**] dated 3-6.05.1988
[557] Dr Gunson, Survey of Anti-HIV Tests on Blood Donations and Related Matters [**NHBT0004514_001**] dated 3-6.05.1988

it was noted three centres were looking at the test with five companies in competition [**NHBT0000072_050**]. At the fifth meeting on 17 January 1990, the outcome of the evaluation was reported. At that meeting Dr Gunson concluded that *'the combined test must be introduced as soon as possible'* and the committee unanimously agreed with a common date to be agreed with the UK blood services [**PRSE0001414**].

8.221 On 23 March 1990, ministerial approval was confirmed to have been given for the introduction of combined HIV testing [**NHBT0004168**]. Shortly following this, on 30 April 1990 the American Association of Blood Banks issued a technical bulletin confirming that a HIV-2 test had been licensed on 25 April 1990. However, the FDA had maintained its view that there was no public health need for routine screening of donors of whole blood or source plasma for antibodies for HIV-2 (although other procedures were in place for deferral of donors) [**NHBT0004153**][558]. Combined HIV testing began in the UK at most RTCs on 1 June 1990, with a small number following in late June and early July [**NHBT0001674**][559].

8.222 In NHSBT's submission, the decision on HIV-2 testing was one guided by the expert bodies advising the government and the blood service (EAGA and then ACVSB). In the context of the worldwide response to HIV-2, and the expert advice that was available at the time, it is submitted that this was the appropriate response in the circumstances. The approach to the introduction of HIV-2 testing is indicative of the different approaches to screening that can be mandated by circumstances over time and is important context (by way of contrast) to the introduction of HIV-1.

[558] Bulletin from the American Association of Blood Banks on Screening for HIV-2 Infection [**NHBT0004153**] dated 30.04.90
[559] Letter from Dr Gunson to Dr Lane [**NHBT0001674**] dated 16.07.1990

9. SECTION 9: NON-A NON-B HEPATITIS / HEPATITIS C

A. Emergence and knowledge

9.1 The following section traces developments in the understanding of viral hepatitis from the mid-1970s. For further details of the early understanding of hepatitis, please see Section 7 of these submissions (*'Hepatitis Generally'*).

9.2 After testing for HBV was introduced in the early 1970s, it became possible to identify that there was hepatitis which could not be explained by HAV or HBV. In 1974, a US study reported that an agent which was neither HAV nor HBV seemed to be responsible for a substantial proportion of cases of post-transfusion hepatitis (**PTH**) [**PRSE0001431**][560]. By 1975, further academic papers confirmed the existence of transfusion-associated hepatitis not due to viral Hepatitis type A or B [**INQY0000006**][561]. This resulted in introduction of the term NANBH [**INQY0000006**][562].

9.3 As a result of these developments, from the mid-1970s, and certainly following the communications between US researchers and Dr Maycock about the transfusion risk associated with NANBH ([**WITN0343003**][563] to [**WITN0343007**][564]), there was an awareness in the blood services that a hepatitis was occurring post-transfusion which could not be explained by HAV or HBV.

B. Getting accurate information on NANBH

9.4 Obtaining accurate information on the prevalence of PTH, from which information on the incidence of NANBH could be derived, was difficult and complex work during this period, primarily because there were no laboratory tests available to identify and confirm the presence of a NANBH agent [**WITN6989011**][565]. In addition, there were reporting issues with PTH, as not all incidents were reported [**INQY1000176**][566]. Clinicians would only report if there was reason to suspect that there was an issue: where the NANBH was

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[560] Prince et al, *'Long-incubation post-transfusion hepatitis without serological evidence of exposure to hepatitis B virus'* (The Lancet) [**PRSE0001431**] dated 03.08.1974

[561] The early history of the identification of NANBH is set out in the Inquiry's Chronology at [**INQY0000006**] and is not repeated in detail here

[562] Expert Report to the Infected Blood Inquiry: Hepatitis with Addendum [**INQY0000006**] at [pg17]

[563] Letter from Dr J Allen of the Stanford University Medical Centre to Dr W Maycock of the Blood Products Laboratory in Elstree Herts [**WITN0343003**] dated 06.01.1975

[564] Haemophilia Society publication including a letter from the minister of the Department of Health and Social Security discussing Factor VIII, commercial blood products, BPL, and self-sufficiency. A second column references an unexplained increase in jaundice cases and mentions NANBH [**WITN0343007**]

[565] J Barbara and M Briggs, Post-transfusion hepatitis in North London in 1981: a review (September 1982) [**WITN6989011**] cited in Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [15/16]

[566] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [19/14]

asymptomatic, or the infection not particularly severe, information simply was not shared with the blood services.

9.5 The lack of laboratory tests for NANBH, and the difficulty of obtaining data on the prevalence of post-transfusion hepatitis from hospitals, meant that identifying donors with suspected NANBH during the 1970s was extremely difficult.

C. Seriousness of NANBH

9.6 NANBH as a distinct disease was '*universally recognise[d] in the 1970s'* [**INQY1000195**][567]. However, the consensus view in the 1970s was that (a) the condition was rarely transmitted by blood and blood products, and (b) the infection was usually not particularly serious.

9.7 In Dr Boulton's evidence, the consensus view in the late 1970s was that:

> '*…the non-A, non-B form hepatitis was often mild, even asymptomatic, and people might get an infection from it, but only be slightly ill, if ill at all, and in time would completely recover'* [**INQY1000181**][568].

9.8 In 1976, there were some early warnings that the long-term effects of NANBH may be more severe than initially realised. A journal article stated that the long-term prognoses for NANBH and the HBV '*may be similar'* [**PRSE0000381**][569]. However, this was just one of many different schools of thought at this time, as knowledge and understanding of NANBH was in a state of development[570].

9.9 Clinicians gave evidence that they were aware of the work of Dr Preston and Dr Triger, a team in Sheffield who undertook liver biopsies of patients, whose results were published in *The Lancet* in 1978 [**WITN6988001**][571]. However, although these studies demonstrated the risks of NANBH[572], they did not overturn the international scientific consensus, at least among haematologists, that NANBH was '*generally benign and non-progressive'*[573]. Professor Hay

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[567] Oral Evidence of Dr Richard Lane [**INQY1000195**] dated 27.03.2022 at [9/24]
[568] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [49/9]
[569] R Purcell, H Alter and J Dienstag, Non-A, Non-B Hepatitis (The Yale Journal of Biology and Medicine, 1976, Vol. 49) [**PRSE0000381**] at [pg4] which states: '*Although type non-A, non-B hepatitis is associated with less severe acute illness than type B disease, as judged by frequency of jaundice and magnitude of SGPT elevations, the long-term prognosis for the two diseases may be similar.'*
[570] In Professor Marcela Contreras' witness statement [**WITN5711001**] at [327] she points to the '*state of developing knowledge at the time',* with reference to a study in 1992 of blood transfusion recipients **[PRSE0003622]** in which '*Seeff at al 1992, in the USA followed up, for 25 years blood transfusion recipients with NANBH who had been identified in the early 1970's and compared their mortality with a control group of matched transfused patients; all case mortality was not significantly higher in test than control groups.'*
[571] The Written Statement of Dr William Wagstaff [**WITN6988001**] confirms that this work '*helped in the appreciation of the possible clinical outcomes of NANB'*
[572] Written Statement of Professor Charles Hay [**WITN3289039**] at [25.1]
[573] Oral Evidence Professor Marcela Contreras [**INQY1000166**] dated 03.12.2021 at [61/16]. Written Statement of Professor Charles Hay [**WITN3289039**]

observed that although papers existed which demonstrated risk, up to and including these studies they tended to show mild disease:

> *'there were papers in the literature that showed very high incidence of abnormal liver function tests in patients with haemophilia, all the liver biopsy studies up to that point, including Professor Preston's study of 1978, tended to show very mild liver disease'* [**INQY1000072**][574].

9.10 Direct evidence that NANBH could be transmitted by blood products was not demonstrated until a paper by Wyke et al in 1979 [**BPLL0016050_003**][575]. Shortly afterwards, in 1980, a paper by Koretz et al involving a two- to five-year follow up of patients demonstrated that NANBH often resulted in chronic biochemical liver disease[576].

9.11 Notwithstanding the growing understanding among academics and clinicians of the risk of transmission via blood and blood products, the widely held view in the early 1980s remained that NANBH was generally not serious [**WITN5711001**][577]. Thus, despite the mounting body of evidence to the contrary during this period, many of the decisions taken can only be understood against the backdrop that '*the concept had been for many years that hepatitis was, in the main, a disease from which people recover.'* That view persisted: the belief that NANBH was not particularly serious *'stayed in most people's thoughts for quite a long time'* [**INQY1000175**][578].

9.12 Even though the severity of NANBH was not fully recognised, the blood services still took measures to minimise risk. On 15 December 1982, a meeting took place at BPL to '*discuss the implications for Haemophilia and Blood Transfusion Services of Commercial Introduction of 'Hepatitis-Safe' Factor VIII and IX*' [**CBLA0001649**].[579] It was agreed, in anticipation of the entry of commercial heat-treated products to the market, that there should be a properly executed national clinical trial lodged with the regulatory authority.

9.13 A letter from Dr Gunson to the MRC dated February 1983 stated that the risk of chronic hepatitis associated with NANBH was not known; therefore, the long-term follow-up of participants in the MRC trial was particularly important, as it

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[574] Oral evidence of Professor Charles Hay [**INQY1000072**] dated 04.11.2020 at [25/15]
[575] R Wyke et al., *Transmission of Non-A Non-B Hepatitis to Chimpanzees by Factor-IX Concentrates after Fatal Complications in Patients with Chronic Liver Disease* (The Lancet) dated 10.03.1979
[576] R Koretz et al, The Long-Term Course Of Non-A, Non-B Post-Transfusion Hepatitis (American Gastroenterological Association, 1980, Vol.79 Issue 5) [**PRSE0002036**]
[577] In the Written Statement of Professor Marcela Contreras [**WITN5711001**] at [327]
[578] Oral Evidence of Dr William Wagstaff [**INQY1000175**] dated 25.1.2022 at [86/6]; see also Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022

[579] Minutes of meeting at BPL [**CBLA0001649**] dated 15.12.1982

could be a '*long time before chronic hepatitis develops'* and any new study '*would not produce information for several years'* [**NHBT0094563**][580].

9.14 For some clinicians, and those who were relying on the work of Dame Sheila Sherlock (who was considered an expert in this area), the understanding was that NANBH was '*mostly benign*'. This accords with Professor Hay's characterisation of the consensus view that NANBH was '*benign and non-progressive*'[581]. The sixth edition of '*Diseases of the Liver and Biliary system',* published in 1981, identified that NANBH '*now accounts for about 75% of post-transfusion hepatitis'.* Dame Sherlock's description of the long-term course of NANBH stated that '*the acute episode is usually mild and often anicteric*[582] *[…] Non-A, non-B hepatitis often progresses to a mild chronic hepatitis. The prognosis of this is, at the moment, uncertain but probably benign'* [**WITN4032023**][583]. Given the work of Triger, Preston and others, the position taken in Sherlock's book reflects the uncertainty of the position, with different respected clinicians taking different views.

9.15 The seventh edition of Sherlock's *Disease of the Liver and Biliary System* was published in 1985. Professor Contreras described the publication as painting a developing picture:

> *'a high proportion (68%) of patients with NANB Hepatitis developed chronic hepatitis with a smaller proportion (19%) going on to develop symptoms of cirrhosis. Fluctuating transaminases were said to be typical of the chronic state. It was commented, significantly, that a relationship with hepato-cellular cancer had not been established (p272). It was noted that there was no test for NANB Hepatitis and that there had been limited progress both in diagnosis and in assessing treatment'* [**WITN5711001**][584].

9.16 The clinicians who relied on Dame Sherlock's expertise included many blood service witnesses (e.g. [**WITN4034001**][585]). Specifically, Professor Contreras explained that she had understood that there were changes in the liver during the '*acute phase and then they went to normal, as she said it'* [**INQY1000165**][586].

9.17 The impression that in the late 1970s and early 1980s the academic literature presented somewhat of a patchwork with no unified view on the severity of

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[580] Letter from Dr Gunson to Dr Gibson at the Medical Research Council on thestate of knowledge and research on NANBH [**NHBT0094563**] dated 11.02.1983
[581] Oral evidence of Professor Charles Hay [**INQY1000072**] dated 04.11.2020 at [43/9]
[582] Patient not affected by jaundice
[583] S Sherlock, Diseases of the Liver and Biliary System (Blackwell Scientific Publications, 1981, 6edn) [**WITN4032023**]
[584] Written Statement of Professor Marcela Contreras [**WITN5711001**]; 7th Edition of Sheila Sherlock's Diseases of the Liver and Biliary System
[585] Written statement of Dr Vanessa Martlew [**WITN4034001**]
[586] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [pg59-61]

NANBH, particularly in relation to long-term consequences, is consistent with Dr Foster's view that '*it was probably not until the early 1980s that it began to seep through that this may be more serious than had been originally believed*' [**INQY1000197**][587].

9.18 Mannucci and Colombo's liver biopsy studies in 1978 showed a mainly '*low grade of inflammation or no inflammation at all',* leading Mannucci, in particular, to make statements that NANBH was '*non-progressive*'[588]. In 1981, a Stevens' paper was published in the British Journal of Haematology entitled '*Non-A, Non-B hepatitis in haemophilia: an overstated problem*'[589]. Further relevant papers include an Australian paper by Rickard[590]. Even as late as 1989, as set out in Professor Barbara's witness statement [**WITN6989001**][591], a study reported no significant clinical sequelae in patients with a history of blood transfusions. This study involved a ten-year follow up of patients who had received transfusions [**NHBT0000098_002**][592].

D. Factors influencing the understanding of NANBH

9.19 There were several other reasons that the blood services took some time to appreciate the seriousness of NANBH.

9.20 First, the knowledge of many blood service clinicians was grounded in what they were being told by '*reports from the hospitals'*: most blood service clinicians only saw a small number of cases each year [**INQY1000165**][593]. As described above, cases were generally underreported, and even when a case did emerge, it was not always reported to the blood services, for several reasons. First, clinical changes take time to appear, as Professor Tedder has observed: '*acute infection was often very mild clinically such that persistence was not associated at that time with an understanding of its ability to cause end-stage liver disease'* [**WITN3436003_0010**][594]. Frequently symptoms would

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[587] Oral Evidence of Dr Peter Foster [**INQY1000197**] dated 24.03.2022 at [149/13]. For more on this see the Written Statement of Professor Marcela Contreras [**WITN5711001**] at [300-302]
[588] Paper referred to in the oral evidence of Professor Charles Hay [**INQY1000072**] dated 04.11.2020 at [35/21]
[589] Paper referred to in the oral evidence of Professor Charles Hay [**INQY1000072**] dated 04.11.2020 at [40/11]
[590] Paper referred to in the oral evidence of Professor Charles Hay [**INQY1000072**] dated 04.11.2020 at [40/11]
[591] Written Statement of Professor John Barbara [**WITN6989001**] at [255]
[592] G Wood et al., Chronic Liver Disease a Case Control Study of the Effect of Previous Blood Transfusion (Public Health, 1989) [**NHBT0000098_002**]
[593] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [pg65-66]. See [66/18]: *'I didn't know that there was a long-term effect so I couldn't have thought that there might be long-term effects, because we -- all we could see was the reports from the hospitals that we encouraged the hospitals to report to us, and we would see a maximum of four cases of post-transfusion hepatitis due to the transfusion of products that we provided, that means labile blood components. But I couldn't know that there were going to be chronic effects'* Also see Oral Evidence of Dr William Wagstaff [INQY1000175] at [87/15].
[594] Written Statement of Professor Richard Tedder [**WITN3436003**]

present after the patient had been discharged from hospital care, in which case the blood services may well not have been notified of an infection [**INQY1000163**]. Second, many patients with NANBH were asymptomatic.

9.21 As with HIV, doctors from each disciplinary speciality developed their understanding of NANBH's potential severity at different rates. Liver disease specialists and haemophilia consultants in general had earlier direct knowledge of its chronic long-term effects [**INQY1000163**][595]. As set out above, the clinicians who relied on Dame Sherlock's expertise – including her view that NANBH was largely benign - included many blood service witnesses.

9.22 During this period there was also a lack of longitudinal data. The evidence continued to be inconsistent: research papers as late as 1983 supported the view that NANBH was not serious. One study of 248 transfused cardiac surgery patients concluded that '*non-A non-B hepatitis after blood transfusion from a largely British blood donor group probably leads to clinically significant chronic liver disease very rarely indeed'* [**CBLA0001773**][596]. Consequently, in the early 1980s many doctors in the blood services simply '*didn't know that there was a long-term effect'* [**INQY1000165**][597], or at a minimum the clinicians didn't fully understand the '*long term consequences'* of NANBH [**WITN4034001**][598].

9.23 Further factors which influenced clinical opinion on the risk of NANBH included, first, that the disease '*didn't have a name';* it was described using a '*vague term*', which made it hard to '*establish the significance'* [**INQY1000163**][599]. Second, the incidence of post-transfusion NANBH had been shown to be significantly lower in the UK than in the USA, leading to a general perception that the disease was less widespread in the general population and therefore less of an issue in the UK [**PRSE0003767**][600]. Third, the initial population exhibiting NANBH included a significant number of injecting drug users, complicating diagnosis [**INQY1000205**][601]. Fourth, prior to the cloning of the Hepatitis C Virus (**HCV**), the number of cases that '*would now have been classified as HCV cases going on to severe disease were small in comparison with the rest of the broad spectrum of jaundice'* [**INQY1000175**][602]. Fifth, the pattern between transfusion and infection showed up much more obviously in

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[595] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [85/14]: he said that the '*problem with non-A, non-B hepatitis is that any change, any clinical changes take some time to appear, and probably well after the patient has been discharged from hospital care."*

[596] J Collins et al., Prospective Study Of Post-Transfusion Hepatitis After Cardiac Surgery in a British Centre (British Medical Journal, 1983, Vol.287) [**CBLA0001773**]

[597] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021

[598] Written statement of Dr Vanessa Martlew [**WITN4034001**]

[599] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [85/14]

[600] M Contreras et al, Testing of Blood Donations for Non-A, Non-B Hepatitis (The Lancet) [**PRSE0003767**] dated 01.08.1987

[601] Oral Evidence of Dr H Pickles [**INQY1000205**] at [12/05] and [33/23] *'In relation to the population I was particularly concerned about, the drug users, they had such chaotic lifestyles, their life expectancy was so short'*

[602] Oral evidence of Dr William Wagstaff [**INQY1000175**] at [90/2]

recipients of pooled products, but for a long period there was not an awareness that conventional blood donation of red blood cells or platelets, or cryoprecipitate, was leading to significant morbidity and mortality [**INQY1000163**][603].

9.24 As knowledge of NANBH, and longer-term sequelae, emerged from expert studies throughout the 1980s, the perception of its importance grew within the blood service. Even before the extent of its seriousness was fully comprehended, it was described as being, by the early-to mid-1980s, '*the biggest single issue or single biggest problem left for Blood Transfusion Services to solve'* [**INQY1000179**][604]. Dr Barbara's evidence supports this position: '*Once a specific test -- and I say specific in the general term -- was able to identify the virus in patients significantly affected, I think we were pretty quick to be aware then. I think beforehand, yes, there may have been a feeling that it was less important than hepatitis B'* [**WITN6989001**][605].

9.25 Dr WM McClelland's oral evidence was that prioritising NANBH as the primary risk to the blood services '*changed with HIV.*'[606] A paper written by Professor Tedder and Dr Barbara in 1984 stated that '*the implications of AIDS in blood transfusion, a topic that has overshadowed NANB, has been reviewed recently'* [**NHBT0000030_009**]. In oral and written evidence Dr DBL McClelland stated that for a period from 1983 the transfusion service '*lost sight'* of NANBH as everybody was '*extremely preoccupied with HIV'.*[607] This is consistent with the position put forward by Dr Napier that '*it was perhaps dominated by, you know, the need to attend to other aspects of blood safety'.*[608] By 1983 the blood services were focused on taking steps to minimise the risk of HIV.

9.26 It is important to note that steps taken to minimise HIV risk (such as screening, or exclusion of intravenous drug users) would also have screened out some of those who were infected with both HIV and NANBH, and therefore would also have been and were effective at reducing the incidence of NANBH in donated blood.

9.27 By the mid-1980s, clinicians were aware that NANBH could be *'acquired from plasma products and blood components and could also progress to serious liver disease'* [**WITN0643001**][609]. A 1985 article by Hay and Triger drew attention *'to the role of liver disease in patients with haemophilia who had been treated with clotting factor concentrates'* [**WITN4002001**][610].

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[603] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [85/14]
[604] Oral Evidence of Dr WM McClelland [**INQY1000179**] dated 01.02.2022 at [86/7]
[605] Written Statement of Professor John Barbara [**WITN6989001**]
[606] Please see Section 8 for more detail on the AIDS timeline, with the San Francisco baby case in December 1982 confirming that there was a significant risk of transfusion by blood and blood products
[607] Oral Evidence of Dr Brian McClelland [**INQY1000177**] dated 27.01.2022 at [97/11]
[608] Oral Evidence of Dr John Napier [**INQY1000163**] dated 30.11.2021 at [89/12]
[609] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [339]
[610] Written Statement of Dr Francis Preston [**WITN4002001**]

9.28 To the extent clinicians knew about NANBH, they were not necessarily conscious that it could give rise to severe chronic disease until the publication of the 8th edition of Dame Sherlock's book in 1989: at this point, clinicians had sufficient information to know that NANBH could cause chronic problems [**WITN5711001**][611] [**INQY1000136**][612]. The Inquiry has also heard evidence that it was not until the late 1980s that it was known by all clinicians that NANBH could cause serious liver disease [**GG OE**][613] [**INQY1000165**][614].

9.29 In conclusion, the fact that the severity of NANBH was not fully recognized until the mid-1980s did not stop the blood services from taking measures to prevent its spread: it was recognized by the early- to mid-1980s as the single biggest problem for the blood and transfusion services to solve. Its position as the primary risk changed with HIV, which took much of the blood services' attention due to the magnitude of risk during this period. By the late 1980s it was understood by most clinicians that NANBH could give rise to severe chronic disease.

E. Surrogate testing

(1) Generally

9.30 The following sub-section addresses the debate over whether to introduce *'surrogate'* tests, for *'surrogate'* or *'indirect'* markers of NANBH, during the period in which there was no way to test for HCV directly. The main tests considered, ALT and anti-HBc, were not specific to HCV but (respectively) detected inflammation of the liver and exposure to HBV.

9.31 The Inquiry Counsel Team has produced a helpful chronology on the introduction of NANBH Surrogate Testing [**INQY0000390**]. The details of this chronology are not repeated in these submissions. Instead, the following developments are highlighted.

9.32 In late 1970s,[615] and early 1980s, groups in the USA reported a correlation between elevated alanine aminotransferase (**ALT**) levels and an increased risk of NANBH among transfusion recipients[616]. Correlation was also reported between antibodies to Hepatitis B core antigen (**anti-HBc**) and NANBH. Neither test, when used to identify NANBH, was conclusive, and the two tests identified different populations with little cross-over. It was then determined by the

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611 See Written Statement of Professor Marcela Contreras [**WITN5711001**] at [339-341]
612 Oral Evidence Dr Diana Walford [**INQY1000136**] dated 19.07.2021 at [109/5]
613 Oral Evidence of Dr George Galea dated 03.12.2022 at [18/3][18/3]
614 Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [70/19]
615 R Aach et al, Transfusion-Transmitted Viruses: Interim Analysis of Hepatitis Among Transfused and Non-transfused Patients [**PRSE0002540**] dated 16.03.1978
616 R Aach et al, 'Serum [ALT] of donors in relation to the risk of [NANB] hepatitis in recipients: the TTV study', (New England Journal of Medicine, 1981, Vol.304 Issue 889): see also Second Written Statement of Dr Angela Robinson [**WITN6926003**]

Advisory Group on testing for the presence of hepatitis B surface antigen and its antibody[617] that it was too stringent to exclude donors on the basis of high ALT levels, as this was a non-specific indicator of liver dysfunction [**DHSC0002191_099**][618]. The same view was taken in relation to donations for anti-HBc based on cost and the risk of discarding harmless donations from immune donors [**DHSC0002211_007**][619].

9.33 Surrogate testing was not adopted in the UK generally. The following section therefore describes the relevant history in relation to the specific question of whether the UK should have introduced general surrogate testing of blood donations for ALT and anti-HBc prior to the introduction of HCV screening. This question was *'hotly debated'* at the time [**INQY1000164**][620].

9.34 Ultimately, the decision to introduce a test would have been for the DH to take following advice from the blood services [**INQY1000166**].[621]

9.35 While surrogate testing was introduced in the US in 1986, this was not a '*unanimous decision'*. It was not recommended by Harvey Alter[622], whose work showed '*it [the anti-HBc test] was ineffective in screening out possible [NANBH] carriers in the donor population'* [**WITN6926003**].[623] Further, in the US it was determined that a '*prospective randomised trial to test [the efficacy of screening tests] will never be carried out for logistical and ethical reasons'* [**PRSE0001435**].

9.36 The ALT test was first suggested in research undertaken in the US and published in 1981. The evidence from the study was not considered '*by any means clear cut'* [I**NQY1000178**][624] [**INQY1000178**].[625] In 1983, a study in the North London Centre found that the prevalence of anti-core and ALT was much lower in the UK than in the United States **[INQY1000166]**.[626] That the levels of HCV were significantly lower in the UK meant that the argument for introduction '*which might seem compelling in the United States didn't necessarily apply in Britain'* [**INQY1000164**][627]

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[617] An advisory committee to the DHSS.
[618] First Meeting of the Reconvened Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody [**DHSC0002191_099**] dated 07.12.1978
[619] Third report of the Reconvened Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody (also referred to as the Maycock Group) [**DHSC0002211_007**]
[620] Oral Evidence of Dr John Napier [**INQY1000164**] dated 01.12.2021 [82/18]
[621] Oral evidence of Professor Marcela Contreras [**INQY1000166]** dated 3.12.2021 at [18/9]
[622] Dr Harvey Alter and colleagues had been conducting research at the US National Institutes of Health (NIH) into post-transfusion hepatitis from a number of countries. Alter et al, Non-A/Non-B Hepatitis: a Review and Interim Report of an Ongoing Prospective Study (Viral Hepatitis, The Franklin Institute Press, 1978) at [pg359]
[623] Second Written Statement of Dr Angela Robinson [**WITN6926003**]
[624] Oral Evidence of Dr Brian McClelland [**INQY1000178**] dated 28.01.2022 at [113/7]
[625] Oral Evidence of Dr Brian McClelland [**INQY1000178**] dated 28.01.2022 at [113/7]
[626] Oral evidence of Professor Marcela Contreras **[INQY1000166]** dated 03.12.2021 at [50/20]
[627] Oral Evidence of Dr John Napier [**INQY1000164**] dated 01.12.2021 at [82/18]

9.37 Research, including the findings of the 1983 North London Centre paper, showed that elevated ALT levels could be attributable to various factors including high alcohol intake, obesity or other liver conditions (and later even to exercise). Although this would not have been relevant to the question of seriousness, it was material to the risk of infection in the blood supply.

9.38 Thus, again, the significant differences in donor demography suggest that the US approach was not necessarily indicative of the appropriate decision to be taken in the distinctive UK context. As set out below, the predictive value of a positive test result is contingent on the prevalence of a particular virus in any given population, and therefore different populations require different approaches to testing (see also Section 4(G) of these submissions, *'Decision-Making and the Reliability of the Blood Supply',* on the approach to testing generally). This was particularly important given that, where tests are non-specific, there will be a much higher number of false positives as a proportion of total tests where a disease is less prevalent in a population (see further below).

9.39 In sum, although the USA did introduce surrogate tests, the support for their introduction in the USA was not comprehensive, and the underlying characteristics of the UK population were, according to the North London study, different.

9.40 The UK blood services undertook studies to consider whether the introduction of such tests would be justified. Details of research into surrogate testing pre-1987 are available in Dr Robinson's second witness statement [**WITN6926003**][628]. Details of research into surrogate testing pre-1987 are available in Dr Robinson's second written statement [**WITN6926003**][629].

9.41 Dr Gunson's views on the risks posed by introducing surrogate testing, set out in a report from October 1986 on ALT and anti-HBc screening of blood donations, are noteworthy. He identifies that surrogate testing would lead to a significant loss of donations. He references the multi-centre trial study of surrogate testing, the TTV study, the Alter study, and the study by Debris et all, and concludes that

> *'…from the evidence available in the UK one might expect that ALT screening will cause the loss of 0.7-0.9% of donations and anti-HBc in the order of 1%. Presumably there will be some overlap in the ALT and*

[628] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [141 – 146]
[629] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [141 – 146]

anti-HBc results but one might expect a loss of donations of approximately 1.5-1.75%' [**PRSE0002161**][630] [**PRSE0000290**][631]

9.42 This would have been perceived to have been a material loss and may impact on the supply of components to patients. In addition, Dr DBL McClelland identified that the study showed limited benefits to surrogate markers and HCV positivity. In his commentary to the Inquiry on the multi-centre trial study [**PRSE0000290**] he stated that '*my interpretation, which I freely admit may be flawed, but my interpretation is that the data from that very substantial study, 10,000 recipients -- 10,000 donors were studied, would suggest that there was an extremely poor correlation between a donor being HCV positive and having a positive surrogate marker*' [**INQY1000178**].[632]

9.43 0n 28 April 1987, in a letter to The Lancet, Dr Anderson, Professor Contreras, Professor Barbara and Dr Mijovic outlined that a *'national study to assess the incidence of raised ALT and anti-HBc in donors in different parts of the country'* was needed to determine whether screening test of *'unproved benefit'* should be introduced [**NHBT0000025_010**]. In April 1987, in a letter to The Lancet, Dr Anderson, Professor Contreras, Professor Barbara and Dr Mijovic outlined that a *'national study to assess the incidence of raised ALT and anti-HBc in donors in different parts of the country'* was needed to determine whether screening test of *'unproved benefit'* should be introduced [**NHBT0000025_010**]. In April 1987, Dr Gunson submitted an application to DHSS for a grant for a multi-centre study of surrogate testing **NHBT0000072_002** (multi-centre trial). The intention was to test 12,000 donors over six months. The application was approved on 28 April 1988, and the trial proceeded with 3,000-6,000 donors initially: it was agreed that there would be *'no recommendation to institute ALT testing until the current study was completed in England'* [**NHBT0000043_002**].

9.44 The results were published in 1992 [**PRSE0001695**]. It is unclear why publication took such a long period of time, but it appears likely that the successful cloning of HCV by Chiron in Spring 1988 led to the matter being treated as superseded. However, the results were ultimately published on the basis that there was still value in sharing the data and analysis.

9.45 An interim report from the study in April 1990 revealed initial issues with surrogate testing. The issues with ALT testing included '*non-specificity of the test, finance, donor loss and donor counselling'* [**NHBT0000014_093**]. The later

[630] Dr Gunson report, Alanine Amino-Transferase (ALT) and Anti-hepatitis B core (Anti-HBc) Screening 1986 of Blood Donations: Proposals for a Multi-Centre Study, for the UK Working Party on Transfusion Associated Hepatitis [**PRSE0002161**]. This document sets out the proposed protocol for screening 3,000 donors.
[631] Multi-Centre trial study of surrogate testing [**PRSE0000290**] also see the Surrogate HCV Chronology [**INQY0000390**] at [41]
[632] Oral Evidence of Dr Brian McClelland [**INQY1000178**] dated 28.01.2022

results demonstrated that alcohol intake and obesity were also causes of raised ALT levels in donors.

9.46 There was a range of good reasons for not introducing surrogate testing. The question of whether to introduce a test depends on sensitivity and specificity (and thus the impacts on donors and supply), the feasibility of introduction, the availability of a confirmatory test, and health economics considerations: see, for further detail, Section 4 (*'Decision-Making and the Reliability of the Blood Supply'*).[633] These are all factors which would remain relevant today in the application of the ABO Risk-Based Decision-Making Framework (discussed in Section 4).

9.47 In the context of HCV surrogate testing, drawbacks included the non-specificity of the tests, which had significant potential to produce false positives. Further, they were not sensitive – they had the potential to deliver false negatives, and so not all of the infected population who did test positive would be caught. The evidence given by blood service clinicians during the Inquiry was, overall, that the sensitivity and specificity of the available surrogate tests was insufficient for the blood services to advise the DH that their introduction would be justified [**WITN6926003**].

9.48 Specifically, Dr Entwistle, Dr Napier, Professor Barbara, Dr Wagstaff, Dr Williamson and Dr Hewitt all agreed on the limited value of surrogate testing.

9.49 Dr Napier noted that raised ALT levels could be markers of *'a number of other factors',* and therefore:

> *'…So it's a rather poor discriminating test, and only limited value, not no value but -- some but limited value in terms of excluding potentially infective donors. And so I think there were varied points of opinion as to whether the value in reducing the infectivity of the donor pool was -- could be balanced against the costs of introducing the tests and the unnecessary loss of donors that would also take place'.* [**INQY1000164**] [634]

9.50 Similarly, Dr Williamson recalled:

> *'…general discussions about ALT testing at Sheffield. It is a very non-specific test, and a very common cause of a raised ALT is excessive alcohol intake. I do recall the very great concern that many donors would be lost due to a high ALT of unknown cause and be worried about what it meant, or have hospital visits and investigations they did not*

[633] These are all currently assessed using the Alliance of Blood Operators International Framework, as set out in the Written Statement of Dr Gail Miflin [**WITN0672006**]
[634] Oral Evidence of Dr John Napier [**INQY1000164**] dated 01.12.2021 at [88]

really need. Another concern was that people would not come forward as donors knowing they would have this test.' [**WITN0643001**] [635]

9.51 Dr Entwistle commented on the practicalities of relying on the ALT test:

'…The ALT was a very unreliable test. Q. So if the reading was then back to normal, would the assumption be that this wasn't a non-A, non-B, this was -- the ALT was raised for some other reason and the donor could continue to donate and the donations could continue be used? A. That was our thinking at the time, bearing in mind that there was no actual specific test for hepatitis C at that time. Q. And if the ALT reading continued to be elevated, what would happen? If it was elevated in the second test what would happen then? A. We would seriously have to consider removing that donor from the pheresis panel'. [**INQY1000167**][636]

9.52 Dr Wagstaff stated in written statement that

'…I believe that the general opinion was one of some doubt about any NANB diagnosis being based purely on ALT and anti-HBc levels'. [**WITN6988001**] [637]

He later confirmed that in his own view:

'…surrogate testing for potential viral transmission was not suitable for NBTS implementation. This view did not change over time and was reinforced by the deliberations of the Council of Europe Working Group, and of UKACVSB (documents NHBT0008816_002 and ARCH0002040_002). As detailed elsewhere in my statement, neither of these bodies felt able to recommend the introduction of ALT and anti-HBc testing as surrogates for NANB infection'. [**WITN6988001**] [638]

9.53 Dr Hewitt noted the *'accumulating evidence'* that screening for both anti-HBc and for ALT levels would identify some individuals at higher risk of NANB/HCV, and that their exclusion as blood donors would reduce the risk of HCV transmission. She *'fully understood'* the need to carry out studies in the UK, to examine the likely impact of such interventions on UK donors and on the sufficiency of the blood supply. However, it was:

'…clear from small studies, including one from NLBTC, that a large number of elevated ALT levels were associated with alcohol intake and with excess body weight, and I shared concerns that using ALT as a surrogate marker would exclude many donors who did not present a risk of transmitting infection. In my opinion there was a need for larger, well controlled studies,

[635] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [473]
[636] Oral evidence of Dr Colin Entwistle [**INQY1000167**] dated 06.12.2021 at [123/1-15]
[637] Written Statement of Dr William Wagstaff [**WITN6988001**] at [455]
[638] Written Statement of Dr William Wagstaff [**WITN6988001**] at [548]

> *but these did not take place, probably because there was no national funding for such studies, and any studies were carried out by individual centres.'* [**WITN6988001**][639]

9.54 Dr Hewitt also recalled concerns in relation to anti-HBc screening that the tests were:

> *'…not as specific as many of the test we were used to using, and there was again the concern that there would be a loss of significant numbers of donors, many of whom did not present a risk'.*

9.55 She further clarified the impact of even 0.8% donor loss:

> *'Although it does not sound a large proportion, the loss of 0.8% of donors would have been a huge concern. I well recall numerous occasions at NLBTC when we had blood shortages and needed to turn to other centres to help us maintain supplies to hospitals. These shortages would have been exacerbated by a loss of almost 1% of blood donors.*
>
> *218. As time went on, and HCV screening tests were developed, I believed that the efforts should be directed on the introduction of screening tests, and that further work on surrogate testing would be a distraction.'* [**WITN3101006**] [640]

9.56 Finally, Professor Barbara commented that his understanding of the value of surrogate testing was based on:

> *'the limited number of reports [from clinicians of post-transfusion hepatitis], our perception of the limited clinical benefit and our awareness of the diversion of resources that introduction of surrogates would have entailed: cost, in other words'.* [**INQY1000176**] [641]

9.57 These statements demonstrate that a range of concerns about ALT and anti-HBc testing were widespread among clinicians.

9.58 Professor Barbara and Professor Contreras' letter of 1 August 1987 to The Lancet [**PRSE0003767**] considered the introduction of surrogate tests and stated that *'transfusion services must not bow to irrational pressure for measures whose efficacy is unproven.*' Professor Barbara explained in oral questioning that to have introduced such measures:

> *'…would involve a diversion – sorry, a reduction in the amount of available blood for issue, and, of course, it would also that [sic] mean donor management and donor counselling.'* [**INQY1000176**][642]

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[639] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [216]
[640] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [215-218]
[641] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [52-53] and [19-1]
[642] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [53/18]

9.59 At the second meeting of the ACVSB, a DH group on the Virological Safety of Blood, the ACVSB considered surrogate testing for NANBH. A paper provided by Dr Mortimer for that meeting provided:

> *'At present there does not appear to be any urgent need to introduce routine surrogate testing for NANB hepatitis among voluntary blood donors in the UK in respect of public health'.* [**NHBT0000061_022**][643]

9.60 At the meeting that then followed on 22 May 1989 the committee agreed that such testing should not be introduced into the blood service prior to the results of the study being known. It was noted that '*anti HBc testing was not without problems'* **[NHBT0000041_020]**[644]

9.61 At the fourth meeting of the ACVSB in November 1989, it was recorded that there was no case for using surrogate tests: this concluded the active consideration of surrogate tests.

(2) Conclusions

9.62 Surrogate testing, of ALT and Anti-HBc, was not adopted in the UK generally. Raised levels of ALT could be attributed to a range of factors, including alcohol intake, obesity and liver conditions. The UK blood services conducted research in 1986 into the introduction of surrogate tests but concluded that it would lead to the loss of a significant number of donations, the significance of which has been explained by Dr Hewitt. Further research in the early 1990s found that ALT testing would cause problems resulting from test non-specificity, cost, donor loss and the cost of donor counselling. The blood service, following this research, concluded that the tests' efficacy was unproved. This position was supported by ACVSB.

9.63 Ultimately, there was an absence of properly powered prospective clinical studies that would have helped resolve some of the uncertainty. The dilemma facing those working in the blood services was therefore whether or not to introduce ALT testing on a precautionary basis. In making that decision, they took into account the low (and uncertain) sensitivity and specificity of the surrogate test, financial considerations and donor loss. It is not possible, in the absence of further data, to determine what the right answer would have been.

9.64 NHSBT's position therefore is that in the UK, at no time was there a sufficient medical or scientific basis to justify the introduction of these two tests as a surrogate marker for NANBH. (In fact, this was also the position taken by the Penrose Inquiry, specifically because: *'the poor sensitivity and specificity of ALT tests meant that the majority of infected donations were unlikely to be*

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[643] Submission from Dr Mortimer to the second meeting of the ACVSB circulated on 12 May 1989 **[NHBT0000061_022]**

[644] Minutes of the second meeting of the ACVSB on 22 May 1989 **[NHBT0000041_020]**

detected, and, of the many thousands of donations that testing positive, the vast majority were likely to be false positives' [**PRSE0007002**].[645]

9.65 NHSBT further notes that the prevalence of HCV was likely higher in Scotland than England due to the higher level of intravenous drug use, meaning that the calculation in relation to introducing a test was differently balanced.

9.66 NHSBT also notes that many of the RTDs were in favour of anti-HBc testing on the basis that it may have been useful for detecting tail-end carriage HepB not detectable by HBsAg testing [**INQY1000166**].[646] This issue is considered further in Section 7.

F. HCV Testing

9.67 The Inquiry counsel team has produced a helpful chronology on the introduction of HCV screening [**INQY0000389**], which is not repeated in detail here.

9.68 The interval between the availability of HCV tests and the introduction of screening of donated blood in 1991 is a significant issue for the Inquiry. The virus, HCV, was discovered in 1989. Discovery of HCV led to the development of a diagnostic test for HCV that relied on enzyme immunoassays ('**EIA**'). EIAs are a form of serological assay and are usually performed on blood serum or plasma samples. EIAs are designed to detect the body's response to infection rather than the virus itself.

9.69 In Spring 1988, the Chiron Corporation ('**Chiron'**) identified the HCV genome. Sequencing of the HCV genome was first announced in a press release on 10 May 1988. At that point there was no UK government body able to assess the potential utility of any test. Although the isolation of HCV was announced in May 1988, the first tests did not become available until 1989. Between the press announcement about the discovery of the first-generation enzyme-linked immunosorbent assay ('**ELISA'**) test and the publication of the test details, the focus was on Chiron – including the transition from Chiron holding a patented assay, to the publication of details of the test and assay in Science in 1989 [**INQY1000176**].[647]

9.70 Dr Gunson, Dr McClelland and Dr Pickles began the process of establishing a UK group to determine transfusion-disease related policy. The Advisory Committee on Transfusion Transmitted Diseases ('**ACTTD'**) was established to '*discuss transfusion transmitted diseases and to provide advice to the Department of Health',* and held its first meeting on 24 February 1989 [**NHBT0000043_002**]. ACTTD was *'purely advisory and had no decision-*

[645] See the Final Report for the Penrose Inquiry [**PRSE0007002**] at [27.398]
[646] Oral evidence of Professor Marcela Contreras [**INQY1000166**] dated 03.12.2021 at [77/15]
[647] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 [pg105]

making powers'. The link between ACTTD and the RTCs was through Dr Gunson [**NHBT0000026_009**][648] [**WITN5711001**].[649]

9.71 Separately, in July 1988 the Advisory Commission on the Virological Safety of Blood ('**ACVSB'**) was established, a year after the committee had initially been proposed by the UK Health Ministers following concerns raised about the lack of advice, in general, to ensure the virological safety of blood. The ACVSB's Terms of Reference describe its remit as:

> *'…to advise the Health Departments of the UK on measures to ensure the virological safety of blood whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing'* **PRSE0001189**

9.72 The ACVSB was chaired by the Deputy Chief Medical Officer. The discussions of the ACTTD were to be communicated to the ACVSB,[650] which was charged with making formal recommendations to the DH to enable it to make the decision on the introduction of tests. Dr Gunson was the NBTS representative for the ACVSB, but according to Professor Contreras there were no representatives of the RTDs on the committee [**WITN5711001**].[651]

9.73 On 11 October 1988, Dr Gunson and Dr Barbara met Chiron staff and offered to carry out tests on samples taken for the multi-centre study on surrogate testing [**NHBT0000026_001**]. In April 1989, Chiron published details of the isolation of the HCV genome in the journal, Science and developed details of a test to detect HCV antibodies. That identified that the first-generation ELISA test missed 20-40% of infected patients. Moreover, it was particularly insensitive to the early stages of the infection and returned false positive results [**NHBT0000025_021**]. The sensitivity of these *'first generation'* ELISAs was low for a high-prevalence population, and the proportion that were false positive were as high as 70% for a low-prevalence population.[652]

9.74 This issue was explored with Professor Leikola during the Penrose Inquiry. Professor Leikola commented:

> *'The test gave positive results in a high percentage of US patients with NANB Hepatitis. European experience was less promising. […] The test was sufficiently specific to study high prevalence populations such as hepatitis patients, but it gave many false positive results when*

[648] Written Statement of Dr Harold Gunson in A and Others [NHBT0000026_009] at [65]
[649] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [243]
[650] Note also the oral evidence Professor Marcela Contreras that information from the ACVSB was not shared with transfusion directors
[651] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [220]
[652] Expert Report to the Infected Blood Inquiry: Hepatitis [**EXPG0000001**] at [21]

> *applied in blood donor screening. There was no true confirmatory test since everything was dependent on only one recombinant antigen.'* [653]

9.75 The deficiencies of the test were also reported by Professor Tedder, who stated in written evidence that there were continuing concerns about the '*absence of a reliable and practicable confirmatory test and the false positive rate.'*[654]

9.76 Ortho Diagnostic Systems Ltd ('**Ortho'**) entered into an agreement to manufacture test kits under licence from Chiron.

9.77 The second ACVSB meeting on 22 May 1989 identified that the Chiron test only picked up 50% of cases, and that there was a need for caution. It also announced that the study of the testing was coordinated by Dr Gunson (the London Ortho study) [**NHBT0005019**].[655]

9.78 The third ACVSB meeting on 3 July 1989 concluded that information from the UKBTS Survey on surrogate testing and Chiron Screening alongside the prospective study of post-transfusion NANBH should be compiled and considered at the following meeting.

9.79 In August 1989, a meeting of the ACVSB [**PRSE0000815**] described a meeting with Dr Gunson, Professor Contreras and Professor Barbara about blood testing, stating that any decision on blood testing:

> *'..would be subject to the advice of the National Advisory Committee on the Virological Safety of Blood. […] If the Advisory Committee were to make a recommendation, then this would go to Ministers in England and Scotland for a final decision.'*

9.80 The same letter set out that the ACVSB view was that any decision on the introduction of testing would require the UK to '*move in unity'* [**INQY0000308**].[656]

9.81 On 8 August 1989, Professor Barbara and Professor Contreras wrote to The Lancet stating that the new Ortho ELISA appeared to be specific for HCV. By specific, here they meant a test for the viral agent (i.e. not surrogate). They went on to consider the sensitivity and specificity of the test, noting that:

> '*…in the context of donor screening, precipitate action should be avoided. As in any other assay the predictive value of a positive result hinges on the prevalence of the marker in a given population.'* **NHBT0000188_017** .[657]

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[653] Penrose Inquiry [**PRSE0007002**] at [31.132–31.133] citing Written Statement Professor Leikola at [193-195]
[654] Written Statement of Professor Richard Tedder [**WITN3436003**] at [321]
[655] Minutes of the second ACVSB meeting [**NHBT0005019**] dated 22.05.1989
[656] Inquiry presentation on Professor John Cash [**INQY0000308**] at [163]
[657] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022

9.82 This demonstrates that it is crucial to distinguish between an assay 'specific' to the HCV agent, and a 'assay of high specificity. The first-generation tests were not assays of high specificity, although they were specific to HCV.

9.83 The letter also identified risks of donor exclusion following the introduction of a low-specificity first generation test, and that there may be a risk of '*contacting and counselling 12500-25000 blood donors',* which would be a significant undertaking when '*the significance of a positive test in a healthy person is as yet unknown.'*

9.84 On 18 August 1989 Dr Gunson sent a letter to all RTDs stating:

> '*…it is important that we act in a co-ordinated manner nationally […]. There will have to be approval of the DH before they are introduced and the means of obtaining this is the agreement of the DH's Committee on the Virological Safety of Blood'* [**PRSE0002340**].

The letter goes on to explain that prior to routine screening commencing: 'it would be prudent [for the RHAs] to include the cost of this test as a development in your budgets for 1990/91.'

9.85 On 24 August 1989, the Guardian published an article titled '*Dilemma on virus blood test'* [**NHBT0000188_028**]. This identified the significant long-term consequences from HCV and the possibility that up to 30,000 pints of blood could be *'contaminated'.* Following the article's publication, Dr Gunson wrote to RTDs identifying that the available tests were only '*an evaluation*. *The fact that a test is positive does not necessarily mean that a person is infected with the virus.'* The letter went to state that '*confirmatory tests were not yet available*' and that nothing had changed within the blood service [**NHBT0000188_032**].

9.86 In October 1989, at a meeting of the Eastern Division of Consultants [**NHBT0017553_001**], Dr Contreras stated that the UK should start testing:

a) after FDA licensing,

b) when confirmatory testing became available and (iii) once provision for counselling was in place

The results from the London Ortho study on the new tests, completed in November 1989, found the repeat reactive rate (where two successive positive results were found on a given sample) averaged 0.67% [**NHBT0000026_001**].[658]

(1) Confirmatory tests

[658] Written statement of The Hon Richard Tedder [**WITN3436003**] [98/318] citing the witness statement of Dr Harold Gunson at [76]

9.87 A letter to *The Lancet* from Professor Barbara and Professor Contreras on 8 August 1989 [**NHBT0000188_017**] considered confirmatory tests. Those were tests that were different from the ELISA on the market and therefore capable of helping to affirm the initial screening test. They confirmed that the new Ortho ELISA for anti-HCV clearly appeared to be a specific assay, and provided a '*welcome advance'*, but that confirmatory assays would be necessary to obtain accurate results: '*it is essential to have confirmatory assays to eliminate, for example, the possibility of cross reactivity'.* The same letter also highlighted the costly nature of introduction of tests; in oral evidence, Dr Barbara confirmed that during this time '*cost-effectiveness did figure very highly in our considerations'* [**INQY1000176**].[659]

9.88 The view that confirmatory tests were necessary was shared across the blood services. Professor Cash stated in a letter to *The Lancet*: '*The apparent absence of a confirmatory test will cause serious problems for blood transfusion services, which are likely to bear the brunt of sensitive donor counselling.'* [**JC OE**][660].

9.89 However, some disagreed: in December 1989, Dr Ludlam of SNBTS expressed the view that on balance, '*it seems to me that a case can be made for using the present anti-HCV assay to screen all donations and discarding all positive units'* [**SBTS0000155_102**]. This communication went on to state that*: 'You will be as familiar as I am with the long-term complications of [non-A, non-B] hepatitis I fear that if there is delay in the introduction of anti-HCV testing we will be exposing patients to preventable viral infection*'.

9.90 A confirmatory test should be distinguished from a supplementary test that repeats the initial screening test. In 1990, Ortho introduced a recombinant immunoblot assay ('**RIBA'**). This was helpful in distinguishing true positives; however, it acted as a supplementary test: '*the assay that gives you the anatomy of the stark antibody response that the ELISA will give you.'*[661] Therefore, non-specific results continued to occur. Abbot produced a HCV neutralisation ELISA – but the performance of this test was similar to the Ortho RIBA. It was not until June 1990 that a true confirmatory test was confirmed available [**NHBT0000026_001**].

9.91 In respect of pilot studies, the first Pilot Study of the First-Generation Ortho Test ('**First Gen Ortho Pilot'**) reported on a preliminary basis on the 23 June 1989. This was presented to the third meeting of the ACVSB on 3 July 1989. The

[659] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [62/14]
[660] Presentation to Counsel for the Inquiry on Professor John Cash 11.11.2021 [37/18] – this emphasis on confirmation testing was expressed by Professor Cash along with Drs McClelland, Urbaniak, Brookes and Follett.
[661] Minutes of the fourth meeting of the ACVSB dated 06.11.1989 at [70/2]

summary results of tests of 3282 donations noted that there were 22 initial reactive samples and 14 repeat reactive samples.

9.92 On 6 November 1989, the ACVSB concluded at its fourth meeting that routine screening should only be introduced once a confirmatory test had become available [**PRSE0001071**].[662] The ACVSB agreed it would support the general introduction of the Ortho test if it obtained FDA approval, and an urgent pilot study was carried out [**NHSBT0000026_001**]. In *A & others*, Dr Gunson gave oral evidence about the major steps in the chronology of HCV testing. He confirmed that the ACVSB decided, in principle, to introduce routine screening in November 1989, and decided to go ahead in July 1990 subject to a pilot trial [**NHBT0000148_001**] [**NHBT0000043_034**]. Professor Tedder's statement gives further background to that pilot study [**WITN3436003**].[663]

9.93 While the Ortho test was awaiting FDA approval, it was agreed that pilot studies should proceed in Birmingham, Sheffield and Brentwood to show the feasibility of adding the test to routine practice. A draft protocol was prepared on 8 November 1989 [**NHBT0000014_083**] which required each participating RTC to perform anti-HCV tests on approximately 5000 donations, without donor recall [**NHBT0000188_103**].

9.94 At the ACVSB meeting on 6 November 1989 [**PRSE0001071**][664] discussed a paper, which confirmed that the Ortho test detected a viral marker associated with NANBH; that anti-HCV positivity meant that the blood of the person might be infectious for NANBH; and that as an unknown proportion might be false positives, it was an issue that a confirmatory test was not available. The recommendation remained that routine screening should be only introduced until after a confirmatory test became available. It was further noted that the Ortho test '*used only small proteins (middle section of the RNA), whereas there were better tests on the way which test for structural proteins*.'

9.95 At an ACTTD meeting on 22 November 1989, it was noted that the DH had agreed to fund £25,000 for the pilot study to enable the purchase of 15,000 tests; equipment was provided by Ortho and the RTCs bore staffing costs [**PRSE0003300**]. The results of the pilot study, which commenced in December 1989, are set out in Dr Robinson's written statement [**WITN6926003**].[665]

9.96 Simultaneously, a Scottish evaluation of Ortho was also taking place, dated the 5 October 1989 (Dow Study). This found a repeat reactive rate of 0.47% overall (13/2745). Further, of the group of 15 patients reported to have developed post-transfusion NANBH, Dr Dow's team found only a third (five) of the group to be anti-HCV positive. According to Dr Dow, this was because the individuals were

[662] Minutes of the fourth meeting of the ACVSB dated 06.11.1989
[663] Written Statement of Professor Richard Tedder [**WITN3436003**] at [319-320]
[664] Minutes of the fourth meeting of the ACVSB dated 06.11.1989 at [23]
[665] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [176-181]

tested early in their illness, and the tests weren't sensitive enough to pick up early-stage HCV. The study suggested that the Ortho test would only have prevented 21% of the cases of PT-NANBH.

9.97 An ACVSB meeting on 17 January 1990, reaffirmed that testing should not be introduced in advance of FDA approval [**PRSE0001477**]. That meeting considered the second interim report of First Gen Ortho Pilot dated 10 January 1990 [**NHBT0000072_060**]. It reported on 5000 anti-HCV test performed by North East Thames, Trent and West Midlands RTCs during a two week period commencing in early December 1989. The test was found to be straightforward and easy to perform, but it was difficult to estimate screening costs.

9.98 The study confirmed that confirmation of positive results would be essential for RTC testing [**NHBT0000072_060**]. The other practical implications are not repeated here, save to state that the studies demonstrated the need for donor counselling, and for clearer estimations of the costs associated with the '*loss of products, counselling and further testing of donors nationwide'* [**NHBT0000072_060**].

9.99 The full report of the First Gen Ortho Pilot dated April 1990, the *'Multi-Centre UK NANBH Surrogate Marker Study'*, was introduced at an ACVSB meeting on 24 April 1990 [**ARCH0003385**]. In total, 9741 samples were tested: more than 3000 at each of three centres (North London, Bristol and Manchester). The report concluded that although from the results obtained so far it appeared that the Ortho HCV ELISA had an acceptable specificity and sensitivity, this could not be definitively assessed, as no samples with well-established links with NANBH had been tested in this particular study.

9.100 The paper considered abstracts from recent Ortho and Abbott symposia and concluded that in light of the lack of samples with established linked to NANBH the Ortho tests were not '*sensitive or specific enough to be reliable; confirmatory tests were needed'* [**WITN6926003**].

9.101 On 29 June 1990 Dr Boulton wrote to Dr Herborn at the Wessex RTC to outline the presumption that HCV testing would be required in all centres from December 1990 or January 1991 [**NHBT0000189_175**].

9.102 By the seventh ACVSB meeting on 2 July 1990, FDA approval had been granted for HCV screening, the USA had introduced tests, and it was understood that RIBA was available as a supplementary test [**PRSE0000976**]. It was concluded that while HCV testing should be introduced in the UK, a separate pilot study comparing the Ortho study with the Abbott alternative should be concluded first. The proposal was to conduct testing using Ortho and Abbott Test systems based at North London, Newcastle and Glasgow (The Abbott Ortho Comparison Pilot). Each centre was to perform 3,500 tests on identified donations using the first-generation Ortho and Abbott tests. The comparative approach was chosen as not all RTCs were using the same

systems and one test might work better in one centre than in another, and it was important to find out which was the better test kit. In the event, the report for the study was not available until February 1991.

9.103 The study would use the PCR confirmatory tests with first generation Ortho/Abbott assays. Dr Gunson drafted a proposal on 27 June 1990, which was revised on 30 August 1990 [**NHBT0000015_009**]: on the same day, he informed several RTDs that funding had been agreed by the DH [**NHBT0000189_212**].

9.104 The purpose of the trial was to ensure that '*both tests are suitable for use'* [**INQY1000183**][666], so as to determine which test to introduce. The ambition was also to ensure that a new test system could be validated, and to identify problems and advantages with wide-scale use in the context of busy blood service laboratories with other demands on them (i.e. to maintain the blood supply and conduct all required tests efficiently, including for HIV).

9.105 During the pilot, a number of HCV positive donors were identified at the NLBTC. On 21 November 1990, Dr Eddleston wrote to Dr Tedder in respect of those donors, noting '*the need for counselling, and advice, and support for families'* and that such advice should be sensitive to *'the need for balanced advice both about the significance of the test itself and the consequence for the patient and their family'* [**NHBT0000190_043**]. At that meeting was confirmation by several members that better tests were being developed and would shortly be issued.

9.106 On the 29 October 1990, Dr Gunson outlined the results from phase 1 of the Abbott Ortho Comparison Pilot: these were reported on the 21 November 1990 ACVSB meeting **NHBT0000073_01**. It found that there was little to choose between the two tests, and that transfusion centres should be able to determine which they would prefer to use.

Introducing the results at the 21 November 1990 ACVSB meeting, Dr Gunson stated that: '*the results of the supplementary testing would be the decisive factor when considering whether one screening test was better than the other'* [**NHBT0000073_018**].[667] Both Dr Gunson and Dr Mitchell felt that if the results of the pilot study giving 6 true positives out of 10,000 donors were borne out in practice, then counselling would be manageable. However, the minutes record that '*better tests were about to be issued. Dr Gunson said that Ortho had brought out a 2nd generation test and had offered 2500 free test kits'* [**NHBT0000073_018**].

9.107 Dr Gunson also reported that:

> *'…some centres had asked for a 6 month period in which to set up testing. Dr Gunson himself thought this to be excessive, but said he*

[666] Oral Evidence of Dr Huw Lloyd [**INQY1000183**] dated 9.02.22 at [96/8]
[667] Minutes of the meeting of the ACVSB [**NHBT0000073_018**] at [6]

would need to consult with other Directors first. It was agreed that he would hold off consultation until the submission had been put to Ministers' [**NHBT0000073_018**].

9.108 The meeting led the ACVSB to conclude that the UK should introduce HCV testing as soon as practicable. In the HIV litigation, Dr Gunson gave the view that he did not:

'*…believe that [the decision taken on the] 21st November 1990 was one which ought to have been made earlier. The factors which influenced the ACVSB in not making a final recommendation earlier appear from the minutes. But I should emphasise in particular the related problems of false positives, confirmatory testing and donor counselling'.* **[NHBT0000026_009]**[668]**.**

The need for FDA approval was a material factor at this time too.

9.109 Decisions on the national introduction of screening tests were taken by officials following advice from ACVSB [**WITN5711001**].[669] The blood service takes the view that the position taken by Dr Contreras in 1989 that testing should only begin:

a) after FDA licensing,

b) when confirmatory testing became available and

c) once provision for counselling was in place, was the right approach.

Pilot studies were also necessary to determine the feasibility of adding the test to routine practice.

(2) Second generation tests

9.110 Ortho introduced its first second generation test, RIBA-2, for experimental purposes in the autumn of 1990. Abbott also introduced its own second-generation MATRIX in late 1990. Both tests were introduced in early 1991.

9.111 The difference of the Ortho Test from the first-generation test was that the second-generation test had *'more antigens on the solid phase of the microplate of the ELISA'*.[670] These '*not only increased sensitivity but increased detection range, so the ability to detect more types of antibody positive samples'.*[671] The specificity was not known, and the problems with the first-generation test could still apply. But with the supplementary RIBA in place, it was more reliable. The

[668] Witness Statement of Dr Gunson in *A v NBA* dated 3 January 2000 **[NHBT0000026_009]** at [82].
[669] Written Statement of Marcela Contreras at [141]
[670] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [69/13]
[671] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [70/15]

Ortho second-generation test had increased sensitivity and an increased detection range and was the better test to introduce.

9.112 On 7 January 1991, Dr Cash noted that *'HG [Harold Gunson] conveyed his concern that DH has still not decided on a start date. It now seemed probable that May/June 1991 would be the earliest possible'* [**PRSE0002858**].[672] The note goes on to report that *'HG advised that he believes that the major problem for DH was mechanisms for finding the money for NBTS RTCs'.* Concerns about a unified start date were thus linked to the need to secure funding for each RTD from its respective RHA.

9.113 At the ACTTD meeting on 8 January 1991, it was agreed that an information leaflet should be prepared for donors prior to the introduction of routine tests. The issue of donor counselling was discussed [**NHBT0000073_028** and **NHBT0000042_067**].

9.114 On the 22 January 1991, Dr Gunson announced the DoH's position that the '*routine testing of all blood donations for anti-HCV can be put into operation'* and that Dr Gunson had been asked to try and ensure that '*testing starts simultaneously'* [**NHBT0000073_029**]. The letter refers to the need to conclude outstanding financial arrangements **NHBT0000076_006**.[673] The response to the memo from Dr Cash identified the end of June 1991 as a start date for the introduction of HCV tests [**PRSE0002763**].

9.115 A round-robin from Dr Gunson on the 15 February 1991, stated that *'I have now been able to speak to all RTCs and an agreed date for commencement for anti-HCV screening of 1st July 1991 has emerged'.* [**NHBT0000191_077**].[674] This was said to be dependent on a *'reasonably normal blood collection pattern at that time',* and the impact of affairs in the Gulf is noted as a basis on which that date may have to be reconsidered.

9.116 At the ACVSB meeting of the 25 February 1991, the summary of results of Phases I and II of the Abbott Ortho Comparison Pilot were presented and second-generation tests were discussed [**PRSE0002280**]. The ACVSB considered a paper tabled by Dr Tedder, and

> *'…discussed the likely availability of second generation tests and operational factors which might influence the decision by RTCs as to which screening tests to choose. Licensing of the test by FDA had not yet been finalised. Members agreed that it was important for proper*

[672] Notes from [**PRSE0002858**], these are headed 'JDC Notes of NBTS/SNBTS Management Meeting (07.01.1991)'.
[673] Memorandum from Dr Gunson, to the Regional Transfusion Directors England and Wales **NHBT0000076_006** dated 22.01.1991
[674] Letter dated 15.01.1991 identifying the end of June 1991 as a start date and identifyingthat by that date all RTC products should be HCV (screen negative).

> *evaluation of the Ortho and Abbott 1&2 tests to be carried out before RTCs decided which test they would adopt.'*

The ACVSB decided to keep the 10,000 samples from the Abbott Ortho Comparison pilots, as this would be '*important for the evaluation of other candidate HCV tests*'.

9.117 Thus, in February 1991 the ACVSB's view was that the evaluation comparing the first- and second-generation tests should be completed before testing was introduced. This view is reinforced by the Chair's summary: '*Any new test should be evaluated against the full 10,000 specimens to ensure it was at least as good as the tests already evaluated.'* A subsequent memo that appears to be from the DH indicates that this perspective was based on the ACVSB group consensus: '*I understand that the sub-group of ACVSB which worked up the proposal recommended a more modest project concentrated on the 3,500 archived samples from the North London NBTS Centre but that the full group felt that the more extensive study at three centres was required'* [**NHBT0000062_039**].

9.118 For the RTCs in late 1990 and early 1991 the primary issue was securing funding for the introduction of tests, and the operational factors that might influence their introduction, for example the particular equipment available at each RTC.

9.119 The ACTTD meeting of 25 March 1991 discussed the start date for the introduction of tests and concluded that the 1 July 1991 date *'presented difficulties since it was considered essential that the second-generation test from both Ortho and Abbott should be evaluated prior to the commencement of routine tests'* [**NHBT0000073_063**]. This advice, given to the DoH, was the decision in principle that the introduction of testing should be delayed. It was further agreed that RTCs would not perform RIBA or PCR tests and that these would be sent to specialist laboratories. Professor Cash reported of the meeting that:

> *'…Harold Gunson would advise DH that the 1 July start date should be delayed until such time as an evaluation of the new generation of HCV screening tests had been completed. If this is accepted it could push a start date until September'* [**SCGV0000163_053**].

9.120 On 13 May 1991, a draft protocol was produced for a trial of the second-generation Ortho and Abbott anti-HCV tests, including at three RTCs in England and one in Scotland. The RTCs using the Ortho tests were Liverpool and Leeds: those using Abbott tests were Newcastle and Glasgow.

(3) Delay in introducing tests

9.121 Dr Gunson's oral evidence in the Hepatitis C litigation was that the decision to postpone the introduction of testing was not taken either at the ACVSB or the ACTTD. It was taking following '*discussion between myself and Dr Pickles'* [**NHBT0000146_001**]. The summary from that discussion was that '*we are going to have a problem completing these tests by 1 July.'* On 3 April 1991 Dr Gunson sent a letter in relation to the new 1 September 1991 start date [**NHBT0000073_065**], stating:

> *'…It has not yet been possible to commence the evaluation using production batches of the second generation tests referred to above and one of these will not be available until later this month. It is undoubtedly in our interest that this evaluation takes place. However, to complete this study and become operational by 1st July 1991 is too tight a schedule. It is difficult to state precisely a revised date, but I think we should aim to commence routine screening for anti-HCV by 1st September 1991.'*

9.122 A letter from Dr Cash stated that a *'start date in September 1991 has the SNBTS Directors' fullest support'* [**NHBT0000191_133**].[675]

9.123 Routine screening of donor blood started on 1 September 1991. Full details of developments following the introduction of testing, in particular in relation to donor counselling arrangements, are set out in Dr Robinson's written statement [**WITN6926003**].[676]

9.124 The decision to delay the introduction of screening tests after 1 July 1991 to ensure simultaneous introduction across the RTCs was taken by the blood services. This decision was taken for a range of reasons which, at the time, appeared compelling; however, in retrospect the blood services should have ensured in these particular circumstances that the RTCs introduced testing after 1 July 1991 as soon as they felt operationally and financially equipped to do so.

(4) Donor counselling

9.125 The introduction of the screening tests led to discussions about donor counselling. Dr Gillon apparently raised this with both Dr Gunson and Professor Cash in September 1990. On 20 September 1990, he wrote to Professor Cash enclosing the first draft of a report based on '*developing our policies towards donors, and also acting as the background information necessary in the training of counselling doctors'* [**PRSE0004114**]. On the 25 September 1990, Dr Gunson replied to correspondence from Dr Gillon indicating that he wanted to wait for the DH to give the *'go ahead'* to introduce routine screening before convening an ACTTD meeting to define a donor counselling policy

[675] Professor Cash's response to Dr Gunson's letter on 3.041991
[676] Second Written Statement of Dr Angela Robinson [**WITN6926003**] from [247]

[**NHBT0000190_013**] and **PRSE0000515**].[677] The contents of Dr Gillon's guidelines are summarised in Dr Robinson's Witness Statement [**WITN6926003**].[678] A further draft of the guidelines followed, dated 23 November 1990 [**PRSE0000515**].

9.126 On 8 January 1991, ACTTD met to discuss the Gillon guidelines [**NHBT0000073_028 and NHBT0000042_067**]. It was also agreed that donors who had a repeatable reactive screen test at the RTCs would also have ALT tests and serum and plasma samples referred to a reference laboratory, where confirmation of the screen tests would be undertaken. Dr Contreras sent comments from the NLBTC on the guidelines on 21 January 1991 [**NHBT0000051_014**].[679] The guidelines were subsequently redrafted and dated February 1991 [**PRSE0000515**]: on 19 February the *'final draft'* was further considered, and it was agreed '*that the latter pages be used nationally as Guidelines in leaflet form within the RTCs'* [**PRSE0002941**].

9.127 Dr Gillon's guidelines were Appendix 3 to the paper for the 25 March 1991 meeting. This also considered the information to be given to blood donors, and it was decided that should be in a leaflet prepared by Dr Gillon at the next meeting.

9.128 On 8 April 1991 Dr Contreras wrote further to Dr Gillon with her comments on his paper [**NHBT0000044_011**]. This included inputting results from the recent study on the incidence of PTH, and views on the need to include comments about healthcare sector workers. She concluded with a concern about the lack of funding made available:

> '*…it depresses me that we have not received any funding for anti-HCV screening let along counselling of donors confirmed to be anti-HCV positive. I believe that we owe it to our donors to explain the significance of findings and give them appropriate advice, but without funding, we are unable to maintain these high standards'*.

9.129 In sum, the Gillon Guidelines on donor counselling were not concluded until 25 March 1991: however, at this point the blood services did not have funding for anti-HCV screening or donor counselling.

(5) Pilot studies of second-generation tests

9.130 As set out above, the Abbott and Ortho kits were included in the microbiological screening by RTCs in Bristol, the North-West Region and North West Thames Region. Following the introduction of the second generation tests, clinicians gave evidence that it was thought essential to evaluate these tests before the

[677] Letter from Dr Gillon to Professor Cash dated 20.09.1990
[678] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [206-210]
[679] Letter from Dr Contreras to Dr Gillon dated 21.01.1991 with the comments of the NLBTC

introduction of routine screening. In addition, United Biomedical Inc ('**UBI**')[680] had also produced a test which needed RTC-level evaluation. An extension of the original study was therefore set up to split three kits among six RTCs.

9.131 On the 13 May 1991, Dr Martlew sent a memorandum to the members of the Mersey RTC Management Group concerning a three-Centre trial of the second-generation Ortho tests [**NHBT0000015_065**]. The arrangements included that donors found to have repeat positive results would have the antibody test repeated locally, and repeatable positives would be referred to the Public Health Laboratory at Colindale [**NHBT0000015_066**]. The ambition was to begin the pilot by 17 June 1991.

9.132 Many preparations took place for the introduction of tests at the local level, including at North West Thames, Trent and North East Thames, a summary of which is available in Dr Robinson's second witness statement [**WITN6926003**][681]. Practically, some seven centres were *de facto* testing from April 1991[682].

9.133 On 26 June 1991, Professor Allain wrote to all RTDs to propose a national extension to the study [**NHBT0000050_016**][683].

(6) The delay

9.134 A number of reasons have been given for the delay, including the Gulf War: see Dr Cash's advice to Dr Gunson on 24 January 1991 that '*anti-HCV donation testing should not be commenced in the UK BTS until after the Gulf conflict is over* [**NHBT0000073_033**][684]. Further reasons included the need to wait for Dr Gillon's guidelines in relation to counselling donors [**NHBT0000073_021**] and to ensure that issues such as the number of counselling sessions, information on repeat test results, production of a leaflet, referral options for the '*worried-well'* [**NHBT0000051_014**][685] how confirmed positive cases would be treated and '*funding for anti-HCV screening let alone counselling of donors confirmed to be anti-HCV positive'* had been properly considered and prepared [**NHBT0000044_011**].

9.135 A further reason was the '*importance reasonably attached to adopting a common start date for HCV screening'* and the '*great deal of work for the RTCs to do before screening could have been effectively introduced'*

[680] Manufacturers of a further new test
[681] Second witness statement of Dr Angela Robinson at [234-244]
[682] This point was also referred to in *A v NBA* [EWHC] QB 446
[683] Professor Jean-Pierre Allain wrote to all RTDs in England and Wales [**NHBT0000050_016**], copied to Dr Gunson and to Dr McClelland, proposing a national extension to a study that had already been commenced.
[684] Response to Dr Gunson's memo on the 22 January 1991 dated 24 January 1991. Dr Gunson responded on 28 January 1991 [**PRSE0004144**] confirming that an immediate start was entirely impractical.
[685] Dr Contreras letter to Dr Gillon on 21 January 1991 with comments of the NLBTC.

[**NHBT0000026_009**][686]. It is notable that in the letter responding to the introduction many of the RTCs mentioned the complexity of simultaneously introduced cross-charging, which was introduced in April 1991. This removed the issue of who would fund the cost of testing (since it was added to the cost of units to hospitals), but that only became possible after April 1991.

9.136 This process took considerably longer than an equivalent process might take today; it required coordination across 14 different centres, relying on information relayed via letters, meetings and minutes.

9.137 Many clinicians maintained during evidence that there were good reasons to postpone the decisions given the deficiencies of the first-generation test [**WITN6988001**], and the lack of an independent evaluation of its successor. However, there was some acknowledgement that it would have been possible to have had an earlier start date.

9.138 When asked about the start date, and under conditions where funding had been different, Professor Contreras responded as follows:

> *'I do not know whether my -- my thinking at the time and my position at the time, and that of my colleagues, would have induced me to introduce the first-generation test because, as I said, you know, I didn't -- the same as with HIV. I didn't want to create an army of worried well. So -- but perhaps we could have introduced it as soon as their second-generation test had been tried and was available'* [**INQY1000166] [INQY1000165**][687].

9.139 When clarifying what she meant by the 'worried well', Professor Contreras referred to her Witness Statement, which stated:

> '*it is unsafe to inform blood donors of a false positive test that would label them for a lifetime […] as I have said above the false positive rate was seven to one donor who actually had the virus'; therefore we would have to be telling potentially seven people that they might be carrying a virus which they did not have and discarding their blood unnecessarily'* [**WITN5711001**][688].

9.140 The consequences of this position for the blood services should not be underestimated: early introduction of a first generation test based on seven false positives for every true one would not have been a reliable basis for screening. It risked jeopardising the process of screening and timely release of blood and components and creating a huge number of mis-diagnosed donors.

(7) Newcastle early introduction

[686] Dr Gunson's Written statement which is at NHBT0000026_009 to the HIV litigation, response on the question of the delayed start date.
[687] Oral Evidence of Professor Marcela Contreras 03.12.21 [110/17]
[688] Written Statement of Professor Contreras [97/389] [104/415]

9.141 Following Dr Gunson's memo on the 22 January 1991, Dr Lloyd of the Northern RTC at Newcastle wrote to Dr Gunson on the 7 February 1991 stating that *'the Northern Region Blood Transfusion Service would be able to start HCV testing from approximately 1st April 1991. The Company (Abbott Plc) would be able to supply the first generation test by that date without any problems.'* The letter acknowledged that there was an improved second-generation test which had just been released, but Dr Lloyd's evidence emphasises that Newcastle *'were ready to go with the first generation test'* [**INQY1000183**][689].

9.142 Dr Lloyd introduced routine testing with second generation tests on 24 April 1991 [**INQY1000183**][690]. On 2 May 1991, he communicated that he had '*decided to keep to the July [introduction] date*'. In his witness statement, he set out that '*a delay until July dismayed me, and a proposed delay until about 1st September was unacceptable'* **WITN6935001** [691]. He explained that he felt he had to introduce testing earlier, and that deciding not to implement testing despite having the capability '*would be indefensible under the current Product Liability Legislation'* [**NHBT0000074_014**] [**INQY100183**][692] [**NHBT0000191_162**] [**NHBT0000074_014**]. In a letter to Dr Gunson dated 24 June 1991, Dr Lloyd apologised for not having informed Dr Gunson of his intention to introduce a test earlier. He set out that second-generation tests could and should be put into use immediately, in spite of the fact that the evaluation programme of the kits had not yet been completed. In evidence, Dr Lloyd also pointed to his view that despite the Chairman of the ACVSB stressing '*the importance of a common date of introduction [for HCV tests] throughout the UK'* that this view is presented '*without any background information'* [**INQY1000183**][693]. Subsequent objections, including concern about the disparity of funding for HCV testing in the regions by various RHAs, demonstrates the issues relating to disparities between regions which drove this thinking, and the need for a unified approach to donors who tested positive for HCV [**NHBT0000193_097**][694].

9.143 Dr Cash responded on the 7 May 1991, concluding that '*this unilateral action is both disgraceful and mischievous'* [**NHBT0000074_019**]: it was an action undertaken despite the agreed position from the ACVSB that screening should begin simultaneously. Much contemporaneous evidence is available criticising the approach taken by Dr Lloyd. Other RTD directors wrote to Dr Lloyd, including Drs Contreras, Martlew, Boulton and Entwhistle [**NHBT0000074** and **NHBT0000074_033**][695]. Criticisms included that the unilateral approach

[689] Oral evidence of Huw Lloyd [**INQY1000183**] 09.02.2022 [108/1]
[690] Oral evidence of Huw Lloyd [**INQY1000183**] 09.02.2022 [128/24]
[691] Written Statement of Dr. Huw Lloyd [**WITN6935001**] at [147]
[692] Oral evidence of Huw Lloyd [**INQY1000183**] 09.02.2022 [123/17]
[693] Oral evidence of Huw Lloyd [**INQY1000183**] 09.02.2022 [101/5].
[694] Written statement of Dr Robinson [**WITN6926003**]
[695] Letter from Dr Fraser to Dr Lloyd about the early introduction of tests [**NHBT0000074**]. Letter from Colonel Thomas of the Army Blood Supply depot dated 17 May 2022 [**NHBT0000074_033**].

adopted in Newcastle undermined the concept of establishing a National Blood Service [**NHBT0000074_020**][696] (Dr Ala), and with Dr Contreras stressing the issue of funding:

> *'a national approach might well have prompted the Department of Health to provide appropriate funding for testing with all its ramifications such as confirmatory assays, counselling and donor referral. Now, I can see no hope of presenting a united front in pursuit of central funding'* [**NHBT0000192_009**][697]

9.144 In oral evidence, however, Professor Contreras also acknowledged that '*I am really sorry to have written this letter, because I think we could have introduced anti-HCV testing in July.'* When asked whether the blood and transfusion service was prioritising the importance of consensus over considerations of patient safety she stated: '*at the time, I didn't see it as prioritising consensus over safety.'*

(8) Conclusions on testing

9.145 The evidence suggests that the first-generation tests were insufficiently sensitive and specific and that it was appropriate for the blood services to wait until the first-generation HCV tests had been properly field tested. The purpose of field testing was to establish how additional testing could be incorporated safely into existing processes and priorities and blood could be released when needed, and to determine the impact on the blood supply and the RTCs in relation to donor counselling before taking a decision on introduction.

9.146 NHSBT submits that there were compelling reasons for the blood services to delay introduction of testing until second generation tests were available. The second-generation tests were more sensitive and specific than the first-generation tests, and delaying the introduction until the second-generation tests had been FDA approved would reduce the risk of individuals without HCV believing they were infected based on a first-generation test which generated a large number of false positives when no appropriate confirmatory test was available.

9.147 Looked at prospectively and not with hindsight, NHSBT submits that it was reasonable not to introduce HCV screening without the appropriate confirmatory testing. At the time, the sensitivity and specificity of the screening tests in a UK context was unknown; the lack of confirmatory test posed a real risk to the sufficiency of the blood supply, and led to the possibility of a significant number of donations falsely identified as positive being discarded. The issues with the proposed tests were known, and there were concerns

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[696] [**NHBT0000074_020**] Letter from Dr Ala on the poor timing of the decision to commence testing.
[697] Letter to Dr Lloyd from Dr Contreras date 3 May 1991 [**NHBT0000192_009**] paragraphs 188 and 351

about the impacts of a false positive rate which was as high as seven to one, causing significant issues for blood donors. In NHSBT's submission, there were good reasons when the first pilot was complete, and a second generation test had become available to delay introduction until that second-generation test had received FDA approval which hadn't taken place by the ninth ACVSB meeting in February 1991.

9.148 NHSBT acknowledges two principal issues. The first was that once the first-generation test was available, each individual RTC could have more rapidly requested funding from the RHAs in anticipation of its introduction. Secondly, in the context of the virus and testing at this point in time, the blood services should have introduced the second-generation test, once funded, as quickly as was feasible, following FDA approval, and should not have waited for a simultaneous introduction despite the associated advantages.

9.149 That these delays occurred should be viewed in the context of a blood service that was not centrally co-ordinated, that was dealing with challenges around the plasma supply position and self-sufficiency, and against the backdrop of the Gulf War[698]. These factors are not intended to excuse delays, but are identified simply in an effort to explain the thinking and the basis on which relevant decisions were made. A decision to introduce screening before there was a confirmatory test would have been a decision effectively to introduce an 'unreliable' test.

9.150 The blood service witnesses at the Inquiry have consistently expressed regret that HCV testing was not introduced earlier and have apologised to anyone who suffered harm as a result. Further, many have expressly apologised for directing criticism at Dr Lloyd. While blood service witnesses identified that concerns in relation to funding, and the need for creating a comprehensive, streamlined service for the simultaneous introduction of screening, were good reasons, it was also acknowledged that this was not an adequate basis for the delay of testing.

9.151 We note the concession made by Dr Gunson during cross-examination in the A v NBA litigation relating to May 1990. However, there were good objective reasons why introduction did not occur in practice. It was at the seventh ACVSB meeting on 2 July 1990, that it was confirmed that FDA approval had been granted for HCV screening. Nor had any of the tests been piloted and validated for use in each centre. NHSBT therefore do not take the view that May 1990 was the appropriate date for first implementation. Further, we submit that it was a reasonable position at the time to consider it necessary to undertake trials

[698] For the economic and policy impact of the Gulf War see the Written Statement of David Mellor [**WITN7068001**] at [0.6], and the extra workload see the oral evidence of Professor Marcela Contreras on 3.12.21 at [99/18]

and field testing of the tests to ensure that screening functioned properly and safely.

9.152 NHSBT accepts with considerable sorrow and regret that the introduction of HCV testing beyond the 1 July 1991 initially planned start date may well have resulted in some individuals being infected with HCV who would otherwise not have been infected. NHSBT apologises unreservedly for that.

G. Summary of conclusions on HCV

9.153 The lack of laboratory tests and the difficulty of obtaining data on PTH from hospitals made identifying donors with suspected NANBH during the 1970s extremely difficult. During the late 1970s the literature tended to show that NANBH generally caused only very mild liver disease. The dominant view among clinicians running into the 1980s was that NANBH was mild, as reflected in the leading contemporaneous textbooks.

9.154 Even as contrary evidence emerged, it took time to overturn the view that NANBH was, in the main, a mild disease. Even though NANBH's severity was not fully recognized, the blood services still took measures to prevent its spread. It was considered by the early- to mid-1980s the single biggest problem for the blood services to solve.

9.155 This changed with HIV, which absorbed significant resources due to the magnitude of risk involved. By the late 1980s NANBH was understood to give rise to severe chronic disease.

9.156 Surrogate testing, of ALT and Anti-HBc, was not adopted in the UK generally. Raised levels of ALT could be attributable to a range of factors: alcohol intake, obesity and other liver conditions. The blood services considered whether to introduce surrogate tests but concluded that it would lead to the loss of a significant number of donations.

9.157 Further research in the early 1990s confirmed that ALT testing suffered from issues with non-specificity, cost (including of donor counselling) and caused donor loss. The ACVSB supported the blood services' position that its utility was unproven. NHSBT's position is that in the UK, at no time, was there a sufficient medical or scientific basis to justify the introduction of surrogate tests.

9.158 In relation to HCV testing the blood service submits that it was a reasonable and appropriate approach viewed prospectively to begin HCV testing only after (i) after FDA licensing, (ii) when confirmatory testing became available and (iii) once provision for counselling was in place. Pilot studies were also necessary to determine the feasibility of adding the test to routine practice.

9.159 The second-generation tests had increased sensitivity and an increased detection range and were the better tests to introduce.

9.160 For the RTCs in late 1990 and early 1991, the primary issue was securing funding for the introduction of tests and the operational factors that might influence their introduction. It was a UK policy decision to delay the introduction of screening tests after 1 July 1991 to ensure simultaneous introduction across the RTCs. The decision was taken for a range of reasons that, at the time, appeared compelling. However, in retrospect the blood services should have ensured that the RTCs introduced testing after 1 July 1991 as soon as they felt operationally and financially equipped to do so.

9.161 Funding and the process of introducing second generation test were two principal issues at play. Further, the delays that occurred should be viewed in the context of a blood service that was not centrally co-ordinated and was coping with challenges around the plasma supply position and self-sufficiency against a backdrop of the Gulf War. These factors are not intended to excuse delays they are identified simply in an effort to explain the thinking and the basis on which relevant decisions were made.

9.162 While the blood service witnesses identified that there were good reasons in relation to funding, and the need for creating a comprehensive, streamlined service for the simultaneous introduction of screening; it was acknowledged that this was not an adequate basis for the delay of testing.

9.163 Thus, for the reasons discussed above, NHSBT therefore does not take the view that May 1990 was the appropriate date for first implementation. Further, we submit that it was a reasonable position at the time to consider it necessary to undertake trials and field testing of the tests to ensure that screening functioned properly and safely. However, NHSBT accepts with considerable sorrow and regret that the introduction of HCV testing beyond the 1 July 1991 initially planned start date may well have resulted in some individuals being infected with HCV who would otherwise not have been infected. NHSBT apologises unreservedly for that.

10. SECTION 10: HIV LOOKBACK

A. Introduction

10.1 The first significant lookback that NBTS undertook in its history was the HIV lookback from 1985. Such lookback was important to ensure, as far as was possible, the safety and proper treatment of recipients. It was also more broadly important in maintaining the reliability of the blood supply.

10.2 The work of NBTS in conducting the HIV lookback is set out in detail in Dr Hewitt's Lookback Statement [**WITN3101006**][699] ('**Lookback Statement**'). This section of these submissions does not repeat her evidence, but instead draws certain matters to the attention of the Inquiry and reaches conclusions.

10.3 There are two broad types of lookback. Targeted lookback is where the possible recipients of the donation are traced to see if he or she is affected.[700] Reverse lookback is where a patient presents with signs and symptoms of an infection and an investigation takes place to identify whether that patient has ever received blood or blood products (so that any other blood or blood products can be traced to other recipients).

10.4 The language of lookback was not available in the 1980s. Instead, terms like follow up or investigations were used. However, that the language used in the 1990s and subsequently was not used does not mean that the same types of processes were not being undertaken.

B. Lookback prior to the development of tests

10.5 Prior to testing for HTLV-III, it was necessary to conduct targeted lookback and reverse lookback through identification of the clinical symptoms of AIDS. This required reporting of AIDS symptoms to the blood service. On 5 March 1984 Dr Galbraith contacted Dr Gunson at the suggestion of Professor Bloom to arrange a meeting. He proposed to discuss surveillance at that meeting, including ensuring that NBTS had access to all the data that CDSC had available, and to get Dr Gunson's views '*particularly on the problems which may arise when an AIDS patient has previously been a blood donor*'. That meeting occurred on 4 April 1984 and a procedure for surveillance through tracing and lookback was agreed between Drs Galbraith, McEvoy and Gunson [**CBLA0001833**]. That procedure is set out in full and commented upon by Dr Hewitt in her Lookback Statement [**WITN3101006**].[701]

10.6 Considering the level of medical knowledge, and the apparent prevalence of AIDS in the UK at the time, NHSBT submits that its extent and approach was

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[699] Lookback Statement of Dr Patricia Hewitt [**WITN3101006**] dated 26.09.21 responding to the R9 request of 14 August 2020 directed to NHSBT

[700] See the Written statement of Dr Angela Robinson at paragraphs 263 to 264 for further details of the different types of lookback [**WITN6926003**].

[701] Lookback Statement of Dr Patricia Hewitt [**WITN3101006**] at [150-151]

appropriate. It provided for both targeted lookback and reverse lookback, covered components and products (through referring matters to Dr Lane), and provided for onwards transmission of information to treating relevant clinicians that had a treating relationship with the patient [**DHSC0002245_002**].[702] It would appear the blood service itself was to manage the recall, interview, and medical examination of donors at the discretion of the relevant RTD [**DHSC0002251_011**].[703]

10.7 References to the precise procedure are lacking in the document, but clearly lookback did occur. In respect of Factor VIII batch HL3186 this was targeted lookback. Not all details are present in the report at [**PRSE0001658**], but some of the steps mandated by the procedure in [**CBLA0001833**] were undertaken. Thus, lookback was being undertaken in this period.

C. Lookback following the development of tests for HIV

10.8 The development of HIV testing is explored in the section of these submissions directed to HIV. As tests were reviewed for introduction into NBTS discussions of an approach to lookback began. The issue of '*follow up of earlier positive donations*' was raised at a meeting of EAGA on 10 June 1985 [**NHBT0000186_033**] and explored further by the working party of the RTDs on the screening of blood for HIV in a report of 11 July 1985 [**PRSE0000832**].[704] In respect of follow up, the procedure adopted was:

> *'7.1 Efforts will be made to determine the names of any patients who received blood and components form the donations taken during the past five years and the information regarding the known or possible seropositivity of the donation given to the Consultant in charge of the patient.*
>
> *7.2 If plasma from any of the donations was sent for fractionation, full follow-up of all patients receiving coagulation factor concentrates may be difficult or impossible. Since patients suffering from haemophilia A and B are being investigated for anti-HTLV III at present, it is recommended that no additional follow-up be carried out.'*

10.9 The difficulties of undertaking something approaching a lookback for fractionated products was an issue that the HCDs had previously grappled with. On 30 November 1984 Dr Craske wrote to HCDs and noted (emphasis in original):

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[702] It would appear Dr Gunson took the advice of the MDU on the route to informing a patient about the giving of '*at risk*' blood [**DHSC0002245_002**]. The prospect of the DHSS setting up a working group to advise on this was noted

[703] Follow-up with donors and patients was explored further over the coming months. By 27 November 1983 the Advisory Committee on the NBTS was advising donors with positive results should be informed. It was noted the issue was *'very difficult and complex*'. The matter was still being considered by IMCD [**DHSC0002251_011**]

[704] With corrigendum [**PRSE0002402**].

> *'We have therefore concluded that retrospective studies of clusters of patients will usually fail to correctly identify batches of factor VIII contaminated with HTLV-3 unless a large number of persons are transfused and the proportion infected is high.'* [**HCDO0000392_107**]

10.10 Thus, the procedure in paragraph 7.2 of the EAGA report cited above was a compromise which effectively took the most efficient route towards identifying those recipients of coagulation factor concentrates who had been infected. In her evidence, Dr Hewitt was unsure whether RTCs would have passed on knowledge of an infected donor to BPL at the time [**INQY1000170**].[705] While the evidence is unclear, in our submission this is likely to have been the case. To not do so would have been a step backwards from the procedure in [**CBLA0001833**]. Further, by 1985 BPL was stockpiling plasma. Thus, it is likely RTDs would pass on the information to at least afford BPL the possibility of disposing of at-risk blood from that stockpile.

10.11 The matter of follow up continued to be discussed, being raised at the EAGA meeting on 30 July 1985 (where the above paper from the Screening Sub-Committee was discussed). Among other matters, the committee agreed that the follow up of donations should go back a minimum of 5 years from the date of donation [**PRSE0002628**]. At the next EAGA meeting on 26 November 1985, Dr Tedder on behalf of Dr Contreras asked that patients instead ask whether they had donated since 1978. The matter was put off to the following meeting [**DHSC0002287_060**]. At the next meeting on 11 March 1986 when the matter was raised Dr Harris said that the matter would be addressed in the next CMO letter [**DHSC0000833**]. In that CMO letter of 23 April 1986 Dr Acheson wrote:

> *'I would like to take this opportunity to ask you to enquire with any of your patients found to be HTLV III antibody positive if they have ever donated blood. If so it would be helpful to discuss this in an appropriate confidential manner with your Regional Transfusion Director.'*

10.12 In her oral evidence Dr Hewitt explored the issue of targeted lookback and the difficulty of identifying donors that had self-excluded [**INQY1000170**].[706] When asked whether such individuals were subsequently identified through other means and targeted lookback undertaken, Dr Hewitt explained that it did happen but '*infrequently*'. Of course, that lack of frequency may be a function of there being a relatively small number of people in the period who (1) tested positive for HIV; and (2) had previously given blood. Dr Hewitt gave a broader explanation of how lookback was undertaken at North London **INQY1000170**].[707]

10.13 The blood service did consider further work to try and identify donors that had donated blood but subsequently self-excluded. Dr Wallington advanced a

[705] Oral Evidence of Dr Particia Hewitt [**INQY1000170**] dated 09.12.2021 at [169/2]
[706] Oral Evidence of Dr Particia Hewitt [**INQY1000170**] dated 09.12.2021 at [172/13]
[707] Oral Evidence of Dr Particia Hewitt [**INQY1000170**] dated 09.12.2021 at [174/14]

study, one aim of which was to further identify possible infected donors and recipients. This study had, however, had difficulties with ethical committees (as was discussed at the RTD meeting on 8 October 1986 [**CBLA0002345**][708] and faced delay. The study is discussed in detail in the Dr Hewitt's Lookback Statement. [709] An explanatory letter for the study from Dr Ala explains:

> *'In the Transfusion Service we feel that it is important to identify as many as possible of the recipients of potentially infectious donations…*
>
> *Some recipients have already been investigated as a result of anti-HIV screening which was introduced in 1985. You may have been involved with one of these. More will be identified in this way. In addition, we are seeking the collaboration of various specialists concerned with the care of patients at high risk of contracting HIV in identifying those who were blood donors before screening was introduced and retired voluntarily once the risks were publicised.'* (emphasis added) [**NHBT0045995_005**] [710]

10.14 The documents available on Dr Wallington's study appear to be limited. However, a meeting on the ex-gratia payment scheme noted the following:

> *'During 1987, Dr Tim Wallington, Bristol RTC undertook a look back study, and was able to trace recipients from only one third of seropositive donors due to resistance from consultants and ethical committees. Clinical opinion about the potential benefits of early diagnosis of HIV was now changing and this together with the potential for payments to the patients concerned should lead to greater cooperation.'* [**DHSC0002941_006**].[711]

10.15 Indeed, Dr Wallington's scheme appears to have various difficulties that delayed its implementation and made auctioning more difficult. The ethical difficulties noted above can be seen in the minutes of the RTD meeting on 8 October 1986 where the ethical committee at Southmead Hospital rejected consent and two physicians on the panel said that '*in no circumstances would their patients be approached*' [**CBLA0002345**]. Local resistance was noted by Dr Martlew in her memo to Dr Gunson 26 May 1987 [**NHBT0004200**]. Also, in that memo she noted that funding issues, particularly in GUM clinics, would make it difficult to obtain consent from consultant colleagues.

D. HIV Lookback in the early 1990s

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[708] These minutes also include an important discussion by the RTDs of informing patients of at risk blood against the views of the treating clinician, and the fact that the death of a recipient was not necessarily the end of the story (see Lookback Statement of Dr Patricia Hewitt [**CBLA0002345**] at [pg191-193]

[709] Lookback Statement of Dr Patricia Hewitt [**WITN3101006**] at [196-204]
[710] The letter goes on to discuss informing recipients
[711] A meeting of the Department of Health, CDSC and NBTS on 21 February 1992

10.16 HIV lookback continued to be undertaken in the early 1990s. Available documentary evidence is set out in Dr Hewitt's Lookback Statement[712]. Procedures at this time were marked by a lack of consistency between RTCs, indicative of the fact that the National Directorate could not mandate policy. Dr Hewitt noted: '*this reflects the fact it was not a national organisation*' [**INQY1000170**].[713]

10.17 One limitation of lookback undertaken in this period appears to be that there was no general policy of following-up possible window period donations (that is, the case of a seronegative donor that is subsequently found to be seropositive). The extent of this limitation on lookback is not clear. In a report on HIV dated 19 February 1990 Dr Gunson noted that such lookback had '*not, in general, been carried out*' [**NHBT0015578_001**]. However, that report does indicate one such case was identified in Glasgow where two recipients were infected. Dr Hewitt in her evidence noted that she was '*very surprised*' that this was the case, as it '*definitely… was something we did in North London*'[714].

10.18 Dr Gunson's paper of 6 March 1990 was discussed at a meeting of EAGA on 6 March 1990. While there had been a study of such possible window donors for six months in 1987 (apparently referring to Dr Wallington's study), the study had not been repeated and the approach was not generally adopted [**NHBT0008216_002**]. However, the report of Dr Mortimer dated 11 September 1990 provides detail on lookback to 1989 **[NHBT0015574_002]**[715]. As part of the report, she considered 39 donations by subsequently positive donors given after the introduction of testing. She noted that '*[f]or those about whom further information had been supplied, no sero conversions had been observed in the recipients*'. However, Dr Mortimer noted that follow-up was not complete due to deaths, difficulties identifying recipients, and reluctance to alarm patients.

10.19 Dr Mortimer also noted of the processes that had been undertaken than there were '*differences in follow-up capacity and practice between centres; computerised records can be a limitation*'. She explained that while some had pursued every identifiable donation, others had curtailed lookback when they identified a negative recipient or the donation pre-dated infection. Gaps between regions were also noted. She suggested further uniformity was desirable and suggested, among other things:

> *'2) That wherever possible look-back continues retrospectively through the previous donations until either a) all have been investigated, or b) an anti-HIV negative recipient is identified, unless there is any doubt*

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712 Lookback Statement of Dr Patricia Hewitt 26.09.21 [**WITN3101006**] at [from 206]
713 Oral Evidence of Dr Patricia Hewitt [**INQY1000170**] dated 9.12.2021 [191/22]
714 Oral Evidence of Dr Patricia Hewitt [**INQY1000170**] 9.12.2021 [190/7]
715 NHBT lookback paper for period October 1985-December 1989 produced by Dr Mortimer dated 11 September 1990 **[NHBT0015573_002]**.

about the accuracy of the record keeping which makes further look-back desirable.

3) That look-back should be applied in the same way to all donors, however discovered to be anti-HIV positive, and not only to those identified by donation screening.' **[NHBT0015574_002]**[716]

10.20 It would appear this paper, or something similar, was examined at the meeting of EAGA on 2 October 1990. The committee concluded:

'While accepting the limitations members considered that the lookback study was very important and should continue. Members agreed to the proposed uniform procedure for follow-up but recommended that previous donations should be investigated until two anti-HIV negative recipients had been identified rather than just one as proposed by Dr Mortimer.' **NHBT0008213_002**

10.21 Recommendation 2 resolved the inconsistencies in practice surrounding window donations as it tied the end of lookback to investigating all donations or identifying negative recipients. Indeed, in a report of Dr Gunson and Ms Rawlinson dated January 1991 [**NHBT0006883**] it was noted that attempts to follow up '*patients receiving blood from previous seronegative donations of donors found seropositive*' was ongoing, but there was '*limited success'*. At this time one such case had been identified. The reasons for these difficulties were linked back to Dr Mortimer's report of the previous year.

E. Widening of the HIV payment scheme

10.22 On 30 April 1992 the CMO announced an extension to the ex-gratia HIV payment scheme [**OXUH0001251_004**]. On 11 May 1992 Dr Gunson wrote to all RTDs asking them to send a list of all donation numbers from confirmed positive donors, with dates of delivery, to consultant haematologists at hospitals. It was noted that this extended to deceased recipients due to the scope of the scheme. Correspondence exists indicating that these steps were undertaken: for example from Drs Ala [**NHBT0015106**] and Hewitt [**NHBT0015104**].[717]

10.23 In a letter from 19 May 1995 Dr Robinson provided a summary of the history of HIV lookback and her understanding of how it was undertaken. She noted that the initial process was '*not completed very well*' initially but it was '*pursued energetically 1992 onwards'* [**NHBT0003037_001**].[718]

F. The practical experience of undertaking HIV lookback

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[716] NHBT lookback paper for period October 1985-December 1989 produced by Dr Mortimer dated 11 September 1990 **[NHBT0015573_002]**.
[717] Dr Patricia Hewitt records the work that she did in her Written Statement at [236].
[718] Letter sent by Dr Angela Robinson to Professor S R McCann summarising her recollection of lookback in the UK.

10.24 The HIV lookback marked the first structured attempt to trace possibly infected donors in the history of the blood service. It was shot through with difficulties caused by organisation, resistance by ethical committees, resistance by treating clinicians, funding, and record keeping. Dr Hewitt noted the practical difficulty at the time of identifying a GP (which could not be done through a centralised database)[719] and the resistance of some treating clinicians once they were successfully contacted. In many respects the RTCs were '*effectively dependent upon clinicians in hospitals co-operating with… requests for information, in order to complete the look-back exercise*'**INQY1000170**][720] This was especially so in the 1980s when there was no treatment for HIV, which is a reason to understand treating clinicians as resistant to the scheme (e.g. the strong resistance to Dr Wallington's scheme).

10.25 While Dr Hewitt noted that cooperation of clinicians was not a problem at North London, she recognised overall that the force of the CMO letter from 1992 assisted considerably [**INQY1000170**].[721] In this respect, while there was a CMO letter asking clinicians to report possible infected donors to RTCs on 23 April 1986, this was framed as a request that the matter be discussed with RTDs. The 1992 CMO letter was significantly more forceful and set out the position in full.

G. Effectiveness of HIV lookback

10.26 Documentary evidence from the time indicates that HIV lookback was difficult. A report from June 1988 of Dr Hewitt and others explains that it was '*time-consuming*' and *'[h]ospital records are often deficient*'. In that report Dr Hewitt considered that:

> *'The benefit produced by these enquiries has been little, but 3 blood recipients have been identified as seropositive and spread to their sexual partners possibly averted.'* [**NHBT0057880**][722]

10.27 In her evidence Dr Hewitt recognised that, for those three recipients, they did benefit from lookback and the comments was '*not very wise*'. What this does appear to reflect is the frustration that RTDs felt in the difficulty of undertaking the scheme which identified relatively few recipients with considerable resources required. Similarly, in a report from mid-1993 the issue of recordkeeping remained a problem:

> *'Investigations failed to reveal any infection arising after screening of blood donations commenced in 1985. Overall, 42% of identifiable recipients died within 6 months of transfusion. Eight of 32 (25%) living recipients were*

[719] Oral Evidence of Dr Patricia Hewitt 9.12.2021 [187/5]
[720] Question posed by Counsel to the Inquiry with which Dr Hewitt agreed. Oral Evidence of Dr Patricia Hewitt 9.12.2021 [198/18]
[721] Oral Evidence of Dr Patricia Hewitt 9.12.2021 [199/2].
[722] The difficulties with look-back exercises were exemplified in a study by Dr Hewitt, Dr Moore and Dr Barbara which was discussed at the IV International AIDS conference in June 1988 in Stockholm.

> *infected with HIV and 5 of these were newly detected through investigation. Laboratory record keeping was generally deficient prior to 1985; accurate recording of transfusion details in patient medical records remains a conspicuous problem up to the date of the report. The investigation confirms the exceedingly small chance of transmission of HIV by transfusion of screened blood and blood components in the United Kingdom.'* [**DHSC0006351_032**].[723]

10.28 This report reflects the fact that lookback continued to identify infected recipients. However, there was an exceedingly small chance of transmission following screening of blood and blood components. The fact remained at this stage that record keeping was a significant difficulty which impacted the scheme's success.

10.29 Such difficulties appear to have been experienced globally in undertaking HIV lookback. An important paper by Busch[724] considered the US case and stated the: '*overall yield and efficacy of HIV lookback programs were poor*' [**PRSE0004329**]. He noted that targeted lookback was limited '*ironically, by the effectiveness of early self-exclusion measures*'. He noted:

> *'Thus, even in San Francisco, where lookback probably has been pursued more aggressively than anywhere else in the world, a substantial portion of HIV-infected transfusion recipients are undoubtedly still unaware of their infection more than 6 years after screening was implemented.'*

10.30 With these difficulties in mind, we submit that the HIV lookback was broadly an appropriate approach to achieve the aim of identifying possibly infected recipients, and to maintain the reliability of the blood supply. In our submission, considering these difficulties, the scheme was appropriate and effective. While the scheme had some problems, in made proper attempts to meet its aims, and was hampered by circumstance. It is disappointing that outside factors, and particularly record keeping, made lookback a difficult endeavour for RTDs.

[723] Report from Dr Patricia Hewitt to CDSC dated July 1983.
[724] Cited in the lookback Statement of Dr Patricia Hewitt 26.09.21 [**WITN3101006**] at [221]

11. SECTION 11: HCV LOOKBACK

A. Introduction

11.1 The submissions below identify the efforts made by the blood services to trace infected blood and blood products in respect of HCV. The two broad types of lookback, being targeted and reverse, are explained in the section on HIV lookback at Section 10 above.[725]

11.2 Factors that affect the effectiveness of a targeted lookback include the length of time during which the infectious agent was present before it was identified, the virulence of the infectious agent, the effectiveness of screening to exclude 'at risk' donors and the number of recipient patients traced and found to be alive which is inversely proportional to the time elapsed between transfusion and lookback.

11.3 Other issues in relation to lookback include that not all components are transfused, inadequate or non-existent hospital records hinder the tracing of transfusion, donors lapse and contact details held by the blood services are out of date, as donors move house, emigrate, marry and change names.[726]

B. The duties of the blood service in relation to lookback

11.4 NHSBT has long realized that it owes a duty of care to blood donors and considers that the Hippocratic Oath applies to both donors and recipients. A duty of care arises where the blood service becomes aware, following targeted lookback, that a recipient of blood or blood products may be at risk of a TTI from an infected donor. The blood service therefore has:

> *'…a duty to maintain appropriate records to enable effective lookback to take place. It must assist with the process of the identification of affected recipients. It may discharge its duty by bringing any concerns related to the recipient to the attention of the medical practitioner caring for the recipient, so that they can be provided with appropriate treatment and / or counselling, or it may be involved in imparting that information, as was often the case during the HCV lookback'.* [**WITN6926003**][727]

C. History of Early Lookback Efforts

11.5 Dr Hewitt's Witness Statement sets out the history of jaundice inquiries in full [**WITN3101006**].[728] It describes how HCV lookback has been ongoing since the first Jaundice Inquiries. These were initiated following a situation where a

[725] Also see [**PRSE0004329**] for details of the primary differences between HIV and HCV lookback.
[726] Details of this list are set out in full at [269] of the Written Statement of Dr Angela Robinson [**WITN6926003_0101**]
[727] Second Written Statement of Dr Angela Robinson [**WITN6926003**]
[728] Written Statement of Dr Patricia Hewitt [**WITN3101006**]

patient was identified to have contracted jaundice administration of a transfusion.

11.6 Dr Hewitt explains that, in 1943, a memo identified that often by the time jaundice had been detected it was difficult to work out the source of the infection: '*very few clinical notes are available [and difficulty of judging whether serum from any given batch was or was not a factor in the subsequent development of jaundice'* **NHBT0000091_011** [729]. The memo states that that the prevention of subsequent infections will depend on:

> *'…the identification and withdrawal of icterogenic batches of serum and plasma' and that it will depend on 'the care with which batch numbers are recorded at the time of transfusion, and on the speedy notification by practitioners to transfusion officers of causes of jaundice following, after a long interval, the injection of blood products.'*

11.7 From 1946, as Dr Hewitt describes, it was identified that precautions should be taken by doctors in administering blood and blood products due to the risk of jaundice. This was on the basis that blood and blood products may be over administered as '*no doubt quite a lot of plasma is given not from clinical necessity but from clinical convenience'* **DHSC0100008_189** [730] and that '*the use of dried plasma is followed by the development of jaundice in about 10% of those receiving it. This incidence is probably halved in plasma is used which is made from plasma pools derived from the blood of only ten donors.'* [**DHSC0100008_191**].

11.8 By 1947 there was no method '*of detecting an individual capable of transmitting jaundice in his blood'* and therefore the focus was to ask each donor if they had '*recently suffered from jaundice'.* Following the report of 78 cases of haematogenous hepatitis in the 18 months running to January 1948 Dr Maycock chaired a meeting of the RTCs in which he '*emphasized the need to establish a reporting system and emphasized the risk of using plasma'* [**INQY0000310**].[731] From the late 1940s therefore the blood services were systematizing the process of identifying potentially infected blood.

11.9 Throughout the 1940s lookback was conducted by the RTCs. One example cited in the Presentation Note on Early Lookback Investigations was a survey of cases of '*suspected homologous serum jaundice'* [**DHSC0100011_006**].[732] At this stage, the issue was raised of clinicians failing to report or

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[729] Memorandum prepared by Medical Officers of the Ministry of Health' published in The Lancet entitled 'Homologous Serum Jaundice'

[730] 13 August 1946, Dr Robb-Smith at the Radcliffe Infirmary, Oxford, wrote to Dr Panton at the Ministry of Health advised that at a recent meeting of the Association of Clinical Pathologists, Dr J Vaughan had presented a paper on the follow-up of plasma and blood transfusions for development of jaundice

[731] Note following letter by Dr Robb-Smith summarising the situation as of 22 August 1946.

[732] 25 October 1949 report completed by Dr G.D Lewis on behalf of the National Blood Transfusion Service for Wales

underreporting cases of post-transfusion hepatitis [**DHSC0100009_103**].[733] Simultaneously, RTC officers wrote to hospitals highlighting that '*hospitals are strongly advised to use blood rather than plasma wherever possible, until the problem of producing a plasma free from this risk has been solved'* [**DHSC0100008_212**]. In addition, were concerns at this time that doctors did not appreciate that both '*plasma and serum carry a risk of homologous serum jaundice',* alongside the need for the medical profession to recognize the dangers of the indiscriminate use of blood and the need to have cases reported to the RTCs so that '*bottles of suspected icterogenic batches can be withdrawn'* [**DHSC0100009_066**].[734]

11.10 In 1952 Dr Maycock wrote to inform the RTCs that the WHO had recommended excluding donors who had had jaundice at any time [**DHSC0100011_202**]. Further developments during the early 1950s included the identification of cases of cirrhosis of the liver following homologous serum jaundice [**DHSC0100011_202**].[735] The WHO met to consider the issue in 1952 [**RLIT0000215**][736] and its report concluded that:

> *'…the dangers of serum hepatitis are not appreciated by many sections of the medical profession, largely owing to the long incubation period which conceals the relationship between a transfusion and subsequent hepatitis.'*
>
> The same committee also encouraged recipients to be given a card that explained that:
>
> *'…jaundice sometimes occurs as a late complication of the treatment and that if it should occur at any time up to 160 days after the treatment he should visit his own doctor or the hospital'.*

11.11 The issues with managing viruses at this point were summarized in a letter from Dr Maycock on 27 October 1953 **DHSC0100011_238** and included that there was relatively little known about the hazards, no methods to detect individuals with jaundice but evidence that they may infective for long periods during which they may be 'well'. The blood services must take care '*not to accept as donors, people whose blood may transmit such diseases'.*[737] In the early 1950s newspaper articles covered issues associated with blood transfusion and jaundice [**DHSC0100012_013, DHSC0100012_022, DHSC0100012_020, DHSC0100012_021**].[738]

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[733] 1 December 1947 – Regional Transfusion Officer letter to Dr Maycock at the Ministry of Health about a case of jaundice following a plasma transfusion at Booth Hall Hospital, Manchester
[734] Dr Maycock letter to Dr Clegg editor of the British Medical Journal
[735] Dr Maycock wrote to Dr R Bevan, Cardiff Regional Transfusion Centre
[736] Group convened by the Third World Health Assembly
[737] Written statement of Dr Patricia Hewitt **[WITN3101006]** at [pg57]
[738] See Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [58-59].

11.12 In the late 1950s there were initial ad-hoc efforts to conduct lookback [**WITN3101006**][739] - this includes 17 May 1957 when Dr Drummond wrote to Dr Maycock stating that the Cardiff RTC was to proceed to follow-up recipients of blood from donors implicated in serum jaundice cases.

11.13 In the 1960s, following a letter detailing a haemophiliac patient who was treated with cryoprecipitate and then died two months later [**PRSE0003714**], the need to '*re-emphasize the potential danger of cryo'* was recognized.

11.14 By 1970 only three surveys, had been undertaken to determine the incidence of icteric hepatitis after transfusion of blood:

> *'- Spurling et al (1946) BMJ 2 409 – 1114 patients surveyed, no cases*
>
> *- Leanne et al (1949) BMJ 2 572 – 2796 patients surveyed, 22 cases (0.8%)*
>
> *- MRC Survey (1954) The Lancet 1 1328 – 2538 patients surveyed, 4 cases (0.16%)'*[740]

1. Lookback during the 1980s

11.15 In the 1980s, there was a system for Jaundice Enquiry ('JE'). A JE took place where a clinician had reported that a recipient of a transfusion had post-transfusion hepatitis. Enquiries would be made subsequently into what had happened [**INQY1000176**].[741] During this period the blood services were trying '*to encourage the hospitals we supply to report <u>all</u> PTH [post-transfusion hepatitis] in the hope we can get more information about non-A, non-B as a cause of PTH'* [**INQY1000176**].[742]

11.16 Examples of identified recipients of NANBH before the screening test was introduced are set out in the Witness Statement of Dr Robinson at paragraph 50 – 51 [**WITN6926001**]. This included a patient with hepatitis following blood transfusion **NHBT0018464_005** and a patient with von Willebrand's disease in June 1987 [**NHBT0054312_014**]. The issues encountered during these ad-hoc lookback exercises that flowed from the fact that the blood service does not have a direct therapeutic relationship with patients were set out in a letter of 7 June 1990 to Dr Gunson [**NHBT0000189_148**].

D. Delayed National Lookback Exercise

[739] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [60]
[740] Section of Experimental Medicine and Therapeutics, Epidemiology of Virus Hepatiits, Meeting June 9 1964, Dr W d'A Maycock – Transmission of Hepatitis by Blood and Blood Products. See: ://www.ncbi.nlm.nih.gov/pmc/articles/PMC1898162/pdf/procrsmed00202-0063b.pdf
[741] Oral evidence of Professor John Barbara [**INQ1000176**] dated 26.01.2022 [14/23]
[742] Oral evidence of Professor John Barbara [**INQY1000176**] dated 26.01.22 [17/1]

11.17 A national lookback exercise was discussed as early as 9 June 1989 where it was concluded that it would not be introduced:

> *'Because of the enormous effort involved and lack of cost-effectiveness, we would not attempt to follow up the recipients of surrogate marker positive donations even though the ethical committees had only withheld permission for checking the recipients of the donations tested during the study, and not the recipients of previous donations from 'surrogate-positive donors'. Although valuable scientific information might be derived from look back, this might constitute the basis of a separate study for which ethical permission and funding would be needed'* [**NHBT0000076_037**].

11.18 Dr Gunson wrote to Dr Cash on 21 May 1990 commenting that RTCs should continue to conduct reverse lookback when a transfusion-associated NANBH case was reported to ensure that a library sample of serum was retained from each donor [**NHBT0000076_037**].

11.19 On 27 June 1990, the NBTS/SNBTS liaison committee attended by Drs Gunson and Cash considered Lookback programmes for HCV. It was viewed that '*whilst tests and policies are evolving it would not be appropriate to establish a lookback policy and that ACVSB should take a view in due course'* [**ARCH0002031_008**].[743]

11.20 Developments during the autumn of 1990 are set out in the Witness Statement of Angela Robinson at paragraphs 316 – 321 [**WITN6926001**].

11.21 Dr Contreras sent a memo on 17 December 1990 [**NHBT0000052_003**] stating that there should be a lookback exercise, however this was prior to the formal introduction of HCV testing. This shows how fragmented the blood services was at this time and demonstrates that to undertake an exercise of this type additional funding would be necessary.

11.22 NHSBT's submissions in relation to HCV testing are contained at Section 9(M). These cover Dr Gillon's report on donor counselling, which appears to have assumed that lookback would be performed as they were based on the equivalent HIV processes which included lookback [**WITN6926003**].[744]

11.23 In August 1991 it was agreed that an ad hoc committee to make decisions on lookback should be formed by the ACTTD [**NHBT0000062_096**].[745] Lookback was next considered on 13 September 1991 [**NHBT0000044_046**].

11.24 The chronology set out by Dr Robinson at paragraphs 350 – 355 which is not repeated here shows that it is not until 18 January 1994 that lookback on

[743] Minutes of NBTS, NBTS/SNBTS Liaison Committee 1st meeting at National Directorate, 27.06.1990 [**ARCH0002031_008**]
[744] Written Statement of Dr Angela Robison **[WITN6926003]** at [334]
[745] Minutes of the ninth meeting of UK Advisory Committee on Transfusion Transmitted Diseases.

recipients of blood from donors subsequently shown to be anti-HCV positive was next discussed. It was raised at Standing Advisory Committee on Transfusion Transmitted Infections ('SACTTI') due to the '*potential benefits of interferon + ribavirin treatment'* [**NHBT0000088_006**] for those infected with HIV.[746]

11.25 In contrast, when anti-HCV screening of blood donations was introduced in September 1991, a lookback programme was not recommended. Doubts about the long-term effects of HCV infection, coupled with the lack of an effective therapy for individuals so infected due to a lack of hepatologists able to give advice and patient confusion between HCV and HIV alongside the fact that early tests produced a high number of false positives [**NHBT0000190_055**] appear to be the main reasons behind this recommendation [**NHBT0005794**].[747] This is consistent with the view taken by Dr Robinson at paragraphs 289 – 291 of her Written Statement [**WITN6926003**].

11.26 It was also considered to be '*illogical to fund counselling since this could not be effectively carried out without confirmatory tests'* [**NHBT0000193_097**]. Nor was there significant evidence of post-transfusion infection during the period following anti-HCV screening in 1991. HCV infection was rarely symptomatic and transfused patients were not systematically tested for ALT or anti-HCV [**NHBT0000073_071**]. Other issues raised in the context of lookback in the USA include the finding that lookback would be

> '*enormously cumbersome and expensive and would also be ineffective for the same reason as the HIV lookback programme: the vast majority of infected former donors would already have been deferred or excluded from donation by the 'surrogate' measures in force long before the anti-HCV test became available'* [**WITN6926003**].[748]

11.27 Issues with the provision of counselling continued throughout the early 1990s, when the NBA was established the treatment and / or counselling of those infected by TTIs was not included within the NBA's statutory functions [**WITN6926003**].[749] Further issues raised about the practicality of lookback include Professor Tedder's concerns about the guidance under which a RTC would notify the fractionation centre should a donor become implicated in an episode of post-transfusion infection [**NHBT0000088_005**]. SACTTI met again in April 1994 where the conflicting impressions of the effectiveness of antiviral treatment for HCV infected patients and the cost-effectiveness of such treatment were discussed [**PRSE0000986**].

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[746] The Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) Meeting on 18 January 1994 [**NHBT0000088_006**] note at paragraph 11.
[747] Recommendations of the Standing Advisory Committee on Transfusion-Transmitted Infection to the MSBT Concerning the Merits of Adopting a HCV 'Lookback Policy'
[748] Written Statement of Dr Angela Robinson [**WITN6926003**] at [271]
[749] Written Statement of Dr Angela Robinson [**WITN6926003**] at [40]

11.28 Dr Martlew confirmed in her oral evidence that one of the reasons for the delay in lookback for HCV was that no treatment was available:

> *'…it would have been easier probably to do at the outset [in 1991], nearer the first screening run, I think, and the only downside of doing it, of course, is that you'd have to tell the recipients that they'd got hepatitis C and, apart from, you know, lifestyle, on a lot of occasions, at that time there was no treatment. I think that's why it wasn't done.'*[750]

11.29 During the period between 1991 and 1994, some centres followed-up anti-HCV positive donors. For example, Birmingham RTC conducted a follow-up of anti-HCV positive donors [**NHBT0000088_005**]. The approach taken was broadly in line with the national lookback programme in 1994. The Edinburgh Pilot Study is detailed at paragraphs 359 – 370 of Dr Robinson's witness statement [**WITN6926003_0133**].

11.30 During this period NHSBT and the NHS was also dealing with significant other competing demands on expenditure, including anti-HBc testing, HTLV-1 and -11 screening, screening for bacterial infection of blood components and quarantine of clinical FFP.

11.31 NHSBT is aware of the report from MSBT [**NHBT0005791**] which notes that there may be legal implications of instituting '*an HCV Look Back Programme 4-5 years after introducing the blood donor HCV antibody screening programme.'* The Committee at that time decided to proceed with a lookback programme. The minutes of that meeting identify that treatment (with Interferon) was still unlicensed with serious side effects and that: '*Despite these reservations, it is recognized that there is a duty of care that needs to be exercised towards these patients and the implicated donors.'*

11.32 NHSBT is aware of the letter written by the Scottish Office to SNBTS on 22 December 1994 relating to the need to expedite the HCV lookback exercise. The reasons referred to in that letter for the delay in instigating lookback include that:

> *'look back had not, until now, been conducted partly out of concern that it would be impossible to identify all recipients of infected blood and even if it were possible, there was a lack of accepted treatment that would be beneficial. It was accepted that if no effective treatment was available, informing patients who were unaware of their situation could not be justified, since this would cause further distress and anxiety without any benefit.'* [**PRSE0000661**].

11.33 Thus, one of the main reasons for not initiating lookback sooner was the fact of the absence of any treatment for the condition which could remain asymptomatic for many years. This, in the view of many at the time, would have

[750] Oral Evidence of Dr Vanessa Martlew [**INQY1000174**] dated 20.01.2022 at [95/8]

led to individuals being given potentially devastating news with no hope and no way of telling how the disease might present. The availability of a possible treatment changed that position.

E. Preparations for National Lookback Programme

11.34 Minutes of the SACTTI meeting on the 18 January 1994 note the benefits of a lookback programme, notes that the committee supports the concept, and that funding would be required [**NHBT0000088_006**].[751] A meeting in August 1994 attended by Drs Hewitt and Robinson and chaired by Dr Ala prepared the case for presentation to DH on the subject of HCV lookback [**NHBT0009383**]. This ultimately led to the national lookback exercise.

11.35 In April 1994, Dr Robinson took up her role as medical director, and initiated the process towards a lookback exercise.

11.36 In September 1994 SACTTI prepared a proposal recommending that an HCV lookback programme should be introduced in the UK in the near future, and this would enable the NBS to extend its future of case to the recipient as well as the donor [**NHBT0009378**].[752]

11.37 The lookback programme for HCV was to be based on the procedures developed for the HIV lookback. The RTCs were to trace potentially infected recipients through hospitals and general practitioners and to interview and counsel surviving blood recipients.

F. National Lookback Programme

11.38 The national programme was announced by DH on 11 January 1995. The meetings and decisions leading to its introduction are detailed in the Written Statement of Dr Robinson [**WITN6926003**].[753] Crucially it was decided that despite the limitations of interferon treatment, including limited information about the long-term outcome, that the duty of care needed to be exercised towards these patients and implicated donors.

11.39 The HCV lookback in 1995 did not include haemophilia patients, as units would have testing anyway: '*by that time haemophilia units which -- would have been or should have been offering hepatitis C testing to all their patients*'[**INQY1000171**].[754] The anticipation was that the lookback programme would lead to a caseload of approximately 3000 for England and Wales.

11.40 On 3 April 1995 the CMO for England and Wales sent a letter containing guidance on lookback procedures [**NHBT0002796_002**]. Background to how

[751] Minutes of the SACTTI meeting on 18 January 1994 note at [11]
[752] Draft Medical Director's report for the 11th meeting of the NBA Executive on 8 September 1994
[753] Written Statement of Dr Angela Robinson [**WITN6926003**] at [385 – 392]
[754] Oral evidence of Dr Patricia Hewitt [**INQY1000171**] dated 10.12.2021 at [133]

that guidance was developed, and subsequent guidance is contained at paragraphs 420 – 441 of Dr Robinson's statement [**WITN6926003**].

11.41 The recipients of lookback would be offered interviews and counselling, during which a blood sample could be obtained for testing. Recipients confirmed to be infected could be referred for specialist advice through their general practitioners. At the time, and reflecting prevailing attitudes, it was considered that '*if the decision is made to follow only recipients in the young age group, the workload would be appreciably reduced*' [**WITN4486085**].[755] This is because transfusion-transmitted HCV had serious implications for the younger transfused population. Concerns were raised by SACTTI that the implementation of a lookback programme for HCV would:

> '*…produce an additional workload for the clerical/secretarial and counselling services in the NBS. Those centres which do not currently counsel donors for HCV infection would need to agree appropriate arrangements'* [**WITN4486085**] [756]

11.42 Practically, the lookback process could be summarised as follows*:*

> *'…records were interrogated to identify all donors who had tested anti-HCV positive since testing began on 1st September 1991. We had installed a computer system, TRACE, in the early 1990s, but it is possible that some relevant donor records were manual. We also interrogated manufacturing records to establish all the blood components (and plasma to BPL) which had been manufactured from previous donations. Finally, we had to look through issue records to establish which hospitals had received which components'.*[757]

11.43 The evidence from the pilot studies in Edinburgh suggested that few, if any, recipients '*are likely to be traceable and alive more than five years after transfusion'* [**NHBT005794**]. Other complicating factors include that hospital records were often deficient [**NHBT0057880**], many records were only available on paper and there were no digital records.[758] Indeed, the lack of a central database of recipients of a blood transfusion was an issue that continued up until vCJD lookback.[759] Where a patient died, the cause of death was not always recorded.[760]

11.44 This led some involved to 'name and shame' hospitals with infected donations:

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[755] Recommendation of SACTTI to MSBT concerning HCV lookback dated 29 September 1994 **[WITN4486085]**
[756] Recommendation of SACTTI to MSBT concerning HCV lookback dated 29 September 1994 **[WITN4486085]**
[757] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [548]
[758] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [549]
[759] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.202 [91] and [1-8]
[760] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [550]

> *'…you were asking to trace the potentially infected products from the HCV infected donors. And what you seem to have done here is done a sort of table, a league of shame to try to get those that had provided you with no feedback and done no investigations, to do so. Is that how to understand this letter? A. That's correct. […] So they certainly were familiar -- or had no reason not to know about this name and shame league table . And I'm afraid that the reaction from most of them at the bottom there was a mere shrug of the shoulders. It was deeply unsatisfying'.*[761]

11.45 As set out in her statement, throughout January 1995 Dr Robinson worked to prepare for lookback, issues included donors who donated before September 1991 whose HCV status was unknown [**NHBT0002754**], and concerns about the costs of testing of these donors, getting information prepared before the Panorama programme [**NHBT0006205_001**][762] and the need to discourage demands for immediate, speculative HCV tests [**NHBT0005885**][763] [**NHBT0092419_001**][764]. A MSBT ad hoc working party meeting on the 20 January 1995 confirmed that the aim was for the lookback process to be completed by the end of the summer [**NHBT0009715**], and that Ministers had '*undertaken to do all that was reasonable to trace, counsel and where appropriate treat those who might have been exposed to HCV through transfusion'* among other things set out in Dr Robinson's Witness Statement.[765]

11.46 In a memo of 26 January 1995 [**NHBT0019915**] Dr Hewitt identified information from the Working Party including the need for GPs to cover positive tests results, the need identified by Dr Walford at DH to collect data, and for PHLS labs to return the test results on a special information request form to the GP. It was hoped that the GP could provide details of the year of transfusion and hospital admission and that RTCs would therefore be able to get information about any anti-HCV recipients of blood not located by the lookback.

11.47 The further tasks and correspondence in relation to the instigation of the lookback exercise undertaken in January and February 1995 are set out at paragraphs 456 – 470 of Dr Robinson's statement. Comments on the proposals of 20 February 1995 by SNBTS are contained in [**NHBT0005835**]. Arrangements in respect of donors who donated in more than one region are contained at paragraph 472 [**WITN6926003**].

11.48 There was a significant increase in persons tested for HCV following the publicity surrounding the Panorama programme. Over 2000 tests were

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[761] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [159/4]
[762] Twentieth meeting of the National Blood Authority
[763] Template letter to go to NBS medical staff to assist them with requests for testing
[764] Letter from Dr Love at the Manchester blood centre to Dr Craske at the PHLS.
[765] See Written Statement of Dr Robinson at [450]

performed from 16 January 1995 to 10 February 1995 of which 11 positive recipients were identified [**NHBT0012318**].[766]

11.49 Issues in relation to rollout were set out in a letter from Dr Hewitt to Dr Robinson on 9 March 1995 [**NHBT0005832**], these include draft template letters to consultants [**NHBT0007906_003**].[767]

G. Records

11.50 NHSBT's full submissions in relation to records and record-keeping are contained at Section 14. However, the availability and quality of record-keeping impacted upon the efficacy of lookback and is therefore considered in brief below.

11.51 Issues emerged throughout the history of lookback investigations due to the challenges in recording batch numbers, and the repeated issues with record keeping. In respect of any efforts at look back, it is important to consider the significant complexities involved in initiating lookback within the context of issues with technologically limited hospital information systems. The issues were particularly pronounced where longstanding donors were involved as the quality and easy accessibility of records reduced over time. Skilled NBS personnel would therefore be required to conduct lookback [**NHBT0005849**].[768]

11.52 There were additional layers of complication where the RTC had large numbers of hospitals to deal with.[769] This is just one example of many issues relevant to the operational complexities of conducting lookback.

[766] Dr Mary Ramsay, Consultant epidemiologist, Immunisation Division at the Public Health laboratory Service to Dr Jean Harrison, the Medical Director at North East Thames RTC
[767] Summarised in the Written Statement of Dr Angela Robinson [**WITN6926003**] at [477]
[768] Letter from Dr Flanagan (Clinical Director of the Yorkshire BTS)
[769] See Oral Evidence of Dr Brian McClelland [**INQY1000178**] dated 28.01.2022 [140/18]

12. SECTION 12: vCJD

A. Emergence and knowledge

(1) The science of CJD

12.1 Creutzfeldt-Jakob Disease (**CJD**) is a prion disease, or Transmissible Spongiform Encephalopathy (**TSE**). As Professor Collinge explained in oral evidence, prion diseases are a group of *'always progressive and invariably fatal degenerative brain diseases',* caused by prions, which are assemblies of misfolded prion proteins in the brain. Prions grow, fragment and spread throughout the brain in a self-propagating process akin to the replication of a virus [**INQY1000206**].[770]

12.2 Classical or 'sporadic' CJD (**sCJD**) was discovered in the 1920s [**INQY0000349**][771] and is the commonest human prion disease. It occurs at random in the population: an individual's lifetime risk of developing sCJD is around 1 in 5,000 [**INQY1000206**].[772] There is also familial or inherited CJD, which occurs through inheriting a genetic mutation in the prion protein gene and accounts for around 5-15% of CJD cases [**NHBT0008903 (5-10%);**[773] **[INQY1000206] (15%).**[774] The third form of CJD is iatrogenic or acquired, i.e. spread through medical or surgical treatment: as at 1996 this accounted for less than 1% of CJD cases [**NHBT0008903**].[775] Iatrogenic CJD was first recognised to result from medical accidents, particularly through growth hormone treatment using infected human pituitary growth hormones [**INQY1000206**].[776]

12.3 Classical CJD's clinical presentation consists of *'pre-senile dementia, involuntary muscle movement and progressive motor dysfunction'.* Peak onset of classical CJD is between 60-65 years, with cases in persons under 30 rare. Survival is short, averaging less than one year and most often between two and six months [**NHBT0008903**].[777] As detailed below, clinical presentation was notably different in cases of vCJD.

12.4 As recorded in the (sCJD and vCJD) lookback proposal of 1996:

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[770] Oral Evidence of Professor John Collinge [21:11] at [6] [INQY1000206] dated 13.05.2022
[771] Counsel to the Inquiry presentation on 18 May 2022 on the chronology of key events relevant to vCJD
[772] Oral Evidence of Professor John Collinge [23:24] at [6] [**INQY1000206**] dated 13.05.2022
[773] J Gillon, Report on Creuzfeld-Jakob Disease and blood transfusion: proposal for a limited look-back study dated 25 June 1996 at [1] **[NHBT0008903]**
[774] Oral Evidence of Professor John Collinge [6:22] at [2] **[INQY1000206]** dated 13.05.2022
[775] J Gillon, Report on Creuzfeld-Jakob Disease and blood transfusion: proposal for a limited look-back study dated 25 June 1996 at [2] **[NHBT0008903]**
[776] Oral Evidence of Professor John Collinge [25:6] at [7] [INQY1000206] dated 13.05.2022
[777] J Gillon, Report on Creuzfeld-Jakob Disease and blood transfusion: proposal for a limited look-back study dated 25 June 1996 at [1] **[NHBT0008903]**

> *'There is no known prophylaxis or treatment for CJD, and the disease is fatal in 100% of cases after the onset of clinical signs and symptoms. There is no available screening assay suitable for asymptomatic general populations'* [**NHBT0008903**].[778]

12.5 It remains the case today in relation to vCJD that there are *'as yet no treatments which alter the course of the disease',* despite much work seeking to develop disease-modifying treatments including clinical trials [**WITN3093001**][779], and that there is no screening assay which can be used to detect vCJD in asymptomatic persons **WITN3093002** .[780]

12.6 The 1996 lookback research proposal explained that:

> *'…there are three basic circumstances in which CJD has been transmitted between people: instrumentation, tissue transfer and tissue extract transfer. These circumstances are distinguished from transfusion in that they feature either peripheral administration of brain tissue (a highly concentrated source), or direct introduction of the infectious agent into the brain'* [**NHBT0008903**].[781]

12.7 Importantly, despite multiple studies seeking to establish whether classical CJD could be transmitted by blood transfusion or plasma products, at the point when vCJD was first recognised in 1996, there was no evidence that classical CJD was transmissible through blood [**NHBT0008903**].[782]

(2) The BSE Epidemic

12.8 Various studies and surveillance projects on classical CJD were carried out in the UK in the first half of the 1980s [**INQY0000349**].[783] Then, in 1985, the United Kingdom was afflicted with an outbreak of Bovine Spongiform Encephalopathy (**BSE**) or *'mad cow disease',* an animal prion disease. It was known that *'many hundreds of thousands of BSE-infected cattle entered the human food chain prior to the introduction of the specified bovine offal orders [from 1989]*[784] *and that such orders were in any case incompletely enforced up to 1996'* **WITN3093002** .[785]

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[778] J Gillon, Report on Creuzfeld-Jakob Disease and blood transfusion: proposal for a limited look-back study dated 25 June 1996 at [1] **[NHBT0008903]**
[779] First Written Statement of Professor John Collinge **WITN3093001** at [5]
[780] Second Written statement of Professor John Collinge at Question 15, which also explains that tonsil biopsy and the 2011 Direct Detection Assay blood test can be used for specific diagnosis in symptomatic individuals.
[781] J Gillon, Report on Creuzfeld-Jakob Disease and blood transfusion: proposal for a limited look-back study dated 25 June 1996 at [3] **[NHBT0008903]**
[782] J Gillon, Report on Creuzfeld-Jakob Disease and blood transfusion: proposal for a limited look-back study dated 25 June 1996 at [4] **[NHBT0008903]**
[783] Presentation on Chronology of events regarding vCJD at [1] **[INQY0000349]**
[784] Circular from Sir Kenneth Calman, Chief Medical Officer [**BART0000554**]
[785] Second Written statement of Professor John Collinge **WITN309300** at Question 8.

12.9 Various groups were set up to investigate the impact of BSE, including the Southwood Committee, and one recommendation was that CJD surveillance in the UK should be reinstated [**INQY1000207**].[786] This resulted in the establishment of what is now called the National Creutzfeldt-Jakob Disease Research & Surveillance Unit ('**NCJDRSU'**) in Edinburgh in May 1990. The NCJDRSU's remit was to keep under surveillance all cases of CJD: this led to the *'new variant CJD'* being identified in 1995.

(3) The emergence of vCJD from 1995-1997

12.10 In considering the subsequent emergence and developing understanding of vCJD, it should be remembered that prion diseases have unique properties, are markedly different from all other known infectious agents, and are therefore challenging to deal with [**INQY1000206**][787]. Prion disease was not an area in which blood services representatives had *'any expertise…at all'.* The blood services were *'very dependent on the Spongiform Encephalopathy Advisory Committee [SEAC] to educate us and to keep us up to date with what was happening in the field',* which was largely evidence from experiments on animals [**INQY1000169**][788]. The blood services relied on SEAC both *'so that we could be kept briefed on scientific developments and, just as importantly, have them interpreted for us by experts in the field'* [**WITN0643010**][789]**.** They also depended on NCJDRSU to identify cases.

12.11 The evidence before the Inquiry suggests, in our submission, that the developing scientific knowledge filtered down from scientists who were specialists in prion diseases, to the DH and the blood services, over the course of 1995-1997.

12.12 On 1 May 1995, an eighteen-year-old died of what was thought to be sCJD but was on 28 October 1995 diagnosed as vCJD [**INQY0000349**].[790] Between 1995 and 1996, NCJDRSU identified ten individuals with a *'novel prion disease characterised by atypical demographic, clinical, radiological features'* [**WITN7034001**][791] [**HSOC0010099**].[792] vCJD predominantly presented in the third decade of life, substantially earlier than classical CJD, and involved early psychiatric symptoms including anxiety, dysphoria and social withdrawal.

12.13 On 8 March 1996, Professor Ironside and Professor Will presented their findings on the *'new variant CJD'* to SEAC [**DHSC0004445_043**].[793] On 20 March 1996, the Secretary of State, Stephen Dorrell, announced in the House

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[786] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022 at [11/1-6]
[787] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022 at [22/10-18]
[788] Oral Evidence of Dr Lorna Williamson **[INQY1000169]** dated 8 December 2021 [108/8-16]
[789] Second written statement of Dr Lorna Williamson dated 21 November 2021 [622] **[WITN0643010]**
[790] Chronology relating to variant Creutzfeldt-Jakob Disease at [3] **[INQY0000349]**
[791] Written statement of Professor James W Ironside dated 28 April 2022 at [19] **[WITN7034001]**
[792] Lancet, A new variant of Creutzfeldt-Jakob disease in the UK dated 6 April 1996 **[HSOC0010099**]
[793] Minutes of 25th meeting of Spongiform Encephalopathy Advisory Committee (SEAC) dated 8 March 1996 **[DHSC0004445_043]**

of Commons that on the advice of SEAC the *'most likely explanation'* for the new cases was BSE exposure prior to the 1989 SBO ban [**CABO0000383_036**].[794]

12.14 On 6 April 1996, Professor Ironside and Professor Will's findings were published in *The Lancet* [**HSOC0010099**]**.** They concluded that:

> *'We believe that our observation of a previously unrecognised variant of CJD occurring, to date, only in persons under the age of 45 years is a cause for great concern. That it is due to exposure to the BSE agent is perhaps the most plausible interpretation of our findings. However, we emphasise that we do not have direct evidence of such a link and other explanations are possible. That these cases have been observed now because of improved ascertainment cannot be completely dismissed. It seems unlikely, however, that such a distinctive neuropathological pattern would have been missed previously, especially among persons dying at a young age.'*[795]

12.15 On 9 April 1996, three days after the *Lancet* publication, there was an *ad hoc* meeting of the blood services in Edinburgh to discuss the implications of the reported cases of vCJD [**NHBT0115407**].[796] The meeting took the view that while there was very limited information on the potential transmissibility of BSE by blood, that this possibility *'could not be excluded',* was a *'major concern'* and there was a need for *'urgent action'* to improve the information base. As explored below, a portfolio of actions was agreed, including a lookback exercise.

12.16 A Standing Advisory Committee on Transfusion Transmitted Infection (**SACTTI**) meeting on 16 April 1996 [**NHBT0000088_013**] recognised that there was now a *'change in perception of CJD as potentially infectious until otherwise proven.'*[797] It was agreed that the first step should be to improve the knowledge base for decision-making. This would be done through: (1) epidemiological surveillance via a lookback study, and (2) research by expert prion research laboratories to understand the distribution of abnormal prions in different elements of blood (red cells, white cells or leucocytes, platelets and plasma), and therefore the potential of different blood components as issued by the blood services to transmit infection to patients [**WITN0643010**][798]. (1) fell within the remit of the blood services; (2) did not.

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[794] Press Release, CJD and Public Health - Stephen Dorrell Statement from the Department of Health dated 20 March 1996 at [1] **[CABO0000383_036]**

[795] Lancet, A new variant of Creutzfeldt-Jakob disease in the UK dated 6 April 1996 at [4] **[HSOC0010099]**

[796] Notes of a meeting held at the Royal College of Physicians of Edinburgh dated 9 April 1996 to discuss the possible implications of a likely new variant of Creutzfeldt **[NHBT0115407]**

[797] Minutes of meeting of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), held on 16/4/1996 paragraph [9] at [6] **[NHBT0000088_013]**

[798] Second written statement of Dr Lorna Williamson paragraph [622].dated 21 November 2021 **[WITN0643010]**

12.17 On 24 October 1996, Professor Collinge and Professor Ironside, among others, published an article in *Nature* reiterating that the new variant CJD *'has strain characteristics distinct from other types of CJD and which resemble those of BSE transmitted to mice, domestic cat and macaque, consistent with BSE being the source of this new disease'* [**MHRA0021347**].[799]

12.18 This paper noted that interest in prion diseases had been intensified by the BSE epidemic and *'the possibility that this may represent a significant threat to public health through ingestion of BSE-infected tissues'.* It noted that the new variant affected *'unusually young people',* and that none of the patients studied to date had a *'history of iatrogenic exposure to human prions',* suggesting that dietary exposure pre-1989 was the *'most likely candidate'.* The paper therefore treated *'primary'* exposure (through consuming infected beef) as the fundamental threat to human health. There was, however, also a reference to vCJD being *'expressed in the lymphoreticular system',* suggesting that *'it may be possible to detect this molecular marker of new variant CJD in tonsil or lymph-node biopsy and thereby avoid brain biopsy'.*

12.19 In oral evidence, Professor Collinge stated that his studies of lymphoreticular tissue in 1996 sparked concerns about a *'secondary'* epidemic of vCJD caused by transfusion [**INQY1000206**].[800] He stated that when it was confirmed that vCJD prions were easily detectable in lymphoreticular tissue:

> *'this much wider tissue distribution, particularly, we thought, involving white blood cells, also raised more concerns that variant CJD might be transmitted by blood transfusion in a way sporadic CJD didn't seem to be transmissible…of course, at that stage we had no idea how many people in the population were infected. We knew that the majority of the UK population potentially had been exposed to BSE prions and there was great uncertainty about what lay ahead in terms of an epidemic size.'*

12.20 Professor Collinge believes these findings were published in *The Lancet* at the start of 1997 **[INQY1000206].**[801] The relevant article is likely to be *'Diagnosis of new variant [CJD] by tonsil biopsy'* [**DHSC0004747_040**]. This explained that the specific pattern of protease-resistant prion protein (**PrP**) is expressed in the lymphoreticular system but did not expressly set out that this potentially had consequences for transmissibility via transfusion.[802]

12.21 In 1996, there was therefore considerable uncertainty about the scale of both the primary epidemic (through dietary exposure to BSE) and a potential secondary epidemic through medical or surgical transmission. The latter was

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[799] J Collinge, K Sidle, J Meads, J Ironside, A F Hill, Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD' dated 24 October 1996 **[MHRA0021347]**
[800] Oral Evidence of Professor John Collinge [**INQY1000206**] dated 13.05.2022 at [30-34]
[801] Oral Evidence of Professor John Collinge [**INQY1000206**] dated 13.05.2022 at [29-25]
[802] Lancet Diagnosis of new variant Creutzfeldt-Jakob disease by tonsil biopsy dated 11 January 1997 **[DHSC0004747_040]**

despite the absence of any positive evidence to indicate that vCJD would be transmissible when classical CJD was not. As elaborated in Professor Collinge's written evidence:

> *'We did not know what amount of BSE-infected tissue would need to be ingested to cause the disease in humans (that is we did not know the oral lethal dose of BSE prions); this would be determined by the so-called "species barrier" effect which we could not quantify in humans. In mice and sheep, where it could be experimentally quantified, oral transmission of BSE was comparatively easy. While a species barrier effect limiting transmission of BSE to humans would be present and probably prevent a huge epidemic, that tens of thousands for example might develop vCJD (albeit spread over many years) in the UK was certainly possible. My view was that we needed to work on that basis in terms of reviewing measures to protect the public health - and in particular with respect to relevance to this Inquiry - and to introduce measures to limit a secondary epidemic by iatrogenic routes (medical and surgical procedures including blood and blood products)'* [**WITN3093002**].[803]

12.22 In November 1996, Dr Williamson and Dr Minor submitted a framework document to SEAC via MSBT, outlining necessary research and their suggestions for how obtain this [**WITN0643010**][804] [**NHBT0004573_001**].[805] Their proposal commented on the *'conservative regulatory position'* taken across Europe in relation to CJD in the absence of evidence of transmission by blood, and the potential significant effect on the blood supply of major donor exclusion or product recall measures. They noted that *'the possibility that BSE may transmit to humans is a further major complication in the UK blood and blood products supply'.* They proposed two relevant questions which could be addressed on an experimental basis:

> *'1. Can TSE be experimentally transmitted by whole blood in transfusion?*
>
> *2. If so, can the frequency be reduced by leucodepletion?'*

12.23 They noted that in infection with naturally occurring TSE, infectivity had never been detected in blood, but that:

> *'in experimentally affected rodents, blood and blood constituents appear to contain the infective agent. Because the infective agent is associated with cell membranes and because of experimental evidence that buffy coat can transmit the agent, the role of leucodepletion of blood components is again under consideration. Leucoreduction could be used initially in experiments designed to establish the risk, if any, of TSE from transfusion of various*

[803] Written statement of John Collinge dated 26 April 2022 paragraph [8] **[WITN3093002]**
[804] Second written statement of Dr Lorna Williamson dated 21 November 2021 **[WITN0643010]**
[805] Report from PD Minor and L Williamson, Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) dated 1 November 1997 at [2] **[NHBT0004573_001]**

blood components. Only once the results of such experiments are available can the question of routine leucoreduction of components be considered.'[806]

12.24 Dr Williamson and Dr Minor did not receive a formal reply to their proposals [**WITN0643010**][807], but minutes from an MSBT meeting on 25 March 1997 record that *'the joint MRC/DH research advisory group thought there was very low risk of transmission of TSE infection through blood or blood products, although this might need to revisited in relation to new variant CJD. The group had not been particularly impressed by the Minor/Williamson proposals'* [**NHBT0006016**].[808] The Chairman also noted that MSBT, SEAC and the Research Advisory Group all had an interest in CJD and blood, and that *'in view of the public sensitivity it was important there should be no difference between MSBT's and SEAC's lines'*: therefore, MSBT should set out its position and convey this to SEAC, *'to ensure there was no difference in their stance'*.[809]

12.25 The position of MSBT here set out was in fact different from the perspective Professor Collinge developed across 1996 and 1997, which was informed by ongoing research and led him to favour leucodepletion (see below).

12.26 In March 1997, the WHO stated that while there was no evidence that classical CJD was transmitted through transfusion, it was becoming increasingly apparent that in vCJD the risk might be different because, in experimental models, white blood cells and plasma were considered possible sources of infection [**NHBT0004510**].[810]

12.27 On 2 October 1997, two papers were published in *Nature* which confirmed, through two different mechanisms, the link between vCJD and BSE **DHNI0000041_123** [**DHSC0004125_011**].[811] For Dr Williamson, this was the *'chilling'* event which truly '*raised the spectre of thousands of cases of vCJD from eating BSE infected beef, plus possibly hundreds of secondary transmissions through other routes, of which transfusion was one'* [**WITN0643001**][812].

12.28 In oral evidence, Dr Williamson explained her position. There had been hundreds of thousands of cattle infected with BSE whereas vCJD had appeared in the population in *'very small numbers.'* There remained a question

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[806] Report from PD Minor and L Williamson, Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) at [5] **[NHBT0004573_001]**
[807] Second written statement of Dr Lorna Williamson dated 21 November 2021 paragraph [626] **[WITN0643010]**
[808] Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting dated 25 March 1997 paragraph [7.16] **[NHBT0006016]**
[809] Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting dated 25 March 1997 paragraph [7.17] **[NHBT0006016]**
[810] Dr P Flanagan, New variant CJD and Blood Transfusion Services - where is it all leading? dated 1 January 1991 **[NHBT0004510]**
[811] Transmissions to mice indicate that 'new variant' CJD is caused by the BSE agent dated 2 October 1997 **[DHSC0004125_011]**
[812] Second written statement of Dr Lorna Williamson at paragraph [428] **[WITN0643001]**

mark over whether it had arisen from BSE or was a new condition in itself [**INQY1000169**][813]. The publication of these two papers was:

> *'…essentially showing, by two different mechanisms, that the fingerprint of BSE and the fingerprint of variant CJD were the same. So that really nailed it, that variant CJD had arisen through people eating BSE contaminated beef and other things made from cows. And that, in turn, opened up the possibility, firstly, that we would have thousands of people infected and affected by variant CJD due to eating beef, but, for us particularly, the horrible prospect of tens or hundreds even of people further infected through transfusion.'*[814]

12.29 This supplemented her written evidence on the scale of an epidemic:

> *'No one knew how big the primary epidemic would be; some estimates by modellers commissioned by DH, Det Norske Veritas (DNV), suggested there could be upwards of 10,000 cases from eating BSE-infected beef. The spectre of tens or even hundreds of transmissions through blood and blood products was a terrifying prospect'* [**WITN0643010**].[815]

12.30 For Dr Williamson, therefore, this was a watershed moment in that it raised the prospect of a significant secondary epidemic through transfusion by virtue of the sheer scale of the potential primary epidemic. Following this, Dr Williamson wrote to Dr Robinson seeking to review current policy on pooled plasma products [**WITN0643010**].[816]

12.31 Over the course of 1997, research on lymphoreticular tissues had progressed. A report of SEAC giving advice to Ministers on *'issues considered by SEAC 1 April 1997-30 March 1998'* [**MHRA0020531**] stated that:

> *'The Committee have recently concluded that the transmissible agent of nvCJD is indistinguishable from that of BSE but distinctly different from any of the forms of classical CJD. Recent research (some unpublished) suggests that the pathogenesis of nvCJD differs from that of classical CJD and the former may have more involvement of lymphoreticular tissues possibly involving circulating lymphocytes. Therefore it's logical to seek to minimise any risk from blood and blood products by reducing the number of lymphocytes present.*
>
> *SEAC recommends that the Government should consider a precautionary policy of extending the use of leucodepleted blood and blood products as far as practicable. It will be for the National Blood*

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[813] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021 at pages 111-112
[814] Oral Evidence of Dr Lorna Williamson [**INQY1000169]** dated 8 December 2021 paragraph [111:4]
[815] Second written statement of Dr Lorna Williamson dated 21 November 2021 paragraph [622] [**WITN0643010]**.
[816] Second written statement of Dr Lorna Williamson dated 21 November 2021 [**WITN0643010]**. [429]-[437].

> *Authority to devise a strategy to implement such a policy. It will take time to achieve full implementation and SEAC recommends that planning begins soon while the risk assessments suggested below are carried out'. Cannot estimate transfusion transmission risk.'*[817]

12.32 This demonstrates that the latest scientific research was shared at a high level at SEAC as it developed and sometimes before publication. This fed into the decision to introduce leucodepletion quickly as a *'precautionary policy'*. SEAC's decision to recommend implementing leucodepletion was made on 24 October 1997 [**NCRU0000174_001**].[818]

12.33 On 6 November 1997, Dr Collinge and John Patterson met directly with the then Secretary of State for Health, Frank Dobson, to explain the recent evidence of widespread prion infection in lymphoreticular tissues. Dr Collinge advised introducing leucodepletion to reduce the risks of transmission of vCJD by transfusion, and *'that day'* the Secretary of State decided to introduce the measure and secured funding from the Prime Minister [**WITN3093002**].[819] The DH then asked the national blood services to prepare an implementation plan: this is addressed below.

12.34 Professor Collinge's recollection of his advice to Frank Dobson on leucodepletion was that:

> *'We considered that the -- on the basis of available evidence at the time, that a lot of the infectivity was likely to be cell associated, white cell associated. And so leucodepletion would probably not remove all of the infectivity from blood but would have a substantial effect. That was our assessment at the time…I think when we discussed it with the Secretary of State, we were thinking in terms of it at least reducing the risk by 50 per cent, hopefully more'* [**INQY1000206**].[820]

12.35 In fact, leucodepletion was *'extremely effective',* with no single case of secondary transmission being identified from blood which was transfused after the introduction of leucodepletion [**INQY1000206**].[821]

12.36 At the time however, even once the link between BSE and vCJD had been confirmed in late 1997, there remained significant uncertainty about (a) the degree of transmissibility of BSE across the *'species barrier'* to humans [**WITN3093002**] (and hence the scale of the primary epidemic), (b) if and when BSE crossed the species barrier, whether and to what degree it would be

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[817] First Annual Report from Spongiform Encephalopathy Advisory Committee (SEAC) 1997/1998 at [35] **[MHRA0020531]**
[818] Minutes of the 45th meeting of the Spongiform Encephalopathy Advisory Group dated 24 October 1997 at paragraph [29] **[NCRU0000174_001]**
[819] Written statement of John Collinge dated 26 April 2022 at [3] **[WITN3093002]**
[820] Oral evidence from Professor John Collinge paragraph [64:21] dated 13 May 2022 **[INQY1000206]**
[821] Oral evidence from Professor John Collinge paragraph [64:25] dated 13 May 2022 **[INQY1000206]**

transmissible by blood and blood products, and (c) the extent to which leucodepletion would mitigate any such effect.[822]

12.37 Dr Williamson recalls that during 1997, the risk from different blood components was also being examined as part of the independent risk assessment by DNV, commissioned by the DoH: *'DNV expressed the view that this issue had a higher degree of uncertainty than anything they had previously tackled. This report was presented to SEAC in June 1998'* [**WITN0643010**] [**MHRA0020526**].[823]

(4) vCJD lookback

12.38 The lookback study began in 1997 and universal leucodepletion was implemented by November 1999. The DNV continued their risk assessments and on 30 November 1998 advised the DH that it was *'not possible to draw any firm conclusion as to whether or not infectivity can be transmitted through blood transfusions or plasma derivatives'* [**DHSC0041249_004**].[824]

12.39 It was not until December 2003 that the first case of transfusion-transmitted vCJD was identified via the lookback study.

B. Response to the emergence of vCJD

12.40 The steps taken in response to the emergence of vCJD were '*collaborative measures taken by numerous stakeholders, not simply or even principally NHSBT. These stakeholders include PHE [previously the HPA], NCJDRSU, DHSC, JPAC and SaBTO [previously MSBT]'* [**WITN0672006**][825]. Within JPAC there was also SACTTI, whose primary remit was to produce guidelines for the transfusion services [**INQY1000169**].[826]

12.41 Dr Williamson reflected that the lack of a formal link between SACTTI and MSBT meant that *'each committee lacked insight as to what the other was discussing…there was a communication route but it went from the chair of SACTTI to JPAC to Dr Robinson to MSBT',* and MSBT was *'very confidential'* and a *'closed environment'* at that time. MSBT minutes were confidential, and if Dr Williamson presented at MSBT she would be excluded before and after her agenda item [**INQY1000169**]. Dr Williamson suggested that with a little more transparency – such as if the SACTTI chair had been able to observe MSBT meetings – SACTTI would have had more insight into how to help MSBT

[822] Written statement of John Collinge paragraph [8-9] dated 26 April 2022 **[WITN3093002]**
[823] Second written statement of Dr Lorna Williamson dated 21 November 2021 paragraph [631] **[WITN0643010]**
[824] P. J Comer, N Veritasm Draft final report for the Spongiform Encephalopathy Advisory Committee and the Department of Health at [5] dated 1 November 1998 [**DHSC0041249_004**]
[825] Written statement of Dr Gail Miflin at [1463] [**WITN0672006]**
[826] Oral evidence of Dr Lorna Williamson dated 8 December 2021 paragraph [73:18] **[INQY1000169]**

reach its decisions. Dr Williamson believes that governance became much clearer when MSBT was replaced by SABTO in 2008 [**WITN0643010**][827].

12.42 Internally, however, the reconstitution of the blood services as an SHA in 1993-1994 allowed it to *'develop on a functional basis as a truly national body with effective funding, governance and lines of accountability'*: this meant the blood services were *'able to speak with one voice when new challenges arise, such as vCJD'* [**WITN0672006**].[828]

12.43 These submissions will focus on actions taken by the blood services in response to vCJD, in particular through the implementation of leucodepletion, lookback, donor exclusion policies and the decision to import plasma. Other actions pursued by government, scientists, fractionators, and haemophilia clinicians, which are discussed elsewhere, include:

a) The development of screening or diagnostic tests (addressed by Professor Collinge and Professor Ironside);

b) The ban on UK-sourced plasma in April 1998 and the subsequent decision to import plasma (addressed in more detail in the evidence of Professor Sir Michael Rawlins);

c) Work done at BPL and PFC to establish prion distribution across fractionated plasma products;

d) Product recall and quarantining of batches at BPL and PFC from 1997-2000; and

e) The development of recombinant and other synthetic blood products.

(1) Initial Response to the Emergence of vCJD

12.44 Following ten cases of variant CJD being identified in the *Lancet* publication of 6 April 1996, on 9 April 1996 the blood services held an *ad hoc* meeting of the transfusion services in Edinburgh to discuss the implications [**NHBT0115407**].[829] It was noted that there was very limited information relating to the potential transmissibility of BSE by blood, in particular in the context of transfusion: *'this was seen as a major concern and it was felt that urgent action should be taken to correct this deficiency. The absence of information severely restricts our ability to provide definitive reassurance that the new variant form of CJD does not pose a threat to the blood supply'*. The possibility of transfusion transmission *'could not be excluded'* on the available information.

12.45 Nine actions were agreed. These included that:

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[827] Second written statement of Dr Lorna Williamson at [266], [290], [736]-[750]; Oral Evidence of Dr Loran Williamson **[INQY1000169]** dated 08.12.2021 at [129-132]
[828] Written Statement of Dr Gail Miflin dated 19 October 2021 paragraph [86] **[WITN0672006]**
[829] Meeting notes dated 9 April 1996 to discuss the possible implications of a likely new variant of creutzfeldt - Jacob disease for UK Transfusion Services **[NHBT0115407]**

a) Direct questioning of donors in relation to a family history of CJD would be implemented, although it was agreed inappropriate to extend donor selection guidelines beyond the regulatory requirements until the position became clearer.

b) '[A]ction should be taken to improve…current knowledge in relation to potential for CJD to be transmitted by blood transfusion, and that knowledge would need to be acquired in relation to both the classical and variant form of the disease.'

c) SACTTI was to formulate questions relating to BSE to be forwarded to the Department of Health via MSBT.

d) '[A]ccurate information is obtained to identify whether identified CJD patients have ever donated blood, and that this would require information to be provided to Transfusion Services to enable interrogation of donor databases'. Dr Robinson was to raise the issue at MSBT.

e) There was 'a need to consider what action should be taken when a new case of CJD is identified in a current, or lapsed, donor, and that the feasibility of introducing a form of lookback being instituted to assist in identifying the transmissibility of this agent by blood needs to be assessed'.

f) '[There is a requirement to investigate systematically whether reported cases of CJD have received transfusions of blood or blood products. This may require the initiation of carefully structured case control studies'. An active collaboration with the CJDSU would need to be developed. The blood services had no expertise in prion disease [**INQY1000169**][830], and prion scientists had not previously worked with the blood services [**INQY1000207**][831].

g) Other agreed actions related to the response of plasma fractionators following notification of donors who have been rejected on a CJD-related basis, and to keep under review the option of quarantining frozen blood components.

12.46 On 16 April 1996 at a meeting of SACTTI, a report was presented on the Edinburgh meeting [**NHBT0000088_013**].[832] The meeting was reported to have been held *'in recognition of a change in perception of CJD as potentially infectious until otherwise proven',* and the limited information available was recognised to be a cause for concern. The SACTTI minutes record that:

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[830] Oral evidence of Dr Lorna Williamson dated 8 December 2021 paragraph [108:9-10] **[INQY1000169]**

[831] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022 At [143/17-144/2]

[832] Minutes of meeting 24/96 of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) dated 16 April 1996 **[NHBT0000088_013]**

'It was agreed that the first priority at this stage was to improve the level of knowledge so that appropriate decisions could then be made regarding donor selection, handling of blood components, etc.'

12.47 Further agreed actions included that Dr Robinson would ask MSBT for approval to undertake lookback on recipients of blood donations from donors who had subsequently developed CJD. Further, Dr Gillon would produce a paper on the potential role of leucocyte depletion as a protective measure from the putative CJD agent. Actions on prion research were also agreed [**WITN0643010**].[833]

12.48 These meetings show a 'whole range of actions considered by the blood services and the fractionators at a fairly early stage after the publication of the discovery of vCJD' **[INQY1000208]**,[834] including both lookback and leucodepletion. This approach was certainly 'precautionary' in the sense that there was no evidence of transfusion transmissibility at the time that these actions were agreed. In our submission, it was also underpinned by the appropriate assumption that *'until further evidence was available it should be assumed that the newly described syndrome is a new disease and that it was inappropriate to assume that this will behave in a manner analogous to classical CJD'* [**NHBT0115407**] [**NHBT0008903**].[835]

(2) Leucodepletion

12.49 The introduction of universal leucodepletion[836] of all blood components was the *'biggest step'* taken to protect the blood supply from vCJD [**WITN6929001**][837], and indeed the *'biggest project ever undertaken by the Blood Services'* [**WITN0643010**][838].

12.50 As set out above, the blood services presented the option of leucodepletion to MSBT in November 1996: however, it was not taken forward until 6 November 1997, when Frank Dobson decided to introduce universal leucodepletion on the advice of Professor Collinge and SEAC.

12.51 vCJD remained a *'huge focus'* for the blood services throughout 1997, and they were following the scientific literature carefully: this included the WHO statement that white blood cells and plasma were now considered possible sources of infection [**WITN0643010**].[839]

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[833] Second Written statement of Dr Lorna Williamson at [622].
[834] Transcript of the Counsel to the Inquiry presentation on 18 May 2022 on the chronology of key events relevant to vCJD paragraph [119:20-22] **[INQY1000208]**
[835] Notes of a meeting held at the Royal College of Physicians of Edinburgh on 9th April 1996 to discuss the possible implications of a likely new variant of creutzfeldt - Jacob disease for UK Transfusion Services **[NHBT0115407]**
[836] Selective leucodepletion was already used to prevent transmission of CMV **[NHBT0004564].**
[837] First Written statement of Dr Angela Robinson at [742].
[838] Second Written statement of Dr Lorna Williamson at [447].
[839] Second Written statement of Dr Lorna Williamson at [425-429].

12.52 Once Frank Dobson decided to proceed with universal leucodepletion on 6 November 1997, events moved quickly. On 10 November 1997 the DH asked the blood services for a costed feasibility report on leucocyte reduction to be provided in three months [**WITN0643010**].[840] This was duly produced by a steering group and submitted to the DH in February 1998: it estimated a cost of £80 million a year, and a 12-month lead time from instruction to completion [**WITN0643010**][841]. This estimate was in line with Dr Metters' view at the 24 October 1997 meeting in which SEAC decided to recommend leucodepletion [**NCRU0000174_001**], which was that *'it would take at least a year to gear the transfusion service up to carry out leucodepletion routinely. Dealing with hepatitis and AIDS had taken considerable time and this procedure would be far more complex.'*[842]

12.53 On 17 July 1998, Frank Dobson announced that universal leucocyte depletion would be implemented [**WITN0643010**].[843] The steering group then became the NBS Leucodepletion Implementation Group.

12.54 An implementation date of 1st November 1999 was later agreed, and by this date (sixteen months after the July 1998 announcement) universal leucocyte depletion was in place [**WITN0643010**].[844]

12.55 Two features of the introduction of leucodepletion should be noted: first, that the decision to introduce it was a *'high cost, highly precautionary decision',* and second, that implementation was a logistical challenge across each stage of the blood supply chain and was *'without a doubt…the most complex programme undertaken by UK blood services'* [**WITN0643010**].[845]

A High Cost, Highly Precautionary Decision

12.56 In oral evidence, Dr Williamson explained why leucodepletion was a high cost and highly precautionary decision [**INQY1000169**]. As to cost:

> *'It was going to add a significant amount to each unit of blood. By that time, there was cross charging in place so we had had to work out the cost of each unit, and leucocyte depletion was going to add something like £20 to a bag of blood, which would otherwise cost something like £100. So it was far more than the cost of any test that we had implemented.'*[846]

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[840] Second Written statement of Dr Lorna Williamson at [447], [703].
[841] Second Written statement of Dr Lorna Williamson at [694], [703]
[842] Minutes of the 45th meeting of the Spongiform Encephalopathy Advisory Group held 24 October 1997 paragraph [20] **[NCRU0000174_001]**
[843] Second Written statement of Dr Lorna Williamson at [704]
[844] Second Written statement of Dr Lorna Williamson at [447]
[845] Second Written Statement of Dr Lorna Williamson [**WITN0643010** [447]. Low priority to resolve
[846] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021 at [117/13-19**]**

12.57 Angela Robinson has further outlined that each leucodepletion filter would cost £20 and would need to be used on 3 million components per annum. Overall, its introduction would cost £82 million per annum, over half of the overall NBA budget of £152 million [**WITN6926001**].[847]

12.58 As to the precautionary nature of the decision, Dr Williamson explained that it was:

> *'…highly precautionary because in 1998 there had not been a single case of transmission of variant CJD through transfusion and we didn't know if there ever would be. But, on the other hand, it would have been quite wrong to sit on our hands and wait until a case occurred. And, in fact, sadly, there were cases, but the first -- there were three clinical cases and the first case wasn't reported until 2003. So if we had waited for another five years many more people potentially could have been infected. So it was absolutely the right decision and it was made in quite short order after the risk became apparent* **[INQY1000169]***.'*[848]

12.59 In his oral evidence, informed by his research on lymphoreticular tissue, Professor Collinge expressed this point slightly differently. He similarly explained that the reason SEAC had described leucodepletion as *'precautionary'* was that there had been no documented transmissions of vCJD by blood or any other route other than primary BSE exposure. It was therefore precautionary in the sense that *'the actual degree of risk at that stage couldn't really be quantified'.* However, he qualified his agreement that the possibility of transmission by blood remained a *'theoretical risk':*

> *'You could call it a theoretical risk, yes, but, you know, given the extent of colonisation of the lymphoreticular system with prions in patients it was a reasonable assumption that there would be infectivity in blood. And, you know, if you're giving someone a transfusion of a whole unit of blood, you know, it seemed to me that that was likely to be a significant risk'.[* [**INQY1000206**][849]

The Logistical Challenge of Implementation

12.60 Implementing leucodepletion was *'the most complex programme undertaken by UK Blood Services':* the logistical challenges are set out in detail in both Dr Williamson's written and oral evidence [**WITN0643010**];[850] [**INQY1000169**].[851] It required the following steps:

> *'…Rebuilding at some centres, hiring of many new staff, re-engineering blood sessions and transport, developing methods that could be applied*

[847] Written Statement of Dr Angela Robinson [**WITN6926001**] at [[725]
[848] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021 at [117/19 to 118/6]
[849] Oral Evidence of Professor John Collinge [**INQY1000206**] dated 13.05.2022 paragraph [63-64]
[850] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [694]; [704]-[708]
[851] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021 at [119-123]

> *at scale for counting the low numbers of white cells left in the components, evaluating filters from several manufacturers, agreeing a specification, and devising statistical methods to provide a high degree of assurance that components sent to hospitals were in fact leucocyte depleted. Manufacturers had to develop/manufacture blood packs where filters were integral, rather than 'docked on', and there had to be a tendering exercise and contracts agreed. We also required manufacturers to provide filters to remove white cells from plasma, which had never been done before. Apheresis machines which removed leucocytes during platelet collection had to be evaluated, and contracts signed for those. Communications for staff, the public, donors, and hospitals had to be developed'* [**WITN0643010**].[852]

12.61 As further explored in oral evidence, the blood service had to *'develop novel ways of counting white cells',* and work with statisticians to develop a sampling plan for quality assurance. They had to talk to manufacturers, since the number of filters required posed supply issues for any single one. In short, implementation entailed that *'the whole blood supply chain…from the donor session to the point where blood went to hospitals had to be re-engineered from start to finish.'* Further, all this was *'all on the critical path to implementation';* a wide portfolio of other safety, quality and best practice issues were pursued in parallel [**INQY1000169**].[853].

12.62 In both oral and written evidence, Dr Williamson confirmed that given the complexities of the project, she did not think it could have been achieved any more quickly than it was.

Achieving Implementation

12.63 The implementation target date of 1 November 1999 was a *'date by which this must be implemented nationally',* rather than an agreed start date for all locations at once, since the blood services now accepted that some centres would be ready before others. Dr Williamson has commented that *'the creation of the NBS, with national accountability, made the introduction of new safety measures much easier to manage'.*[854]

12.64 At an MSBT meeting on 28 October 1999 [**NHBT0004333**], proximate to the implementation target date of 1 November 1999, Dr Robinson reported that the target date for leucodepletion of all red cells and platelets had been met. 56% of FFP was being leucodepleted and this was *'growing rapidly to target'.* Scotland, Wales and Ireland were all to schedule. It was recorded that:

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[852] Second Written Statement of Dr Lorna Williamson [**WITN0643010]**
[853] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021 at [119-123]; Second Written statement at [705].
[854] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [495].

> *'Dr Troop thanked all those who had been involved in the complex task of introducing leucodepletion. It was commendable that despite the complexities and the enormous workload the targets had been met.'*

12.65 In oral evidence, Professor Ironside was asked to explain the suggestion in his statement that leucodepletion might have been capable of being introduced earlier [**INQY1000207**].[855] He replied that leucodepletion had been used in other countries and so was *'nothing completely new'*, so it *'may have been possible to do it before'.* The possibility had first been discussed at the Edinburgh meeting in 1996, yet was not implemented until 1999. Professor Ironside concluded:

> *'…other countries introduced it…so it wasn't such a novel thing entirely, but it's just a question of making the decision and trying to scale up the needs and meet those needs. That was done eventually. I don't know if that was as quick as it could have been. That's what I'm trying to say'.*

12.66 However, he *'couldn't say'* how much earlier it could have been implemented.

12.67 The first point here is that Professor Ironside's comment that *'I don't know if that was as quick as it could have been'* should be interpreted as an expression of a genuine lack of knowledge, not merely one of doubt. Just as the blood services were not experts in prion disease, prion specialists such as Professor Ironside were not experts in the logistics of running a blood service. Secondly, Professor Ironside's criticism only makes sense if it is seen partly as a comment on the time taken to make the policy decision to implement leucodepletion. To the extent that this criticism relates to any suggested delay in scaling up operations to operationally implement leucodepletion, in our submission Dr Williamson's evidence provides a robust explanation of the sheer scale and unprecedented nature of the operational complexities involved, in granular detail. It is our submission that in light of these many complexities, leucodepletion could not feasibly have been introduced any more quickly once the policy decision to implement it was made.

Effectiveness of Leucodepletion

12.68 Leucodepletion turned out to be *'extremely effective'*: not a single case of secondary transmission of vCJD from leucodepleted blood has been identified. This far surpassed the expectations which underpinned the 1997 decision to pursue its implementation, which were of an at least 50% reduction [**INQY1000206**],[856] in other words that it would *'significantly reduce but not*

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[855] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022 at [142-145]

[856] Oral Evidence of Professor John Collinge [**INQY1000206**] dated 13.05.2022 at [64/20-65/1]

eliminate the risk' [**WITN3093002**].[857] The results suggest that *'this step may have completely interrupted a secondary epidemic'* [**WITN3093002**].[858]

12.69 Leucodepletion also brought co-benefits for the blood supply, in terms of reduction of viral transmission, graft vs host reactions and increasing shelf life [**WITN3093002**][859]. The leucodepletion of all blood components continues to this day [**WITN0643010**][860].

Other Blood Safety Measures

12.70 Since both white blood cells and plasma were implicated in the lymphoreticular tissue research, the blood services also implemented measures to remove as much plasma as possible from cellular blood components, through the Safer Plasma in Components ('**SPIC'**) Group [**WITN0643010**].[861]

12.71 The work done at BPL and PFC to establish prion distribution across different fractionated plasma products fell outside of the blood services' remit.

12.72 Further blood safety measures implemented by the blood services included the use of paedipacks for all neonatal components; the exploration of autologous transfusion and other blood sparing initiatives; and the EASTR study on transfusion recipients. Further, the NBS:

> *'…realised early on in the vCJD era that major efforts would have to be made to work with hospitals on a shared approach to blood use, both to drive down over-prescribing and to develop and trial alternatives', which was a 'major shift in policy and thinking…it was necessary to create a whole new infrastructure to deliver this'* [**WITN0643010**].[862]

12.73 Finally, the blood service also played a role in evaluating commercially developed prion filters which were developed in the mid-2000s: ultimately, in 2012 SaBTO concluded against the introduction of these filters [**WITN0643010**][863]. An important finding in assessing their efficacy was that leucocyte depletion alone gave a very high degree of prion removal [**TSTC0000047**].[864]

(3) Donor selection and exclusion policies

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[857] Second Written Statement of Professor John Collinge **WITN3093002** at Question 5.
[858] Second Written Statement of Professor John Collinge **WITN3093002**
[859] Second Written Statement of Professor John Collinge **WITN3093002** at Question 14.
[860] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [43].
[861] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [83], [679]-[680].
[862] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [681]-[692].
[863] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [712]-[715].
[864] Oral Evidence of the House of Commons Science and Technology Committee regarding the risk of prion transmission [**TSTC0000047**] dated 30.04.2014

12.74 Before the emergence of vCJD, donor exclusion policies were already in place in relation to relatives of patients dying of sCJD, in line with Council of Europe requirements [**SBTS0000518**].[865]

12.75 A number of donor selection and exclusion policies were considered in relation to vCJD and ultimately rejected, including sourcing blood only from vegetarians; genotyping for codon 196 of the gene encoding prion protein; and the use of 'Club 96' donors born after 1 January 1996 for neonates and children [**WITN0643010**].[866]

12.76 Two steps which *were* implemented were (1) the exclusion of certain donors at particular risk, by late 1997, and (2) the exclusion of previously transfused donors, which was agreed by MSBT at the meeting of 22 January 2004 following the first confirmed case of transfusion-transmitted vCJD [**NHBT0035101**].

12.77 At an MSBT meeting on 25 March 1997 [**NHBT0006016**], it was reported that the NCJDRSU lookback study was under way, and that there were *'three new variant CJD patients known to have given donations.'* Dr Warren raised the question of deferring recipients of blood donations from CJD patients: it was suggested that this would involve breaking the conditions (of non-notification) set by the Lothian LERC.

12.78 By late 1997 the blood services, acting on the advice of SACTTI, had excluded as donors certain categories of high risk patients, namely (1) anyone who had been treated with any material derived from tissues near the brain, i.e. a corneal transplant, a transplant of dura mater (one of the coverings of the brain), or (2) hormones (human growth hormone and gonadotrophins) extracted from the human pituitary gland, sited at the base of the brain[**NHBT0004564**][867] [**WITN0643010**].[868] These donations would have been excluded via the *'flagging'* mechanism within the TMER [**INQY1000171**].[869]

12.79 The decision to exclude anyone who had themselves been transfused in the past was the *'biggest donor exclusion step'* taken in relation to vCJD [**WITN0643010**][870]. This was discussed at several MSBT meetings from 1998 through to October 2003 [**SBTS0000523**] [**DHSC0004026_032**] [**NHBT0008129**] [**NHBT0034821**] [**NHBT0035101**], but there were '*real concerns that if this were implemented, the Blood Services would be unable to*

[865] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**SBTS0000518**] dated 02.05.1996
[866] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] **at** [650]-[658].
[867] Report from Dr Peter Flanagan, Dr Brian McClelland and Dr Lorna Williamson, entitled 'an assessment of strategies, including leucocyte depletion, to minimise the risk of transmission of new variant CJD by transmission.'
[868] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [653]
[869] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [138/4-9]
[870] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [654]

maintain supplies to the NHS, with donor loss estimated to be 5-10%' [**WITN0643010**][871].

12.80 In oral evidence, Dr Williamson explained that earlier on, leucodepletion had been the priority as it was '*doable, it could be applied to all blood components, [and] we wouldn't lose any donors'.* In contrast, the donor population was *'enriched with previous recipients'* as *'they wanted to give something back':* there was therefore *'real concern that the NHS would suffer and patients would suffer if there wasn't enough blood on the shelf because we had suddenly excluded previously transfused individuals'* [**INQY1000169**].[872] Professor McClelland noted the further difficulty in ascertaining whether people had actually been transfused, and the consequences of giving the benefit of the doubt [**INQY1000178**].[873]

12.81 On 22 January 2004, following the first confirmed case of transfusion-transmitted vCJD, MSBT decided to exclude previously transfused donors [**NHBT0035101**]**.** This recommendation was made to the DH on 11 March 2004 and was accepted: it took effect from 5 April 2004 [**DHSC0038559_047**]**.**[874] In August 2004 this was extended to whole blood and plamapheresis donors, and to any donors who have been treated with UK plasma derived intravenous immunoglobulin or have undergone plasma exchange. This was further extended in July 2005 to live bone donors and in November 2005 to transfusions anywhere in the world [**WITN0672006**].[875]

12.82 The blood services prepared a letter which was sent to blood donors [**DHSC0004555_008**], stating that:

> *'We are sorry that we have had to ask you to stop giving blood for the time being. This new rule has been introduced as a purely precautionary measure in light of the latest scientific information. Our aim is to ensure that patients always receive blood and blood products that are as safe as we can make them. In this instance we are reducing the possible risk of vCJD [...] being passed from donor to patient.'*

12.83 It is important to remember, when reviewing the steps taken on donor deferral, that not a single case of transfusion-transmitted vCJD has been identified as arising from blood components donated after the implementation of leucodepletion in 1999. In Professor McClelland's summary [**INQY1000178**]:

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[871]Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [654]
[872] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021 at [116/5-24]
[873] Oral Evidence of Dr Brian McClelland [**INQY1000178**] dated 28.01.2022 at [144-146]
[874] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**DHSC0038559_047**] dated 11.03.2004
[875] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1129(f)-(h)]

'As we now know -- throughout this period, for a long period there had been no incidence of transmission by blood and, even today, the numbers are spectacularly small'.

12.84 Considering that at the time it was believed that leucodepletion would substantially reduce but not entirely eliminate secondary transmission (as set out above), taking this major donor exclusion step was a notably precautionary decision, which would have had a real impact on the blood supply. We note that it was taken shortly after the February 2004 *Lancet* article which detailed the first case of likely secondary transmission and set out that the TMER had identified 48 recipients of vCJD-implicated blood components.

(4) The Decision to Import Plasma

12.85 In July 1998, the Committee on the Safety of Medicines ('**CSM'**) decided that UK plasma should not be used to manufacture plasma products: this decision is addressed in the evidence of Professor Sir Michael Rawlins [**WITN6406001**]. Dr Williamson has similarly described this decision as *'a high cost, highly precautionary decision. No recipient of plasma product had developed vCJD by that point. In my view, this was a timely and appropriate decision'* [**WITN0643010**].[876]

12.86 Subsequently, in June 1999 MSBT discussed importing Fresh Frozen Plasma ('**FFP'**), some of which could be used to produce cryoprecipitate [**NHBT0004351**].[877] MSBT asked the blood services to investigate the possibilities of importing the entire UK FFP supply, with a preference for using plasma for neonates and children if supplies were limited.

12.87 Dr Williamson reported back to MSBT in February 2000 [**DHSC0006163 060**],[878] January 2001 [**DHSC0014973_005**][879] and April 2001 [**NHBT0008129**].[880] The importation options investigated by the blood services were *'complex'* and *'complicated',* due to both the logistical challenges of sourcing sufficient plasma, and the need to *'balance the various risks associated with FFP'* [**WITN0643010**];[881] risk reduction measures would of course impact on the quantity of supply.

12.88 First, the blood services' research indicated that US plasma was increasingly difficult to obtain, due to increasing worldwide demand and escalating costs.

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[876] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [694]
[877] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**NHBT0004351**] dated 03.06.1999
[878] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**DHSC0006163 060**] dated 30.01.2022
[879] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**DHSC0014973_005**] dated 22.01.2001
[880] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**NHBT0008129**] dated 19.04.2001
[881] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [695]-[698]

The *'significant operational difficulties'* and costs of the menu of options presented by the blood services are set out in [**NHBT0008129**],[882] and in Dr Williamson's evidence [**WITN0643010**];[883] [**INQY1000169**].[884] It was therefore very difficult to source 100 tonnes of plasma, the amount necessary for the entire UK FFP supply, without introducing other risks into the blood supply.

12.89 As to risks, there were risks associated with FFP in general, namely the greater risk of TRALI, which could be mitigated by using only male donors. It was also of *'great concern'* that US rates of HIV and Hepatitis were 4-9 times higher than UK rates: imported plasma would therefore need to be subject to an MSBT-approved virus reduction step. Dr Williamson found that Methylene Blue ('**MB**') treatment would need to be carried out under contract to Grifols in either Spain or the UK as a separate operation, which would be a *'very complex process presenting significant operational difficulties',* would cost £27.5 million and would take 16-29 months to implement [**NHBT0008129**].[885]

12.90 Ultimately, on 22 October 2002 MSBT recommended that neonates and children born on or after 1 January 1996 should receive US, single unit, MB treated FFP, ideally from untransfused males [**NHBT0034821**].[886] The supply of FFP for adults would continue from UK sources [**INQY1000169**].[887] This was announced on 16 August 2003 and implemented by June 2004: Dr Williamson could not comment on the reason for this delay [**INQY1000169**].[888]

12.91 On 8 October 2020, the Commission on Human Medicines (**CHM**) concluded that there was a negligible risk of vCJD cases arising from the use of UK plasma for immunoglobulin products [**WITN7034044**].[889] The CHM therefore recommended that the ban on UK-sourced plasma be lifted, subject to certain risk-reduction measures.

12.92 Dr Williamson has commented on the difficulties which regional transfusion centres faced historically with providing both blood components to regional hospitals, and plasma to BPL [**WITN0643010**][890], and stated that:

> *'771. The creation of the NBA brought BPL and the RTCs together, so that for the first time, we could coalesce around a shared vision and priorities. Success for BPL meant success for the whole organisation.*

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[882] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**NHBT0008129**] dated 19.04.2001
[883] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [664]-[669], [695]-[698]
[884] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021 at [123-127]
[885] Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**NHBT0008129**] dated 19.04.2001
[886] Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**NHBT0034821**] dated 22.11.2002
[887] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021
[888] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021
[889] Critical Risk Assessment Report on Use of UK plasma for the manufacture of immunoglobins and vCJD risk [**WITN7034044**]
[890] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [770]-[771]

BPL was certainly a changed organisation by the time vCJD appeared, unfortunately resulting in a ban on UK plasma being made into products. Now that UK plasma is again going to be fractionated, but with BPL no longer part of the NHS, efforts must be made to bring it back close to its plasma supplier, the NBS. There is a generation of staff in both organisations who will not know much, if anything, about the other. It concerns me greatly that we could return to those days when BPL was sometimes seen as a distant irritant rather than the partner that it should be in providing safe, high-quality medicines for patient benefit.'

(5) Lookback: the Transfusion Medicine Epidemiology Review (TMER)

12.93 The TMER lookback study was developed throughout 1996 and commenced in 1997. Its main aim was to try to establish whether there was any link between vCJD (or sCJD) and blood transfusion. It was not designed to investigate fractionated products [**WITN3101009**],[891] as the transfusion services had not been asked to investigate this [**INQY1000171**].[892]

12.94 These submissions will comment on:

a) The design and operation of the TMER;

b) Ethical issues, in particular whether to notify recipients; and

c) The results of the TMER.

The Design and Operation of the TMER

12.95 The TMER involved two separate arms, a *'lookback'* and a *'traceback'* arm, designed as far as possible to replicate processes which were already in place in blood centres and embedded in routine practice. The main difference was that there was no blood test for CJD which could be offered to determine whether infection had taken place: instead, the blood services were dependent on NCJDRSU passing on the personal details of those who had been diagnosed [**WITN3101009**].[893]

12.96 The *'lookback'* arm would establish whether individuals who had been diagnosed with sCJD or vCJD had been blood donors. If so, the blood service would trace the donations through blood centre records, identify relevant blood donations, establish what blood components had been prepared from them and identify the fate of these components through to their final destination. If the final destination was recorded as issued to a hospital blood transfusion laboratory for clinical use, the relevant laboratory would be asked to trace its

[891] Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [335]-[336]
[892] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021
[893] Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [336]-[343], [346].

fate through laboratory records. If it was recorded as transfused to an individual recipient, the recipient's details would be notified to the blood centre.

12.97 Once the blood services received the identity of a recipient, this was forwarded to NCJDRSU for *'passive surveillance'*. Passive surveillance entailed NCJDRSU checking the details against the database of individuals who had been diagnosed with CJD and performing further checks at intervals over time in order to detect cases which might develop at a later date. It also involved NCJDRSU applying to the ONS for a copy of the individual's death certificate upon their death, in order to check whether any evidence of CJD or other neurological disorder was recorded. There was no way of undertaking *'active'* surveillance, in the sense of following what happened to a patient year on year [**INQY1000171**].[894]

12.98 Whereas only cases of sCJD who were known by their relatives or next of kin to be blood donors were notified to the blood services for checking, *all* cases of vCJD were notified by NCJDRSU, whether or not known to be donors. Dr Hewitt notes that *'this decision has been vindicated by the fact that donor records have been traced for a small number of individuals diagnosed with vCJD, whose relatives had not reported a knowledge of blood donation'* [**WITN3101009**].[895]

12.99 The second TMER 'arm' was the reverse process, termed Reverse TMER/R-TMER or *'traceback'*. This started from the point of a patient who had developed CJD and who had a prior history of blood transfusion, analogous to the traceback process carried out in cases of possible transfusion-transmitted infection. The TMER was *'devised as a way of double-checking that no possible case of CJD linked to blood transfusion would be missed'* [**WITN3101009**].[896]

12.100 Unlike the lookback arm, TMER relied on the hospital of transfusion being known, since there is no national database of blood recipients, and enquiries can only be made to the identified hospital. The blood services therefore needed to enquire at the relevant hospital whether there was a record of transfusion for that person, in order to trace back to the donors [**INQY1000171**].[897]

12.101 In fact, no cases were identified through the R-TMER which had not already been identified through lookback. This gave the blood services confidence that the process devised was operating as intended [**WITN3101009**].[898]

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[894] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021

[895] Written Statement of Dr Patricia Hewitt [**WITN3101009**]
[896] Written Statement of Dr Patricia Hewitt [**WITN3101009**]
[897] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021
[898] Written Statement of Dr Patricia Hewitt [**WITN3101009**]

Ethical Aspects of Lookback

12.102 Dr Hewitt explains that as the TMER qualified as a research study, it required ethical approval from the Lothian LERC [**WITN3101009**].[899] Further, Dr Metters as Deputy CMO insisted on ethical approval, in particular due to concerns about non-notification of recipients.

12.103 There were two ethical dimensions to the TMER. First, since patients would either be deceased or beyond the stage at which they could give a capacitous consent at the stage of diagnosis with vCJD, the review would involve the NCJDRSU passing patient details to the blood services in the absence of patient consent. Second, and more fundamentally, the decision that patients identified would not be notified itself gave rise to an ethical concern requiring ethical approval [**INQY1000171**].[900]

12.104 On 22 April 1996, days after the SACTTI and Edinburgh meetings set out above, Dr Robinson wrote to Dr Hewitt to pursue the lookback proposal [**NHBT0008485**] and stated that a *'key element'* would be the '*exchange of donor/patient information only between the NBS and the CJD surveillance unit, with no notification of recipients who may have received blood transfusions from donors who later developed CJD. I haven't time now to completely brief you but I know that Peter Flanagan [the Chair of SACTTI] will be contacting you in the near future to fully brief you with regard to this situation'.*

12.105 On 22 April 1996, in a letter to Dr Hewitt, Dr Robinson asked Dr Hewitt to draft a lookback proposal for ethical approval, and to '*obtain legal advice […] with regard to not informing recipients'* [**NHBT0008485**]. It was noted that the Minister and MSBT were keen to obtain ethical approval, with it being *'Jeremy [Metters]'s suggestion that any proposal (where the recipients will not be informed) needed to be submitted for Ethical Committee approval and legal advice'.*

12.106 The MSBT met on 2 May 1996 [**SBTS0000518**].[901] Lookback was discussed in relation to both CJD generally (since Dr Will at NCJDRSU had reported 50 cases of CJD patients who were believed to have donated blood) and vCJD (since one of the ten reported cases was known to have donated blood). It was recorded that *'there would be no question of contact with any patients or GPs. The first step would be to develop Bob Will's proposal into a research paper. Ethical clearance would be essential given the implications'.* It was agreed that the NCJDRSU and the blood services would prepare a protocol for submission to the Health Departments. Donor deferral was also discussed.

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[899] Written Statement of Dr Patricia Hewitt [**WITN3101009**]
[900] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [24]
[901] The previous meeting had taken place on 8 January 1996: **[DHSC0020692_118]**

12.107 It therefore appears that the decision not to notify recipients identified through lookback was made within the Department of Health shortly after the SACTTI meeting, through discussions between Dr Metters, the Minister and members of the MSBT.

12.108 On 25 June 1996, Stephen Janisch provided legal advice to Dr Hewitt which addressed the possible duty of care on the NBA to take some form of action regarding recipients, such as to inform them of the situation and to arrange counselling or treatment. This concluded that *'I was not able to advise with confidence that there is no such legal duty owed to these individuals'* [**NHBT0004398**].

12.109 Dr Hewitt also sought ethical advice from Professor Ian Kennedy, who advised that recipients should not be notified. The advice itself could not be located, but is summarised by Dr Hewitt in a further letter to Professor Kennedy on 15 April 1999 [**NHBT0017407**]:

> *'Your advice at the time was that no notification of recipients should take place, in view of:*
>
> *The lack of scientific evidence that CJD is transmitted by blood transfusion.*
>
> *The lack of a screening or diagnostic test to diagnose infection with CJD.*
>
> *The lack of any effective intervention which could be offered to those who are infected.*
>
> *You raised two important caveats at the time. Firstly, if there was any change in the capacity to diagnose the disease and secondly, if any intervention became available, then the means to contact identified recipients must be in place. You made the point that the information we were seeking to obtain is important for public health purposes in terms of planning the extent of resources needed for possible future cases. Having considered all these factors, you concluded that the balance lay in favour of not notifying identified recipients.'*

12.110 The research proposal was subsequently submitted to the Lothian ERC; formal approval was received on 15 January 1997 [**NHBT0008903**]. The proposal noted that the UK Transfusion Services were in an *'ideal situation to help accumulate knowledge about CJD and blood transfusion, both the classical and variant forms'.* This was due to the *'now…well-established procedure for recipient lookback'*.

12.111 The proposal set out the policy of non-notification, adopting Professor Kennedy's views on (i) the ethical basis for non-notification and (ii) the need to

have a contact mechanism in place to be used if there was any advancement in diagnosis or treatment.

12.112 The *'issues arising'* from the proposal were (1) the duty of confidentiality owed to donors, and the lack of a standard consent by donors to pass on personal medical information to other parts of the NHS, and (2) the need to take a precautionary approach to donor exclusion:

> *'The transfusion services must exercise a high level of suspicion about possible transmissibility of CJD by blood and err on the side of caution in deciding whether to accept donations from individuals believed to be at risk of developing CJD. To wait until a causal connection is established on a scientific basis may not be regarded as acting with reasonable care. Thus, decisions about selection of donors must not be delayed pending results of the limited lookback, but must be taken in the light of current knowledge and guidelines.'*

12.113 On 5 December 1997, Dr Hewitt wrote to Dr Robinson in light of reports that recipients of eye tissue donated by donors later identified with vCJD had been notified of this, which had implications for the different situation of blood transfusion recipients [**NHBT0001259**]. Dr Hewitt expressed feeling uncomfortable that two different decisions had been taken, and sought an explanation: further, *'as MSBT was involved in the initial considerations relating to blood transfusion recipients, could MSBT be asked to review the policy'*

The 'Flagging' Policy and Non-Notification

12.114 The policy of non-notification continued; in February 1998, Dr Winyard issued guidance related to plasma products [**NHBT0004382_001**], '*based on the unanimous opinion of a range of ethical committees, that recipients need not be informed …However, an individual clinician might decide to inform patients and there would be some situations which could not be avoided such as the recall of an implicated product'* [**SBTS0000523**].[902]

12.115 MSBT discussed donor deferral throughout 1998, initially taking the view that the impact on the blood supply would outweigh the risks [**SBTS0000523**][903] [**DHSC0004026_032**][904]. By February 1999, the NBA were seeking legal advice on preventing blood from donors subsequently diagnosed with vCJD from entering the blood supply [**NHBT0004389**].[905] The NBA proposed that it 'flag' individuals on the NBA computer database: consequently, individuals

[902] Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**SBTS0000523**] dated 26.02.1998
[903] Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting [**SBTS0000523**] dated 26.02.1998
[904] Minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) meeting [**DHSC0004026_032**] 29.10.1998
[905] Letter from Stephen Janisch, Le Brasseur J Tickle Solicitors and Privy Council Agents, to Mr A Slopecki, NBA [**NHBT0004389**] dated 25.02.1999

would not be excluded from the panel of blood donors, but if they made further donations their blood would not be used and would be discarded. It was *'not considered appropriate to inform the individuals concerned'.*

12.116 Dr Hewitt's written statement records that the blood services had pressed for notification, but in the absence of notification proposed flagging as an *'interim action'* to protect the blood supply. However, the blood services *'continued to press for these individuals to be notified of their risk, despite the very real concerns about the enormity of that information and the possible effect on the individual'* [**WITN3101009**].[906]

12.117 On 25 February 1999, Alan Slopecki (National Quality Assurance Manager at the NBA) received further advice from Stephen Janisch. [**NHBT0004389**] [907] He remained concerned that the NBA could be said to owe a legal duty of care to inform recipients, and that it remained his view that he was *'not able to advise with confidence that there is no such legal duty owed to these individuals'*. However, he noted the DoH's position that *'it would put an enormous burden on people to tell them that they had a remote risk of contracting the disease and that the relevant ethics committee advising the Department had decided it was just not appropriate to tell them. This is clearly a mixed ethical and legal issue.'*

12.118 Other relevant points included that '*failing to tell the donor involves an element of deception rather than a simple, considered omission*' and that continuing to take blood from a donor in these circumstances would vitiate informed consent to donation. He stated that flagging individuals without their consent would in principle be legally permissible, save that he did not see how this complied with the Data Protection Act 1998.

12.119 On 15 April 1999, Dr Hewitt wrote to Professor Kennedy for a second time, setting out his 1996 advice on notification and asking *'whether you consider that the ethical advice now needs reviewing'* given two developments [**NHBT0017407**]. The first was the development of a tonsillar biopsy test which had potential future application as a diagnostic test. The second was that the blood services had been asked to take donor exclusion measures, which could only practically be implemented by the flagging system. Dr Hewitt wrote that it now further appeared clear that any individual presenting as a blood donor should be notified of their ineligibility, and expressed concerns that this would create a discrepancy in donor notification: *'Thus, it is conceivable that in the future a small specified group of these recipients will be notified although the majority will not'.*

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[906] Second Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [392]

[907] [907] Letter from Stephen Janisch, Le Brasseur J Tickle Solicitors and Privy Council Agents, to Mr A Slopecki, NBA [**NHBT0004389**] dated 25.02.1999

12.120 In oral evidence, Dr Hewitt stated that two things had changed to lead her to seek further advice on notification: first, that the risk assessment relating to vCJD had changed over the last three years, and second, that '*one of the main reasons was that we in the Blood Services were trying to adopt the precautionary principle'* [**INQY1000171**]. That approach entailed the move towards donor deferral/exclusion, which renewed questions of notification, and which led to the proposal to flag patient details in the database.

12.121 No evidence has been identified to suggest that Professor Kennedy did in fact provide the further advice sought, and Dr Hewitt subsequently approached Professor Len Doyal for ethical advice [**INQY1000171**].[908]

12.122 On 6 October 1999, there was a meeting at the DH with NBA representatives to discuss donor flagging [**NHBT0004382_001**]**.** Dr Robinson noted that MSBT had asked the NBA to defer at-risk donors, and referred to the legal advice from Stephen Janisch on the need to inform donors., Dr McGovern agreed that if donors presented to donate, they must be informed. Dr Hewitt agreed to draw up a protocol.

12.123 On 28 October 1999 the MSBT reported the 6 October meeting concluded with an exclusion decision:

'for public health and legal reasons the NBA should set up a system to exclude individuals from giving blood who had been identified by the NBA/CJD Surveillance Unit Study as having received blood from people who subsequently developed vCJD' [**NHBT0004333**].

12.124 The meeting considered that flagging and deferral complied with the Data Protection Act 1998, but that the Act required that if flagged individuals presented as blood donors, the NBA had a duty to tell them why their donation could not be accepted, as part of the duty of care to the donor. It also stated that:

> *'…The NBA was seeking independent ethical advice and in collaboration with the experts from the CJD Surveillance Unit was drawing up a protocol on the management of deferred donors who received implicated vCJD blood. It would be necessary to discuss each deferral on a case by case basis with the Health Departments.'* [**NHBT0004333**].

12.125 On 22 December 1999, Dr Robinson wrote to Dr McGovern stating that he had advised her on 27 October 1999 that there was *no* legal or data protection issue with flagging individuals, and that should a donor present themselves to the NBA, before proceeding to inform them of the reason for deferral, the NBA should submit their procedural counselling material to the new Ethical/Scientific Committee (the Jeffries Committee), who would provide advice on how to proceed [**NHBT0015384**]**.** The Committee would also

[908] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021

consider sharing these names between all UK transfusion services so all their donor databases could institute flagging. Dr Robinson reported this to the NBA, with the flagging system put in place on 25 November 1999.

12.126 On 12 January 2000, Dr McGovern replied detailing a further conversation with DH lawyers, whose legal view was that flagging *was* compliant with the Data Protection Act 1998:

> *'…it was also considered that there was probably no requirement under either the old or the new DPA on national blood services to inform people who have received implicated blood components that they were being or had been flagged'* [**NHBT0015384**].

12.127 However, the lawyers also stated that the blood services should, in the '*spirit of openness and 'contracts' with donors'*, consider informing donors why their blood could not be accepted. Each case should be treated individually and *'the appropriate Health Department should be contacted in the first instance. The NBA agreed to develop a protocol for dealing with these cases in discussion with the Department of Health and the proposed 'Expert Group on the Management of CID Incidents'.*

12.128 The Expert Group (which became the CJD Incidents Panel[909]) was due to have its first meeting on 25 January and would consider developing a consistent approach to such situations. Dr McGovern wrote that it was '*clear from all the discussions that the decision to flag such potential donors was purely precautionary, not based on any new scientific information, and taken in the face of profound uncertainty'*. There was agreement that '*the policy will be kept under review in the light of developing science'.*

12.129 On 20 December 1999 Dr Hewitt received further ethical advice from Professor Doyal [**NHBT0004392_002**]. This advice '*relied much more strongly on the individual's right to know information relating to them'* [**WITN3101009**].[910] Professor Doyal referred to the previous justification that non-notification *'could in no way impinge on their interests'* due to the uncertainty about transmission, the lack of a screening or diagnostic test and the lack of any effective intervention. Regarding the latter, he stated:

> *'I would discount this as relevant to any new policy about notification. Many terminally ill people both need and want to know confirmation about their diagnosis and prognosis, despite the absence of effective treatment. They require such information because of decisions of their lives or deaths which they may wish to make on its basis. It is impossible with any certainty for clinicians effectively to judge who these individuals are or what kind of information they require, even when they are actively treating them. Indeed, there are obvious difficulties in assuming that when some patients reject information which they may find distressing,*

[909] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [116/8-12]
[910] Second Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [361]

> *they can be said to be making an informed choice about their rejection. It certainly cannot just be assumed that recipients or donors who are linked to [new variant CJD] will not wish to be informed of this fact -- if anything can be said to practically turn on the provision of such information.*
>
> *Therefore, the key moral issue is whether or not there is a) evidence -- or the appearance of evidence -- that there is a link between nvCJD and blood and b) an effective diagnostic test'.*

12.130 As to the former, Professor Doyal noted that while there was little sound evidence, both the flagging policy and the implementation of leucodepletion *'suggest – and will certainly do so to the public – that there is evidence of transmissibility'.* Therefore, patients whose blood is excluded must be told why. If patients were allowed to give blood which was then destroyed, this would be under *'false pretences'* and would be *'both immoral and illegal'.*

12.131 In oral evidence, Dr Hewitt agreed that this was markedly different from Professor Kennedy's advice, and stated: *'I think it was quite an eye opener for me that there is no such thing as "this is ethical and this isn't". There are different opinions amongst ethicists. And Professor Doyal felt very differently from the previous ethical committee, both ethical committee [sic] and Professor Kennedy'* [**INQY1000171**].[911]

12.132 On 30 January 2000, a representative of the Lothian Ethical Research Committee wrote to Professor Will in light of the NBA's new stance of donor flagging and notification, noting Professor Doyal's advice [**NHBT0004364_004**] and responding:

> *'..I would agree that it is usually reasonable to tell someone that they are definitely terminally ill so that they may, as the saying has it, "put their affairs in order". I know that we both feel that this is a far cry from being told that there is a possibility (which can be neither confirmed nor refuted) that one may have been "donated" a virus, which may or may not be responsible for causing a lethal illness at some undetermined time in the future!*
>
> *Nevertheless, a National Policy, with which the Department of Health is in agreement, must be adhered to. As a consequence I have no alternative to refuse your request for renewal of Ethical Approval for the above study.'*

12.133 On 1 February 2000, Professor Will wrote to Dr White at the DoH, asking whether the DH could give ethical approval to continue the TMER, given its

[911] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [108/17-22]

public health importance NHBT0004364_003. Dr Hewitt cannot recall what happened with regard to this request [**INQY1000171**].[912]

12.134 In our submission, the documentary evidence from 1996-2000 demonstrates:

a) That blood service representatives were concerned about the policy of non-notification, which was decided by the Department of Health, from an early stage, and on several occasions pressed for explanations and reviews of the policy;

b) That the situation was kept under review, and that the blood services and the Department of Health both sought legal and ethical advice from a range of sources on an ongoing basis; and

c) Crucially, that the advice received showed a wide range of strongly held, widely diverging opinions from both the legal and ethical experts consulted.

Change in Policy in Favour of Notification

12.135 Over the following three years, there was a shift in view which ultimately resulted in recipients being notified in December 2003. In Dr Hewitt's opinion, this was partly influenced by more up-to-date risk assessments produced by the DH [**INQY1000171**].[913] Concerns were also raised at SACTTI in December 2002 that inconsistent approaches were being taken in Scotland and England, in the absence of clear guidance from the CJDIP [**JPAC0000086_019**].[914]

12.136 The CJDIP was established in the summer of 2000 [**PRIU0000015**].[915] Its remit was to advise the DH regarding whether notification should take place [**INQY1000208**].[916] In 2001, the CJDIP issued a Consultation Exercise to a wide range of bodies, seeking views on issues including notification [**NHBT0096710_001**]. This noted the *'difficult ethical dilemmas which arise in dealing with a disease which is always fatal, for which there is no cure, which has an unknown incubation period and no diagnostic test, and where'* the transmission risk was *'not fully understood'.* On notification, it was proposed that most people would not be informed, with the exception of a small-subgroup of people who *'the Panel considers to be at sufficient risk to warrant public health action.'* However:

> *'There is a strong argument that people should be able to choose whether or not they are told about their possible exposure. Therefore it is proposed that possibly exposed people are not asked for their*

[912] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021
[913] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [113/15-23]
[914] Minutes of the meeting of the SACTTI Working Group on vCJD [**JPAC0000086_019]** dated 13.12.2002
[915] Letter from Caroline Flint, MP to Mr Arthur J Hooper dated 12.10.2006
[916] Oral Evidence of Dr Nicky Connor [**INQY1000208**] dated 18.05.2022

> *informed consent before being recorded on this register. This is because such action would remove the choice of not being told about their exposure. Instead it is proposed that individuals who wish to know if they are on the database, and the details and significance of their exposure, should be able, after appropriate counselling, to obtain the information through their doctor.'*

12.137 This consultation document was based on a *'distillation of the consensus views of the CJDIP'*: Dr Hewitt *'strongly supported'* the proposal to notify recipients [**WITN3101009**].[917] While the intention was therefore that the majority would have the choice of whether to be informed, that is not what was put in place [**INQY1000171**].[918]

12.138 A wide range of views were expressed in response to the consultation. In light of these, CJDIP revised its proposals and now recommended that patients considered *'at risk'* should be notified, and the necessary support mechanisms put in place. The four CMOs from each country accepted this proposal in June 2003 [**PRIU0000015**]**.** As far as Dr Hewitt was aware, no steps were actually taken in June 2003 to notify recipients: the lack of further action or information on this was a *'source of frustration'* for CJDIP [**INQY1000171**].[919]

12.139 At this point, there was still no proven link between blood transfusion and transmission of vCJD.

12.140 On 1 December 2003, CJDIP's working *'framework document'* for the management of possible exposure to CJD through medical procedures was circulated [**DHSC0020839_003**]. It proposed notification of a *'small subgroup of possibly exposed people which the panel considered to be at sufficient risk to warrant public health action',* and proposed counselling these individuals.

12.141 In December 2003, the first case of vCJD transmission via blood transfusion was confirmed through the TMER. At that point, the DH instructed that notification should take place [**WITN3101009**].[920] This resulted in notifications being sent out over the Christmas period: Peter Buckland, the father of Mark Buckland, gave evidence on receiving a letter from the Health Protection Agency dated 31 December 2003 [**WITN0694001**].

12.142 Peter Buckland's Written Statement sets out that the NCJDRSU knew that Mark likely had vCJD from around 1999-2000, discussed whether to inform him, and ultimately decided in favour of non-notification due to fears that Mark might commit suicide. However, *'they didn't consider that had he been told he could have lived his short life to the full'* [**WITN0694001**]. In oral evidence, Dr Hewitt *'totally agree[d]'* that this consideration pointed in favour of notification.

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[917] Sixth Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [391]
[918] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [123/15-20]
[919] Sixth Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [125-126]
[920] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [393].

She added that the family of the first recipient to be identified as developing vCJD *'very rightly made the comment'* that had they known, they would have been able to manage his last few months very differently [**INQY1000171**].[921]

12.143 In her written and oral evidence, Dr Hewitt affirmed that from her perspective, the notification process could and should have taken place earlier. There were concerns about the mechanism of notification, and the provision of support for those affected [**WITN3101009**].[922] However:

> *'I was quite clear [that notification should have happened earlier] and it was an example of how not to do a notification exercise. The time was awful. Individual GPs and local public health teams were put in the position of "This is something you must do now", without any plans really having been made in place. A lot of work was done, a lot of teleconferences with a lot of people working out it could be done well and quickly [sic], and that really wasn't the situation we should have been in'* [**INQY1000171**].[923]

12.144 Commenting on the ethical obligation to inform individuals of infection risk more generally, Dr Hewitt stated that she *'strongly believed that the obligation towards recipients existed separately to any consideration of potentially available treatment'*, and that this pointed in favour of vCJD notification in the absence of any screening test or treatment [**WITN3101009**].[924] Dr Hewitt has also stated that:

> *'With hindsight, I think the difficult issues and strongly held views from both sides (those who supported notification of the possibly affected, despite the potential for psychological harm, and those who felt that such harm outweighed the benefits) may have led to erring on the side of not acting soon enough to impart potentially devastating news in terms of possible exposure to HCV and vCJD ...'* [**WITN3101006**].[925]

12.145 Dr Williamson was also asked, as a matter of general principle, whether she considered that there was an ethical obligation to inform patients who may have received transfusions from infected donations. In her view, *'there has always been an absolute ethical responsibility to inform patients of clear-cut harm'.* The situation *'becomes more difficult when the probability of transmission is uncertain and likely to be very low',* as the CJDIP had to consider over the years with vCJD, balancing *'causing unnecessary worry versus concealing information which the patient may which to know'.* Dr Williamson drew the tentative conclusion that *'I think that over the years, I have*

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[921] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [129/-14]
[922] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [397]
[923] Oral evidence of Dr Patricia Hewitt dated 10.12.202 at [127].
[924] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [312]
[925] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [105]

increasingly moved towards telling the patient in these grey areas' [**WITN0643010**].[926]

12.146 Considering the specific ethical issues surrounding patient notification which arise in the context of a disease like vCJD, the apparent (and, following leucodepletion, actual) remoteness of the risk of transmission via transfusion, coupled with the extreme severity of the fatal and unpreventable impact of which recipients would have to be informed, led many people to demur over patient notification. While the opinion of blood service witnesses now tends towards favouring patient notification in these circumstances, it remains a difficult area for decision-makers.

Notification Exercises from 2003 Onwards

12.147 The process of notifying identified recipients of at-risk blood components, from December 2003 onwards, fell outside the blood services' remit. CJDIP was primarily responsible for decision-making on notification, and the notification procedure was undertaken by the HPA. Issues arising from the conduct of the notification exercises, including (a) the reliance on an informal *'cadre of experts'* who were not all aware of their proposed role, and (b) the broader issue of counselling and support for recipients, are addressed in the evidence of Dr Nicola Connor [**WITN7091001**],[927] Professor Collinge [**WITN3093002**][928] and Professor Ironside [**WITN7034001**][929] and are not repeated here.

12.148 There were also tracing and notification exercises undertaken in relation to fractionated products, i.e. factor concentrates, which fell within the remit of the HPA, BPL or PFC, the UKHCDO and HCDs. These are addressed in the evidence of Professor Hay [**WITN3289039**] which is not repeated here. Professor Hay's evidence comments on cases of mistaken notification of vCJD exposure arising from these exercises, which is further addressed in the Expert Report on Psychosocial Issues. The blood services' involvement in these exercises was limited to providing information to the fractionators so they could identify which batches of product were implicated, and to dealing with cases where batches of albumin had been used within the blood service [**INQY1000171**].[930]

12.149 The blood services did carry out a donor notification exercise in 2005 in relation to donors identified through the R-TMER, which was managed by Dr

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[926] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [581]-[585]
[927] And the Oral Evidence of Dr Nicky Connor [**INQY1000208**] dated 18.05.2022
[928] And the Oral Evidence of Professor John Collinge [**INQY1000206**] dated 13.05.2022 see in particular [pg43-57], referring to Professor Collinge's concern to ensure those notified were not just counselled, but informed that they could access diagnostic interventions, a therapeutic trial and long-term follow-up while asymptomatic, at the National Prion Clinic.
[929] And the Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022 – addressing, in particular, the appropriate thresholds for notification.
[930] Oral Evidence of Dr Particia Hewitt [INQY1000171] dated 10.12.2021 at [135/12-23]

Hewitt. In Dr Hewitt's oral evidence, this exercise remained with the blood service as *'at the time we felt very strongly that these individuals whose risk for vCJD had been identified because they were blood donors, because they had volunteered to give blood, and we felt that it was our responsibility, as the Blood Service, to give them the information, and that outsourcing it to another organisation might seem very strange'* [**INQY1000171**].[931]

12.150 The blood services communicated directly with donors, after first approaching the GP to ensure contact was appropriate. They wrote directly to donors with extensive information and the offer of a telephone discussion, and provided a 24-hour helpline. They requested follow-up information from GPs. Dr Hewitt later received funding for a donor satisfaction survey, which commenced in 2009: following a hiatus, the paper is now being prepared for publication [**WITN3101009**].[932]

Results of the TMER / Statistics on vCJD Infection

12.151 The TMER led to the first case of vCJD transmission via blood transfusion being confirmed in December 2003. That was the date an individual died of vCJD who had received a transfusion some years earlier, including a blood component originating from a donor who later developed vCJD. This provided, if not the *'confirmation'* of secondary transmission, at least the *'likely evidence'* [**INQY1000171**].[933]

12.152 The case was described in a February 2004 *The Lancet* article co-authored by Professor Will, Dr Hewitt and others [**WITN3101018**]**.** The authors found that:

> *'48 individuals were identified as having received a labile blood component from a total of 15 donors who later became vCJD cases and appeared on the surveillance unit's register.*
>
> *One of these recipients was identified as developing symptoms of vCJD 6.5 years after receiving a transfusion of red cells donated by an individual 3.5 years before the donor developed symptoms of vCJD.*
>
> *[…] our findings raise the possibility that this infection was transfusion transmitted.'*

12.153 Subsequently, two further cases of vCJD were confirmed in recipients from a common donor: this confirmed the link between vCJD and blood

[931] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [134/11-17]
[932] Seciond Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [411]-[414]
[933] Oral Evidence of Dr Particia Hewitt [**INQY1000171**] dated 10.12.2021 at [130/16-22]: see also the Oral Evidence of Dr Nicky Connor [**INQY1000208**] dated 18.05.2022, who stated that this one case did not 'prove' the route of transmission, as it was possible that the individual had been infected with vCJD through dietary exposure.

transfusion [**WITN3101009**].[934] One of these recipients was Mark Buckland, whose father Peter Buckland has given evidence to the inquiry.

12.154 The TMER continues to this day to carry out routine surveillance of vCJD cases (as well as for possible cases of transfusion-transmitted sCJD) [**WITN3101009**]. [935]

12.155 The NCJDRSU's 26th Annual Report 2017 [**RLIT0001605**] provides an overview of the overall results of the TMER, whose figures remain the same today [**INQY1000207**].[936] The report states: *'up to 31st December 2017, 178 cases of definite or probable vCJD had been identified in the UK (123 definite and 55 probable cases who did not undergo post-mortem).'* 'Probable' here means a very high probability, but in the absence of post mortem [**INQY1000207**].[937] The median age at onset of disease was 26.5 years, and the median age of death 28 years. The last known UK case of vCJD was reported in 2016, with onset in 2014: this also remains the case today [**INQY1000207**].[938]

12.156 Out of the 178 cases, *'four instances of probably transfusion transmitted infection have been identified'* [**RLIT0001605**].[939] The first recipient was the individual who died in December 2003. The second recipient died from a non-neurological disorder and was confirmed at post-mortem to have a *'presumed pre-or sub-clinical vCJD infection]* [**INQY1000207**][940] from prion proteins detected in the spleen but not the brain. The third and fourth recipients were the recipients who received transfusions from the same donor. All had received units of blood prior to the introduction of leucodepletion.

12.157 The latest report of the results of the TMER study, dated 29 November 2019 [**WITN7034001**],[941] stated that thirty-one vCJD cases were reported to have been blood donors, and one additional case registered with UKBTS (but not reported by relatives) was found to have been a blood donor. Of the twenty-one of these cases which had been traced at blood centres, components from 18 were issued to hospitals, and *'it has been established that 67 components were transfused to named recipients (53 dead, 14 alive)'.* The report reiterated that four instances of probable transfusion-transmitted infection had been identified.

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[934] Written Statement of Professor John Ironside [**WITN7034001**] at [377]-[379]
[935] Written Statement of Professor John Ironside [**WITN7034001**] at [379]
[936] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022
[937] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022
[938] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022
[939] 26th Annual Report of the NCJDSU titled Creutzfeldt-Jakob Disease Surveillance in the United Kingdom, 2017
[940] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022
[941] Written Statement of Professor John Ironside [**WITN7034001**] Question 8(a)(iii).

12.158 There has not been a single case of vCJD transmission via a surgical instrument [**INQY1000207**].[942]

12.159 Transmission figures among those who received full plasma product, as opposed to whole blood or blood components, are also addressed in the evidence of Professor Ironside. Only one positive result has been identified (in 2009) through the prevalence study of vCJD infection in haemophilia patients funded by the Department of Health [**WITN7034001**].[943] This was an asymptomatic infectee with severe haemophilia A who had been exposed to vCJD-implicated Factor VIII and tested positive at autopsy.

12.160 These figures are explored in the evidence of Professor Ironside, and in the Expert Report on Statistics which is before the inquiry. The statistical experts have further interpreted this data, and also highlighted the difficulties with doing so. Out of 67 identified at-risk recipients, three went on to develop the clinical disease. However, 34 died within five years of transfusion with no clinical symptoms in their lifetime, but also with no post-mortem. A further 11 died over five years from transfusion, again with no post-mortem. For these individuals, there is *'no evidence one way or the other'.* Therefore, '*if you look at that original 67, actually, we've got information about eight. And four of those eight either had variant CJD or abnormal prion'* [**SB OE**][944]. Professor Bird stressed the importance of consented post-mortems to improving the current level of statistical knowledge about the transmissibility of vCJD by blood.

C. Conclusions on vCJD

(1) Nature, Adequacy and Timeliness of Response of the Blood Services

12.161 The principal steps taken by the blood services in response to vCJD were leucodepletion, donor exclusion measures and the TMER. Leucodepletion was *'extremely effective'* [**INQY1000206**],[945] above and beyond the risk reduction anticipated, and appears to have *'completely interrupted a secondary epidemic'* [**WITN3093002**][946]**.** Dr Williamson has provided a robust, granular explanation of the huge and unprecedented operational complexities involved in introducing leucodepletion: in short, *'the whole blood supply chain…from the donor session to the point where blood went to hospitals had to be re-engineered from start to finish'* [**INQY1000169**].[947] In our submission, Dr Williamson's written and oral evidence is compelling evidence that

[942] Oral Evidence of Professor James Ironside [**INQY1000207**] dated 17.05.2022
[943] Written Statement of Professor John Ironside [**WITN7034001**] Question 8(a)(viii).
[944] Oral evidence of Prof Sheila Bird from the Expert Group on Statistics dated 9 November 2022
[945] Oral Evidence of Professor John Collinge [**INQY1000206**] dated 13.05.2022
[946] Second Written Statement of Professor John Collinge **WITN3093002**
[947] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021

leucodepletion was implemented in the shortest possible time, after the policy decision was made to introduce it.

12.162 Targeted donor exclusion measures were introduced at an early stage in 1997, and the significant decision to exclude all previously transfused donors, which came at a cost of 5-10% donor loss, was taken by MSBT soon after the first confirmed case of transfusion-transmitted vCJD. In fact, this step appears to have been unnecessary as leucodepletion, which was implemented in 1999, has been completely effective.

12.163 The TMER was also instituted very quickly after the emergence of vCJD: Dr Hewitt was tasked with pursuing a lookback proposal days after the Edinburgh and SACTTI meetings in April 1996 [**NHBT0008485**]; Dr Hewitt sought ethical advice and submitted a research proposal in accordance with this advice, which was approved by the Lothian Ethics Research Committee on 15 January 1997 [**NHBT0008903**]; and the TMER was implemented in 1997.

12.164 The blood services continued to press the issue of donor/recipient notification [**NHBT0001259**][948]**;** [**WITN3101009**],[949] and both the NBA and Department of Health sought a range of legal and ethical advice on the issue from 1996-2000: both the legal and ethical experts consulted held widely diverging views. CJDIP was established in the summer of 2000 to advise on notification: as a member of CJDIP, Dr Hewitt *'strongly supported'* notification [**WITN3101009**][**950**], but its consultation also elicited a wide range of views. The failure to implement notification on CJDIP's recommendation in June 2003 was a *'source of frustration'* [**INQY1000171**].

12.165 Nonetheless, it should be pointed out that the ethical issues surrounding notification of donors and recipients who had potentially been exposed to vCJD remain difficult and contested, given the extent of scientific uncertainty surrounding transmissibility, the overall remoteness of the risk of transmission, and the severe nature of the information about harm which would have to be imparted, namely that vCJD is unpreventable and invariably fatal.

12.166 The TMER has operated as intended, with no case of CJD identified through traceback which had not already been identified by the lookback arm [**WITN3101009**],[**951**] and the TMER continues to operate today.

12.167 To this day, only four cases of transfusion-transmitted infection have been identified, all of which resulted from blood transfused prior to the introduction of leucodepletion. While the Expert Report on Statistics has highlighted the incompleteness of the data on the 67 identified at-risk recipients, even accounting for this uncertainty the number of cases is very

[948] Letter from Dr Hewitt to Dr Robinson [**NHBT0001259**] dated 05.12.1997
[949] Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [392].
[950] **Second** statement of Dr Patricia Hewitt [**WITN3101009**] at [391].
[951] Sixth Written Statement of Dr Patricia Hewitt [**WITN3101009**] at [343].

small, and significantly lower than was feared at the time. This does not in any way diminish the tragedy of the impact of infection with vCJD for infected and affected individuals, which whom NHSBT has the deepest sympathy.

(2) What, if anything, was new about the response to vCJD?

12.168 The response to vCJD was precautionary in the sense that high-cost risk-reduction measures were taken in the face of profound scientific uncertainty. Leucodepletion, lookback, certain donor exclusion measures and the UK plasma ban were all implemented before the first confirmed case of secondary transmission in 2003, while the decision to exclude all previously transfused donors was taken immediately after this point.

12.169 The precautionary nature of the response has been attributed to a number of factors. First, at the point where vCJD emerged, the information already known about the BSE epidemic meant that it was immediately possible to envisage the sheer scale of the potential primary epidemic: *'many hundreds of thousands of BSE-infected cattle entered the human food chain'* **WITN3093002**,[952] and this by 1997 '*raised the spectre of thousands of cases of vCJD from eating BSE infected beef, plus possibly hundreds of secondary transmissions through other routes, of which transfusion was one'* [**WITN0643010**].[953] Professor McClelland has also speculated that the *'horrific'* scenes of pyres around the country during the BSE epidemic led to a *'psychological real fear'* surrounding TSEs, which was absent from the prevailing mood surrounding NANBH [**INQY1000178**].[954]

12.170 In our submission, these considerations are likely to have influenced decision-makers outside the blood services to act decisively: for example, the Secretary of State for Health's decision to implement leucodepletion as soon as it was advised by SEAC, and the Prime Minister's apparent decision on the same day to fund its introduction.

12.171 Second, blood service representatives have also suggested that their precautionary approach was informed by earlier experiences with HIV and HCV [**WITN0672006**];[955] [**INQY1000169**][956] (and assisted by the fact that the logistics to undertake lookback were therefore in place in the blood service). Dr Williamson stated:

> *'…I guess we had learned from the mistakes of the past that if things took a long time to be decided or where the risk was uncertain, there was much more use of the precautionary principle, which is designed to cover the situation where you may have a risk, it is not very clear what the magnitude of the risk is, but if there is a risk and its outcome is*

[952] Second Written Statement of Professor John Collinge **WITN3093002** at Question 8
[953] Second Written Statement of Dr Lorna Williamson [**WITN0643010**] at [428]
[954] Oral Evidence of Dr Brian McClelland [**INQY1000178**] dated 28.01.2022 at [148-149]
[955] Written statement of Dr Gail Miflin [**WITN0672006**] at [117], [1129]
[956] Oral Evidence of Dr Lorna Williamson [**INQY1000169**] dated 08.12.2021

> *dreadful, as this would have been, you have to act. You can't wait for data to become available. And, of course, we had learned from the HIV and hepatitis C experiences. I think we were very -- everyone was in agreement we had to get on and do what we could.'*

12.172 Third, as Dr Williamson suggests, the profound scientific uncertainty about the transmissibility of vCJD necessarily entailed a precautionary response. In 1997, there was significant uncertainty about the scale of both the primary and secondary epidemics. The degree of uncertainty was and is bolstered by the lack of any clinically available test to detect vCJD in asymptomatic patients: this significantly affects NHSBT's ability to identify the risks of vCJD infection associated with the use of blood and/or blood products, and has necessarily meant that the response to vCJD has been on a *'far more precautionary basis'* [**WITN0672006**].[957]

12.173 Dr Miflin has explained that the level of uncertainty surrounding a particular risk will necessarily influence the extent to which the response is precautionary, and that vCJD is an example of this:

> *'1466. […] Whilst the precautionary principle is rightly used when the risks are not known, for example with decisions made when vCJD first arose, decisions when risks are known require judgement. This judgement requires a weighing of the risks and benefits and of the cost-effectiveness of both implementation and omission, as is true of all decisions in healthcare and blood services are no different. It is not possible to introduce every beneficial healthcare intervention and choices always have to be made. Decisions on the extent to which a risk can and should be reduced are considered by SaBTO according to a number of calculations and perspectives including health economics and risk tolerability. […]*[**WITN0672006**][958]
>
> *1467. As the SHOT reports show, there are many adverse events that can happen during the process of transfusion and TTIs are small in number and also small in proportion to the total events.'*

12.174 Fourth, regardless of the impossibility of quantifying the degree of risk in 1995-1997, the blood services' response from April 1996 onwards was also underpinned by the assumption in principle that vCJD was a new disease which could not be assumed to behave in a manner analogous with sCJD.

12.175 In our submission, the answer to whether this was a new approach, or reflected the blood services' approach to previous emerging viruses and diseases, is that it was a mixture of the two. Evidently, every new epidemic or pandemic is a new disease, which would always be concerning for the blood services, and in which, necessarily, the blood services and other experts would

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[957] Written statement of Dr Gail Miflin [**WITN0672006**] at [116]-[117]
[958] Written statement of Dr Gail Miflin [**WITN0672006**]

(to a significant extent) not know what they were dealing with. On the other hand, as set out above, prions were a genuinely novel and distinctive problem for the blood services to grapple with, and the atypical extent of their lack of knowledge on prion disease would have driven decision-making in a slightly different way.[959]

12.176 The appropriateness of the assumption that vCJD was a new, distinct disease is illuminated by Professor Collinge's findings on prion infectivity in lymphoreticular tissue, which led him to believe in 1997 that there was more than a *'theoretical risk'* but *'likely to be a significant risk'* of infectivity in blood, albeit that the degree of risk could not be quantified [INQY1000206]**.** Therefore, while the scientific uncertainty under which decisions were taken was very high, it was not absolute.

12.177 Similarly, Professor Michael Rawlins was asked about the Committee on the Safety of Medicines' recommendation to exclude UK plasma *'because of the theoretical risk of transmission'* [**WITN6406033**].**[960]** When asked whether this constituted a different, more precautionary approach to the CSM's approach in the 1980s, he replied that *'ultimately, it was really based on a judgment',* namely that vaccines were prepared using foetal bovine serum and therefore that in his view it seemed unlikely there was a species barrier. Professor Rawlins therefore disagreed that CSM were taking a *'radically different…precautionary approach'* in the face of purely theoretical risk, answering:

> *'…I don't think so, no. I think we were just acting on what we regarded as reasonable…eventually, we decided that the risk of having outbreaks of measles, you know, MMR, and so on, outweighed…the theoretical risks of transmission of CJD'* [**INQY1000211**].**[961]**

12.178 Further, Dr Robinson has noted that the *'concept of the precautionary principle'* was only introduced at around the time of the vCJD, and that the term *'came into the language through the public's perception of risk, which developed and changed over time'* [**WITN6926001**].[962] Similarly, Professor Barbara has said that the use of the precautionary principle to manage vCJD risk was not a *'shift'* but a *'drift':* there was not a formal change of attitude and direction, but rather a *'gradual process'* [**WITN6989001**].[963] In oral evidence, Professor Barbara linked this *'drift'* to (a) the development of SHOT and (b) the fact that the precautionary principle was espoused by Frank Dobson, who told

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[959] These nuances also emerge on a comparison of the approach taken in response to a wider range of emerging viruses. For example, the high mortality rates seen in Ebola and Viral Haemorrhagic Fevers were unique and distinctive problems to grapple with. On the other hand, HEV and Zika virus are examples of viruses which were already understood to a greater degree on their emergence
[960] Written Statement of Professor Michael Rawlins [**WITN6406033**]

[961] Oral evidence of Sir Michael Rawlins [**INQY1000211**] dated 07.06.2022 at [126-131]
[962] Written Statement of Dr Angela Robinson [**WITN6926001**] at [306] and [308]
[963] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [270]

the British Blood Transfusion Society that *'the precautionary principle ruled'* when it came to vCJD interventions [**INQY1000176**].[964] The gradual adoption of the precautionary principle in medical ethics is further discussed in Section 4.

12.179 In our submission, the evidence on the extent to which the response to vCJD was radically different from other transfusion-transmitted infections, in the sense that it was newly precautionary, is a mixed picture. Fundamentally, the blood services had learned from the experiences of HIV and HCV and were anxious both to improve their scientific knowledge of vCJD, and correspondingly implement safety measures, as quickly as possible. There was a similar direction of travel externally, in government and society: Frank Dobson as Secretary of State for Health embraced the precautionary principle, and it is suggested that the public's perception of risk had also evolved.

12.180 However, there were also unique factors underpinning the response to vCJD, including the very distinctive nature of prion disease, and the very high level of scientific uncertainty surrounding the disease at the point where key decisions were taken, which meant that it was impossible to make well-informed risk-based judgments. Further, the country's experience of the BSE epidemic created real fears about the sheer scale (and nature) of the potential epidemic from the point at which vCJD first emerged.

12.181 To a certain extent the blood services' approach was not a radical departure from existing principles, which mandated that any emerging disease is treated as a potential threat to the blood supply until proven otherwise. Dr Miflin, Professor Collinge and Professor Rawlins' evidence all indicates the way in which risk-based decision-making always involves a degree of judgment which corresponds to the level of information known about a particular risk. In the face of uncertainty, the blood services did and do assume infectivity, and in our submission the blood services acted in appropriate and effective ways at the time in their response to vCJD.

[964] Oral Evidence of Professor John Barbara [**INQY1000176**] dated 26.01.2022 at [91]

13. SECTION 13: CONSENT

A. Patients Generally

13.1 NHSBT agrees with the SaBTO position that patients should be fully informed of the reasons for blood transfusion, its benefits, risks, and alternatives, and give their consent. Best practice requires that blood and blood products should only be given where these are essential to quality of life, health, or survival and where there is consent [**WITN0672006**].[965]

13.2 NHSBT notes the recent review and revision of the SaBTO recommendations on patient consent for blood transfusion, and the UK Supreme Court decision in *Montgomery* concerning the test of materiality: whether:

> *'…a reasonable person in the patient's circumstances 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'.*[966]

NHSBT notes the move towards a more collaborative approach to consent between patients and health practitioners.

13.3 NHSBT notes that there has been a cultural shift in relation to consent in recent years. As described in the written statement of Dr Barbara [**WITN6989001**]:

> *'…The culture in 1995 in respect of consent was completely different from the culture of consent today. As blood transfusion became microbially so much safer, we became more focused on the ever-decreasing residual risk. This was because we developed more meaningful ways of assessing those residual risks, either mathematically or more directly through Haemovigilance. As the culture of openness and patient involvement developed, it became appropriate to get patient consent before transfusion, where possible. Paradoxically the openness which better informed the general public may have made them more concerned because they then became aware that transfusion actually carried risks.'*

13.4 NHSBT is not responsible for the consent of patients in relation to the receipt of blood products. However, it notes the importance, given that the transfusion of blood components is not and is unlikely to ever be risk free, of ensuring that professionals are fully educated in the risk, and that informed consent of recipients is paramount.

13.5 In this respect NHSBT focuses on ensuring that clinicians are appropriately educated about the risks of blood transfusion so that they can consent the

[965] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1130]
[966] *Montgomery v Lanarkshire Health Board [2015] UKSC 11*

patient appropriately. NHSBT has for a long time worked to the Good Clinical Practice standards required for licensed medicines which required patient information and written consent to be incorporated into NHSBT's standard operating procedures from the outset [**WITN0643010**][967].

13.6 NHSBT also tries to minimise errors across the system and the risk of adverse events in blood recipients.

B. Consent and Donors

13.7 As with any other procedure, giving blood is not without specific risks and there are reasons that some volunteers should not donate. The blood services have long understood that it is important to obtain *'informed consent'* before making the decision to give blood.

13.8 Donors are asked to read NHSBT '*Donor Consents for Blood Donation'* booklet – this ensures that donors properly understand the importance of accurately answering the health check questionnaire. This also exists for platelets and plasma donation and makes clear where these should never be donated.

13.9 Where a donor receives a positive test result, the blood services share clinical information with the donor's GP or consultants in secondary care. NHSBT consents donors before contacting their GP or a consultant [**WITN0672006**][968]. Where a donor cannot be contacted, NHSBT asks the GP if they are able to contact the donor. NHSBT's privacy policy is GDPR compliant.

13.10 There were some historical occasions on which the GP was told without the donor's content, Dr Hewitt set out that these were limited to situations where:

> *'…there was evidence that there was another person who was at risk, who were unaware that they were at risk, and the donor had indicated that they would not be sharing that information with the person who was at risk. So, one case related to a mother and a child and one case related to a man whose wife subsequently arrived at our -- one of our blood donor sessions and who clearly did not know she was at risk and shouldn't be donating blood.*' [**INQY1000170**] [969]

13.11 Details of the consents obtained in relation to Non-Clinical Issue material are contained in the written statement of Dr Miflin. [**WITN0672006**][970] This includes the decision taken by Ministers to agree the sale of surplus material derived from blood. [**CBLA0001448**][971]

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[967] Written Statement of Dr Gail Milfin [**WITN0672006**] at [190]
[968] Written Statement of Dr Gail Miflin [**WITN0672006**] at [189 – 190]
[969] Oral evidence of Dr Hewitt **[INQY1000170]** dated 9 December at page 141.
[970] Written Statement Dr Gail Miflin [**WITN0672006**] at [765]
[971] Minutes of the Joint Meeting of Representatives of Haemophilia Directors, Blood Transfusion Service Directors and DHSS dated 15.09.1981 at [**CBLA0001448**]

C. Historical Consent to donation

13.12 The relationship between the donor and consent in the early 1980s is set out in a memorandum provided to an October 1984 RTD's meeting, [**NHBT0090316**][972] which demonstrates that the Medical Protection Society deemed the level of consent provided valid [**INQY1000167**]:[973]

> *'As we understand it, the prospective donor takes the initiative in contacting the Blood Transfusion Service and expressing a willingness to give blood and is then sent an appointment to attend a session. Before any blood is taken the donor is asked to read and sign a form ... which is addressed to 'Blood Donors'. In our view all the circumstances point clearly and unequivocally to implied consent. The consent is implied not only by the signing of the document ... but from all the circumstances, ie the initial volunteering, the attendance at the session, the signing of the form, and the permitting of blood to be taken without raising any objection.'*

D. Informed Consent in relation to HIV

13.13 At the time of introduction of HTLV-III testing the question of informed consent was discussed at length. Donors were informed that their blood would be tested for HIV, as it was considered that many might not be prepared to give blood if they knew it would be HIV tested. The decision was taken that the blood and transfusion services would inform donors that a test would be carried out [**WITN0672006**][974]. The donor would then be asked to provide their GP's contact details with consent to disclose their positive result to the GP.

13.14 Practically, donors were sent information prior to their appointment. Dr Jean Harrison stated:

> *'…I recall that people who had donated blood before were sent notification that HIV testing was to start, with their 'call up' letter. All donors were informed at the donor session that their blood would be tested. When they signed their form to consent to giving blood, they would also agree to having an HIV test and they gave consent to that as well as confirming that they were not in an 'at risk' group'* [**WITN7046001**].[975]

This was confirmed by Dr Wagstaff, who described how:

> *'…In all cases, donors were required to sign a consent to donation which included an affirmation that they had read and understood all*

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[972] Memorandum to the Medical Protection Society dated 1.08.1984 from a firm of solicitors, Le Brasseur & Bury
[973] Oral evidence of Dr Colin Entwistle [**INQY1000167**] dated 06.12.2021 at [70/14-22]
[974] Written Statement Dr Gail Miflin [**WITN0672006**] at [1314]
[975] Written Statement of Dr Jean Harrison [**WITN7046001]** at [457]

donor leaflets including and in particular the AIDS leaflet and in due course included consent to having the donation tested for HIV' [**WITN6988001**].[976]

E. HCV Test Consent

13.15 Donors were also required to sign a consent form in relation to HCV testing [**WITN7046001**].[977]

[976] Written Statement of Dr William Wagstaff [**WITN6988001**]at [472]
[977] Written Statement of Dr Jean Harrison [**WITN7046001]** at [502]

14. SECTION 14: RECORD KEEPING

A. Introduction

14.1 Keeping quality records is a matter of significant importance. As described by the Expert Report on Public Health [**EXPG0000047**], records contain information that '*may be important and they provide evidence of – and potential accountability for – the organisation's functioning*'.[978] The principles governing record keeping have considerably evolved over the course of the last fifty years and have been impacted by the centralisation of the blood services and the digitisation of records.

14.2 This section is largely confined to consideration of record-keeping by NHSBT and its predecessors.

14.3 We note that the Infected and Affected have had significant difficulties with accessing their records generally. There are only a few occasions where those difficulties have arisen in relation to seeking documents from the blood services. We have sought to address these issues, to the extent that they arise, below.

14.4 At the outset it is important to note that NHSBT does not hold medical records or details of which patients have been transfused. It only holds information on previous blood donors or records of those who have been contacted as the result of a transfusion investigation.

14.5 Therefore, it was:

a) the responsibility of the RTC to contact hospitals to inform them of the records of any blood components sent, when a donor had subsequently been informed they were positive for a TTI; and

b) for a hospital to review its own records and trace the patient who had received the blood and blood products [**WITN6926003**].[979]

B. History of record keeping

14.6 The history of the storage of information and record keeping by NHSBT is set out in Dr Gail Miflin's written statement [**WITN0672006**],[980] which is not repeated in detail here. Instead, NHSBT highlights the following features.

14.7 From the 1940s until the late 1980s, records were primarily held on paper using 'Donor 101 cards'. In some RTCs equivalent systems were used, such as 'Kardex' cards.[981] Paper records from this period are primarily held in

[978] Expert Report to the Infected Blood Inquiry: Public Health and Administration [**EXPG0000047**] at [68]
[979] Second Written Statement of Dr Angela Robinson [**WITN6926003**]
[980] Written Statement of Dr Gail Miflin [**WITN0672006**] at [134–205]
[981] Written Statement of Dr Gail Miflin [**WITN0672006**] at [137] and [141]

commercial record storage facilities under a national NHSBT contract. The NBA adopted a policy of indefinite storage of Donor 101 cards from 1980 onwards [**WITN0672006**].[982] It is worth noting that there has been an embargo in place on destroying records that relate to blood product traceability since 2001.[983] Dr Boulton described these paper-based records as *'meticulously maintained'*, which meant that when it came to computerisation '*the data that was transferred was pretty reliable'.*[984]

14.8 In her oral evidence, Dr Hewitt described the history of the management of records. Donors had what was called the 'buff card' (so called because it was buff coloured):

> *'…and the donor's details would be completed and the record of that donation would be on that buff card, together with the information about where the donor had previously donated. And then when the blood and the records were returned to the centre, the clerical staff would then match that up with the donor's permanent record, transfer that information onto the permanent record'* [**INQY1000170**].[985]

14.9 Professor Contreras described how as a result of these processes, when a blood product or component left the hospital it would be possible to trace this back to the donor.[986] Other helpful evidence was given setting out the management of records during this period: Dr Entwistle in oral evidence gave a comprehensive description of stock control in Oxford [**INQY1000167**].[987] Dr Boulton described the historical approach towards record confidentiality [**INQY1000181**],[988] and Dr Martlew described the physical information management of donor records [**INQY1000174**].[989]

14.10 Details about donors were stored in drawers and filed in alphabetical order. Dr Martlew described how:

> *'…Anything to do with donor referral or medical matters was kept in a completely separate place, and there might be an allusion on the donor card that there was some further information elsewhere. But that wasn't available to clerical staff. Everything was compartmentalised on a need-to-know basis. And similarly, all the donation records were on paper, big ledgers and so on, and there were unique donation numbers that went with the donor. So, the laboratory staff might find a property [sic] in a donor. If it was a clinical matter, that would be filed on their clinical record in one place. If meant deferral, then there would be an*

[982] Written Statement of Dr Gail Miflin [**WITN0672006**]
[983] Written Statement of Dr Gail Miflin [**WITN0672006**] at [179]
[984] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [142/1]
[985] Oral Evidence of Dr Particia Hewitt [**INQY1000170**] dated 09.12.202 at [134 / 4-22]
[986] Oral evidence of Professor Marcela Contreras **[INQY1000165**] 2/12/2021 [110/4-8]
[987] Oral evidence of Dr Colin Entwistle [**INQY1000167**] dated 06.12.2021 at [pg131]
[988] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [170/21]
[989] Oral Evidence of Dr Vanessa Martlew [**INQY1000174**] dated 20.01.2022 at [89/9]

> *instruction to defer from the geographical file, if you like'* [**INQY1000174**].[990]

14.11 Dr Martlew further described how donors were then deferred, and donations discarded where medical files were lacking [**INQY1000174**].[991]

14.12 The history provided by Dr Miflin is supplemented by SPN1042/2 [**WITN0672027**], which explains the history to date of donor information record keeping and archived data linked to blood supply. The document also describes the processes in place for retrieval of that data depending on the relevant storage medium, itself dependent on when the data was entered into the archives. The document identifies the timelines for individual site records and shows the format in which records were kept as they relate to a specific period at a specific site. Formats include off-site files, microfilm/microfiche, electronic heritage system records, PULSE archive system records and PULSE live system records.

C. Issues with RTC record keeping

14.13 In the 1980s there was no central organisation of the NBTS, and as described by Dr Hewitt:

> *'…there were no formal information-sharing measures to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations, but in the presence of manual maintenance of records, it is difficult to envisage how such a measure could have been devised'* [**WITN3101009**].[992]

However, if a donor had been identified as carrying a blood-borne infection, he or she would have been notified and given appropriate advice. If for any reason that donor gave a further donation, it would be detected through testing and the donor would be re-contacted.

14.14 There was no system between the RTCs for enabling one RTC to tell another the details of excluded donors prior to the establishment of the NBA. However, the centres could contact each other to request further information. Professor Contreras described how

> *'…if the donor told us that they'd been a donor at another centre, then we would immediately contact the other centre and say, "Could you please tell us whether this donor is fit and send us the 101 card for that donor"* [**INQY1000165**].[993]

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[990] Oral Evidence of Dr Vanessa Martlew [**INQY1000174**] dated 20.01.2022 at [89/9]
[991] Oral Evidence of Dr Vanessa Martlew [**INQY1000174**] dated 20.01.2022 at [93/12]
[992] Written statement of Dr Patricia Hewitt [24/11/2021 148]
[993] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [121/1]

14.15 As acknowledged by Professor Contreras, this did create risks, including of a donor who was positive and presented twice at different centres to donate, as set out in an article by (then) Professor Contreras, Professor Barbara and Dr Briggs [**NHBT0000030_007**]. In this, case the donor was:

> *'…asked to refrain from blood donation until further notice and his records were withdrawn from our routine donor file. Despite these recommendations, he returned as a new donor 7 months later and his donation was one of four units given as whole blood to a patient'.* [**NHBT0000030_007**].

14.16 On being asked about this particular patient, Professor Contreras described how old records would have been checked before any blood component was taken, and how the '*donor was adequately counselled to please not come and donate again'* [**INQY1000165**].[994] That this incident was written up suggests that this was an unusual occurrence.

14.17 Historically, there was no uniformity between RTCs as to record keeping. Drs Huw Lloyd and Alan Beal and Mr Tony Martina put together a report for the National Directorate on record retention [**WITN6935001**].[995] This report described a system which would include working within the constraints of a formal written policy, and with records of document destruction (as required within the policy) being maintained. This policy was implemented within the Newcastle Transfusion Centre.

14.18 With the establishment of the NBA there was a new opportunity to exchange information [**INQY1000165**].[996] Prior to its introduction, the NBTS in its various forms had limited control of the record keeping arrangements at each centre: however, with centralisation came increased conformity in approach. In addition, came the creation of the management information system (**MIS**) following early discussions on its introduction in 1989 [**NHBT0046964_001**].[997] The full extent of the transformation for information management and record keeping is described at Section 4 of Dr Miflin's written statement [**WITN0672006**].

D. Record keeping elsewhere

14.19 Obtaining reliable information on patients treated with blood or blood products was difficult. Contemporaneous record-keeping of those patients who received blood and blood products suffered from being both incomplete and unreliable. The below section on lookback demonstrates the difficulties faced by those attempting to trace the history of blood and blood products.

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[994] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [124/11]
[995] Written Statement of Dr Huw Lloyd [**WITN6935001**] at [97]
[996] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [15/13]
[997] Minutes of the sixth meeting of the NMC's [**NHBT0046964_001**] dated 2.11.1989

14.20 Witness evidence during the Inquiry repeatedly identified that poor or unavailable hospital records was a major theme which persisted throughout the formal lookback exercises [**WITN6926003**].[998] As summarised by Dr Diana Walford:

> *'…it was largely the poor record-keeping at the hospital blood banks rather than at the Regional Transfusion Centres, and we were sort of alerted to this by a scandal, if that's the right word, at the National Heart and Chest Hospital, I think it was called in those days, where there appeared to be potentially some sale of blood to the private sector going on and I was asked to get in touch with Dr Wagstaff to get it investigated very quickly. It turned out that the record-keeping at the Regional Transfusion Centres was not bad at all and they knew where they had sent the blood. What was a problem was that the record-keeping at the hospital blood banks was not good and they were supposed to return outdated plasma to the Regional Transfusion Centres and they were certainly supposed to say what was the end user of whatever was the unit of blood, and that information wasn't getting back consistently to Regional Transfusion Centres and that was obviously a major issue which needed attention'.* [**INQY1000138**] [999]

14.21 The oral evidence of Dr Morris McClelland called attention to the fact that although guidelines were issued to hospitals about record keeping, there were a lot more opportunities for error and failure to trace records at the hospital level than at the transfusion centre level [**INQY1000179**]. [1000] Dr Hewitt described how the quality of record keeping hugely improved *'after the issue (in 1984) of HC 84(7) relating to Record Keeping and Stock Control.'*[1001] Dr John Napier also identified the issues caused by the highly pressurised environment of hospital transfusion laboratories [**INQY1000163**].[1002] The significant issues with hospital record keeping became apparent during the lookback exercises described below.

E. Lookback

14.22 The blood service has a duty to maintain appropriate records to enable effective lookback to take place to discharge its duty to recipients.

14.23 Further details regarding the complexities of lookback in a context of incomplete record keeping are included in the written statement of Dr Angela

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[998] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [261]
[999] Oral Evidence Dr Diana Walford [**INQY1000138**] dated 21.07.2021 at [283/1]
[1000] Oral Evidence of Dr William Mcclelland [**INQY1000179**] dated 01.02.2022 at [41/9] For further issues in relation to the availability of records at hospitals also see Oral Evidence of Dr Vanessa Martlew [**INQY1000174**] dated 20.01.2022 at [101/12] and Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [67/12]
[1001] Written Statement of Dr Patricia Hewitt [**WITN3101006**] at [136]
[1002] Oral Evidence of Dr John (Tony) Napier [**INQY1000163**] dated 30.11.2021 at [130/8]

Robinson [**WITN6926003**]. The lookback process, and in particular the first lookback exercise in 1995 described in Section 11 of these submissions, was significantly frustrated by the major issues of poor and / or unavailable hospital records. Despite this patchy record keeping, however, the blood services endeavoured to provide, as part of lookback efforts, a complete list of components issued and the date of issue. These efforts were undertaken so that even if hospitals did not have the required records, it would remain possible to estimate how many potentially at-risk recipients could not be traced, and when and at which hospital they were transfused.

14.24 Dr Robinson further describes how computer records were also limited: this was most marked where longstanding donors were involved, as the quality and easy accessibility of records reduced over time (an issue which varied in its intensity from centre to centre). [1003] As part of the lookback exercises, information was retrieved manually from hospital records: Dr Robinson also addresses the process for dealing with lost records,[1004] and the *ad hoc* strategy deployed at hospitals which had lost records.[1005] Dr Robinson identifies the numerous issues posed by lost records in relation to lookback,[1006] including difficulties related to tracing the cause of death, issues caused by the transition from manual to computer records [**NHBT0040501_004**][1007] and complexities in relation to record-keeping in the context of an inter-uterine transfusion [**NHBT0002892**].[1008]

F. Computerisation

14.25 Working processes were computerised in the RTCs from the early 1980s. This is because *'one of the requirements of the blood transfusion centre is you aim at zero errors, and that is that you mustn't make any mistakes with regard to the labelling of something or the assignment of the blood grouping of something. It must be absolutely correct'* [**INQY1000163**].[1009] The transfusion centres therefore focused on early computerisation to try and tighten up the whole of information management throughout the centres in a secure and error-free fashion. However, some issues did arise with computerisation, such as in relation to donor numbers [**INQY1000167**] [1010]. When records were computerised '*these were maintained to a very high standard*' [**INQY1000163**].[1011] Despite the highly pressurised, busy situations of many labs, attempts were made to ensure that '*a record of the information [donors]*

[1003] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [442]
[1004] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [466-470]
[1005] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [472]
[1006] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [491-492], [504] and [574]
[1007] Northern Ireland report on the lookback dated 23.05.1995
[1008] Memorandum by Dr Sue Knowles dated 24.05.1995
[1009] Oral Evidence of Dr John (Tony) Napier [**INQY1000163**] dated 30.11.2021
[1010] Oral evidence of Dr Colin Entwistle [**INQY1000167**] dated 06.12.2021
[1011] Oral Evidence of Dr John (Tony) Napier [**INQY1000163**] dated 30.11.2021 at [130/8]

been given in terms of allowing tracing of the destination of any blood and blood products' was kept.[1012]

14.26 Dr Miflin's written statement [**WITN0672006**] describes the computerisation of records through the introduction of PULSE, which acts as a central database of blood donors, between 1996 and 1998.[1013] Responsibility for review and destruction of documents is divided among the Storage Agency, Records Manager, IAO or Appointed Deputy, and Departmental Managers/Operators.[1014] There are arrangements for information sharing with other organisations for reasons including the best interests of the donor, maintaining blood safety, or public health reasons.[1015] Dr Miflin also describes the relevant regulatory and policy requirements that govern the maintenance of records today.[1016]

14.27 Prior to the introduction of PULSE, there was a computer system called TRACE which was initially installed in Cardiff.[1017] The internal workings of TRACE were set up in two sections, one handling donor information and donation test results, and the other handling manufacturing and product issues. This design was to protect donor confidentiality and minimise access to sensitive information such as a positive HIV screening test[1018]. However, despite the computerization, this remained a local system without coordination to enable the passing of information between regions [**INQY1000174**].[1019]

14.28 Before PULSE was introduced, because the blood service was originally fragmented, computerisation developed differently in different centres, but the blood service was an early adopter of computerisation because of the benefits to its work. Professor Contreras has described the information and samples retained at North London BTC (NLBTC) [**WITN5711001**],[1020] but also how an early version of PULSE was developed in the 1980s in response to the theft of plasma.[1021]

14.29 Looking to the future, NHSBT has set out interim submissions on possible recommendations [**SUBS0000018**][1022] relating to the use of systems which allow full electronic traceability of blood transfusion from donor to recipient (vein-to-vein tracking).

[1012] Oral evidence of Dr John (Tony) Napier INQY1000163 (135/18/21)
[1013] Written Statement of Dr Gail Miflin [**WITN0672006**] at [38] and [145-147], [161-170]. The rules for storage of records within PULSE are set out at [195]
[1014] Written Statement of Dr Gail Miflin [**WITN0672006**] at [180]
[1015] Written Statement of Dr Gail Miflin [**WITN0672006**] at [188-199]
[1016] Written Statement of Dr Gail Miflin [**WITN0672006**] at [203-204]
[1017] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [300]
[1018] Second Written Statement of Dr Angela Robinson [**WITN6926003**] at [301]
[1019] Oral Evidence of Dr Vanessa Martlew [**INQY1000174**] dated 20.01.2022 at [94/8]
[1020]Written Statement of Professor Marcela Contreras [**WITN5711001**] at [120], [121] and [160-170]
[1021] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [44] and [119]
[1022] Interim written submissions on behalf of NHSBT [**SUBS0000018**] at [29] and [58-60]

14.30 It is clear that historically, there have been issues with record-keeping across all organisations. This in part relates to the difficulties with information management prior to computerised record keeping. Record keeping in the blood services has been good, and today, because of the requirements of the Blood Safety and Quality Regulations 2005 (**BSQR 2005**) NHSBT has very complete records that enable components to be traced. Hospitals have systems designed to ensure traceability from the blood bank to the patient, but these use a different notation (e.g. from a donation number, to NHS number). In future, NHSBT would like to link these systems.

15. SECTION 15 TEACHING & TRANSFUSION PRACTICE

A. Historical Approach to Teaching and Transfusion Practice

(1) Introduction

15.1 This section addresses the involvement of the blood services in teaching and transfusion practice. This should be viewed against the following backdrop:

a) The primary remit of RTCs was to provide sufficient safe blood and blood components to hospitals, and sufficient plasma to BPL [**WITN5711001**].[1023]

b) The need for good practice, commonly applied, by the RTCs was considered essential to patient care. This included ensuring the provision of safe products to BPL and to other transfusion centres on the occasions that products were transferred between centres [**NHBT0000013_001**].[1024]

c) Achieving consistency in practice across multiple different RTCs, with different resource levels in the decentralised system that existed before the creation of the NBA was a significant operational challenge. A further operational challenge related to the drive for self-sufficiency (see Section 6 for further details), which led to the prioritisation of efforts to increase plasma supply, and only limited resource available to focus on transfusion and teaching practice [**INQY1000166**].[1025]

d) The responsibility for teaching and transfusion medicine services was shared with clinicians in hospitals and haemophilia centres. The primary responsibility for the decision to transfuse lay with the treating clinician. The role of RTCs also included providing hospitals with diagnostic services. Teaching and transfusion practice were therefore only one aspect of the blood services' role.

e) Nor were the blood services the only external body to provide such support. Haematologists received transfusion medicine advice from specialist professional bodies, such as guidelines produced by the British Society for Haematology [**INQY1000187**].[1026] Similarly, haemophilia clinicians had distinct committees for sharing expertise within the specialism. Regular product updates from BPL also assisted with new developments **WITN6988001**.[1027]

[1023] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [87]
[1024] Guidelines titled 'Guidelines for the Blood Transfusion Services in the United Kingdom 1989', prepared jointly between the United Kingdom Blood Transfusion Services and the National Institute for Biological Standards and Control. 'The Red Book'
[1025] Oral evidence of Professor Dame Marcela Contreras Transcript of 2 December 2021, 18/24-19/4
[1026] Evidence of Dr Jonathan Wallis, transcript of 24 February 2022 [**INQY0000187**] [e.g. 8/22-9/16]
[1027] Written Statement of Dr William Wagstaff [**WITN6988001**] at [469]

15.2 Historically, there was extensive contact between RTCs and hospitals. Many haematologists considered they had good and close relationships with their local RTC. For example, during his oral evidence Dr Mike Murphy described how the relationship between the RTC and St Barts hospital was very good, and that RTC colleagues were available to provide clinical advice to hospital colleagues when the clinicians wanted **[INQY1000187].**

15.3 Dr Jonathan Wallis's Written Statement described how the division of logistics played out between the Haemophilia Treatment Centres (**HTCs**) and the RTCs [**WITN6982001**].[1028] HTCs generally looked at any adverse events, sampling errors, and any new developments and guidelines – for example the role of cell salvage and autologous transfusion. The contractual role of the RTC in developing transfusion practice was to lead on any new component formulations, logistical changes to the centre, and any particular aspect of transfusion safety. This however was not always a formalised division, and much of the request for input and expertise was only initiated on the hospital's request [**INQY1000187]**.[1029]

15.4 Thus, while the blood services had a role in relation to teaching and transfusion practice development on the use and management of blood and blood components, the executive role in relation to the treatment of specific diseases (for example – haemophilia) was the responsibility of the treating clinician. This is explored further in section 3.

(2) Teaching and Training 1970-2000

15.5 Before the creation of the NBA of the blood services in 1993, the *'autonomous nature of the RTCs'* meant that *'each adopt[ed] their own approach to…training and professional development'.* As a result, the documentary evidence does not provide a *'complete record'* of the approach to training [**WITN0672006**].[1030] The oral evidence from RTDs demonstrates the autonomous approach of each region in relation to training and professional development, subject to collective initiatives driven through meetings of the RTDs. The same is true for transfusion practice.

15.6 Efforts to educate clinicians on transfusion practice centred on the fundamental principle of appropriate use of blood - that blood components should only be used *when* strictly necessary, in the absence of alternatives, and only to the *extent* necessary. Historically, these efforts took place in an engrained culture of clinical freedom, and many clinicians – in particular, surgeons – were resistant to change.[1031]

[1028]Written statement of Dr Jonathan Wallis at paragraphs [101]-[110].

[1029] Oral evidence of Dr Jonathan Wallis **[INQY1000187]** at 38, 16-25; 110, 4 and 22-23, 111, 2-4 and 22-112, 8; 125,7-15; 128, 18-25

[1030] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1499]

[1031] For further information on this issue, see Section 3 the Blood Service and its Role.

(3) Internal Training

15.7 There was a wide range of internal training programmes provided within RTCs. In 1997, Dr Gunson's proposals for reorganising the blood service noted the technical expertise required in RTCs, and the need to train specialists in blood transfusion to maintain their medical staffing [**CBLA0000612**].[1032] In the mid-1970s, the RTDs also discussed medical laboratory training for RTCs [**DHSC0105496_010**],[1033] training for clinicians [**DHSC0200019_002]** and the expanded role of nursing staff for training donor attendants [**NHBT0016487**].[1034] The role of trained nurses within RTCs continued to expand into the 1990s and drove improvements in donor selection and care [**WITN6933001**].[1035]

15.8 With the emergence of HIV, RTC staff were trained to perform donor counselling [**NHBT0000186_033**][1036] and how to undertake new forms of testing for HIV and HCV. Internal training has been attributed as a key factor driving successful outcomes at NLBTC [**WITN5711001**];[1037] [**WITN6989001**].[1038]

(4) External Training

15.9 External training was carried out on an autonomous regional basis. For example, Professor Contreras notes that there was a close relationship between NLBTC and BPL due to geography: *'given our Region's proximity to BPL, we had a closer relationship with BPL than perhaps other regions did. BPL would send their staff to us for training and learning regarding the production of plasma and the screening of blood donations'* [**WITN5711001**].[1039] Training of students and clinicians, however, was undertaken by staff at multiple RTCs.

15.10 In terms of training clinicians, it is important to note that many clinical haematologists were required to undertake a period of training within RTCs. Dr Wallis spent six months training at his local RTC [**JW OE**].[1040] Dr Williamson recalls that in 1985, all senior registrar posts in haematology included a six-month period of training at an RTC. Her own training separately involved sitting in haemophilia clinics and haematology departmental meetings in hospitals [**WITN0643001**].[1041] Dr Wagstaff recalls that in-RTC training for consultant

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[1032] A letter written by Dr Gunson to the Royal Commission on the NHS in 1977
[1033] Minutes of the 164th meeting of the Regional Transfusion Directors held on 8 December 1976,item (d) page 2-3
[1034]Minutes of the 155th meeting of the Regional Transfusion Directors, held on Wednesday 19 February 1975 item 3 pages 4-5
[1035] Written Statement of Dr Peter Flanagan [**WITN6933001**] at [318]
[1036] Minutes from a meeting of the EAGA Screening Test Subgroup on 10 June 1985
[1037] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [49]
[1038] Written Statement of Professor John Barbara [**WITN6989001**] at [661]
[1039] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [123]
[1040] Transcript of 24 February 2022 at 2
[1041] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [5]

haematologists was mandated by the Royal College of Pathologists WITN6988001.[1042] This helped to build solid links between the transfusion centres and the hospitals. In oral evidence, when asked to explain the relatively late set-up of a hospital transfusion committee in Trent, Dr Wagstaff made reference to these arrangements in his response:

'I think a lot of this hinged on the fact that the great majority of the haematologists active in Trent region had been trained partly at transfusion centres and were quite au fait with what was going on and were certainly kept up to date by their colleagues in the transfusion centres' **[INQY1000175].**

15.11 Blood service clinicians held clinical and teaching roles before [**WITN3456002**],[1043] during WITN6988001][1044] and after [**WITN3456002**][1045] their roles in RTCs. Again, reflecting the *ad hoc* nature of regional organisation, Dr Williamson describes how in the 1980s, when all three consultants at East Anglia RTC were about to retire, ad hoc arrangements were made to share expertise between different disciplines:

'A plan was therefore developed by the Professor of Haematology (Professor Robin Carrell) and the Regional Director of Public Health (Dr Michael O' Brian) to create an academic Division of Transfusion Medicine within the University Department of Haematology, as a joint activity between the University and the East Anglian Regional Health Authority. This involved converting the EABTC Director post into a University Professorship, with 50% time for research and teaching, and 50% as an Honorary NHS consultant and Director of EABTC. The other 2 consultant posts were converted into 50:50 University Lecturer/Honorary Consultant posts' [**WITN0643001**].[1046]

15.12 Some degree of co-ordination on clinical and educational training is evident in the decision to open the new Wessex Transfusion Centre in 1971. Dr Boulton described this decision as partly motivated by Southampton University becoming an undergraduate school of medicine, and the benefits for students and staff of having an RTC sited on the grounds of the new teaching hospital **[INQY1000181].** These types of links helped expose medical students to the processes of RTCs.

(5) Liaison with Hospitals

15.13 Consultants at the NLBTC were *'heavily involved'* with the training hospitals in their region, and '*taught doctors and nurses at all levels about the safety of blood and the need to avoid unnecessary transfusions'* [**WITN5711001**].[1047] Professor Contreras' evidence states that around the time when she was

[1042] Written Statement of Dr William Wagstaff [**WITN6988001**] at [468]
[1043] Written Statement of Dr Frank Boulton [**WITN3456002**] at [5]
[1044] Written Statement of Dr William Wagstaff [**WITN6988001**] at [8]
[1045] Written Statement of Dr Frank Boulton [**WITN3456002**] at [7c]
[1046] First Written Statement of Dr Lorna Williamson [**WITN0643001**] at [5]
[1047] Written Statement of Professor Marcela Contreras [**WITN5711001**] at [278].

writing her *Vox Sanguinis* article on the risks of AIDS in 1983, NLBTC was providing '*regular'* training on the appropriate use of blood to students and registrars, with Professor Contreras clearly conveying the message *'BLOOD CAN KILL'* on her chalkboard. At this time NLBTC also undertook clinical audit of blood usage and queried whether the usage was appropriate with hospitals[1048] to try to minimise the risks associated with transfusion.

15.14 In oral evidence, Professor Contreras emphasised the autonomous nature of this hospital liaison, and the fact that NLBTC consultants, rather than hospital staff, drove these initiatives **[INQY1000165]**:[1049]

> *'We were very, very involved… in going to hospitals and asking to – more or less to be invited and going to grand rounds [sic] and going to hospitals and educating the consultant haematologist and MLSOs, inviting clinicians to our centre. We had regular meetings, annual meetings, with consultants and MLSOs in charge of the blood banks to educate them about transfusion, and we also taught at all the medical schools that were in our catchment area and we lectured nationally and internationally…we more or less asked to be invited to meetings to the College of Surgeons, College of Anaesthetists, so that we would -- and we involved them in transfusion medicine'.*

15.15 Professor Contreras explained that regional variation in the extent of hospital liaison was a weakness of the blood services' historic structure [**WITN5711001**].[1050] In oral evidence, she recalled that transfusion medicine was '*hardly ever discussed'* at RTD meetings, which tended to focus on

> *'…exchange of information between centres and agreeing some national issues, like donor selection or introduction of testing…exchanging information about plasma procurement'* **[INQY1000165]**.[1051]

When asked why transfusion medicine was not a significant feature of discussions, she replied that she was *'speculating'* on behalf of other RTDs, but thought that:

> *'…it was because they were mostly concerned mostly concerned about collecting enough blood and collecting enough plasma for BPL, and issuing the different components. So I would say that some centres were so concentrated on the collection that they had very little contact with the hospitals'* [**INQY1000165**].[1052]

15.16 There is, however, evidence of clinicians at other RTCs undertaking clinical training of their own initiative. For example, in addition to the mandatory training for consultant haematologists, Trent RTC organised a one-month course for

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[1048] Written Statement of Professor Marcela Contreras [**WITN5711001**] [268].
[1049] Oral Evidence of Professor Marcela Contreras [**INQY1000165**] dated 2.12.2021 at [158-159].
[1050] Written Statement of Professor Marcela Contreras at [**WITN5711001**] at [227(k)].
[1051] Oral Evidence of Professor Marcela Contreras [**INQY1000165**] dated 2.12.2021 at [18]
[1052] Oral Evidence of Professor Marcela Contreras [**INQY1000165**] dated 2.12.2021 at [19]

local haematology registrars, including a lecture on the hazards of transfusion, and organised basic and advanced courses for local scientists and hospital blood banks **WITN6988001** [1053]

15.17 Dr Martlew, who was a consultant haematologist at Manchester RTC from 1984-1988 and at Mersey and North Wales RTC from 1988-1994, recalled that as part of the response to hepatitis:

> *'377. Educational sessions were arranged at hospitals, in undergraduate and postgraduate teaching and at regional specialty meetings. I would always advise colleagues that they must be able to justify their indication for prescribing transfusion as there was a small chance that the recipient could develop an infection from a blood transfusion, which might possibly only become apparent many years later. For instance, if someone had symptoms of jaundice or abnormal liver enzymes and they had had a blood transfusion, we would ask that they inform the Blood Centre. The cause of the jaundice on occasion might be multifactorial - for example after surgery on the biliary tract. This could be a complication of the surgery, but it could be from a transfusion and we needed to know so that we could trace the donor and any other recipients after the date of seroconversion.*
>
> *378. We encouraged clinicians who thought they had a patient who had an infection from blood transfusion to call us. We would impound any other blood components prepared from the donation they had received, test that blood and call the donor in for further blood test. I would have investigated all the cases referred in Manchester while I was there and some of those in Liverpool.*
>
> *379. I would also have been asked by clinicians how to prescribe blood and to discuss the associated risks and I would provide them with advice in this respect'* [**WITN4034001**].[1054]

15.18 The Mersey and North Wales Transfusion Centre was involved with undergraduate and postgraduate teaching at three Liverpool universities [**WITN4034001**].[1055]

15.19 Dr Boulton also gave evidence that on arriving at the Wessex RTC in 1990:

> *'I regarded part of my job as going round the hospitals, talking to the consultants, where I could, and talking to the laboratory staff as well, so that they were on board with the concept that it doesn't matter what you -- what the prices are, what you need to do is to cut down your use for*

[1053] Written Statement of Dr William Wagstaff **WITN6988001** at [468]
[1054] Written statement of Dr Vanessa Martlew [**WITN4034001**] at [141].
[1055] Written statement of Dr Vanessa Martlew [**WITN4034001**] at [141].

> *the benefit of the patients… that was my ideology, that there needed to be a rational, clinically justifiable system for the use of any blood or blood products that was entering a patient's veins'* [**INQY1000181**].[1056]

15.20 In addition to training in hospitals, blood service clinicians attended meetings of specialist clinical groups. Dr Wagstaff and Dr Boulton recalled attending meetings of regional haematologists which were decided upon at the local level. At Trent, the haematologists met around twice a year [**WITN6988001**],[1057] and similarly at Wessex they met 2-3 times a year [**INQY1000181**][1058].

15.21 The level of communication between RTCs and haematologists was not always matched by communication with other relevant clinicians, such as anaesthetists. For example, a meeting of the Trent RHA Subcommittee in 1986 records that Dr Wagstaff had happened to learn about a planned increase in open heart surgery at a regional hospital via the notes of an anaesthetist committee meeting [**DHSC0032165_115**].[1059] A clinical committee recorded that this lack of communication was an issue:

> *'…the Sub-Committee found this information very disturbing and stated their concern about the apparent lack of communication. The Committee stressed the need for any District Health Authority planning a service which would increase the use of blood or blood products to notify the Regional Blood Transfusion Service as a matter of urgency.'*

15.22 In oral evidence Dr Wagstaff confirmed that he did not think that such communication from clinical committees was routine, but that he was sent these particular minutes by *'someone on the committee'.*[1060]

15.23 What emerges from the evidence overall during the 1970s and 1980s, and prior to the creation of the NBA is the lack of any consistent formal mechanism for liaison between regional blood centres and the hospitals they supplied, or particular specialist clinical groups. The widespread establishment of Hospital Transfusion Committees (**HTCs**) around 1988-1990 was a significant step towards formalising these relationships, and in particular embedding the principle of the appropriate use of blood.

(6) Hospital Transfusion Committees

15.24 HTCs were set up to drive appropriate blood usage and transfusion practice within a hospital and to prevent misuse of blood. Their origin is not entirely clear. There was certainly an HTC at the Freeman Hospital in Newcastle by the

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[1056] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [144-147]

[1057] Written Statement of Dr William Wagstaff [**WITN6988001**] at [135; 468]
[1058] Oral Evidence of Dr Frank Boulton [**INQY1000181**] dated 04.02.2022 at [159]

[1059] Trent Regional Health Authority, Regional Blood Transfusion Service, Notes of the meeting of the RHC sub-committee held on 26 September 1986, item 86/14 at page 5
[1060] Transcript of 25 January 2022 at 27-28.

time Dr Wallis joined in 1990, set up by his predecessor, which he believes started '*either in 1977 when the hospital first opened or shortly afterwards'* [**WITN6982001**].[1061]

15.25 However, by and large, the first few HTCs appeared to come onstream around 1990, and to have been driven certainly by NLBTC around 1988-1990, following their regional work on clinical audit.

15.26 In May 1990, Professor Contreras wrote to Dr Hilary Pickles at the Department of Health setting out the need for HTCs (and why she did not believe that cross-charging would lead to a *'better'* use of blood) [**NHBT0000189_142**]:[1062]

> *'The consultants at this Centre firmly believe that it is only through continuous contact with, and education of our user hospitals that we will be able to improve the practice of clinical blood transfusion and make the best use of blood derivatives….[…]*
>
> *We believe that the way forward in clinical blood transfusion is the establishment of Hospital Transfusion Committees with representatives from those clinical specialties most concerned with blood usage, including a nursing representative. Such committees should meet on a quarterly basis and should deal with matters such as transfusion practice within the hospital, use and abuse of blood and blood components, audit of the use of blood etc.'*

15.27 Professor Contreras noted that as a first step, NLBTC had audited five major hospitals for their use of fresh frozen plasma and platelets and concluded that:

> *'…improvement in all aspects of transfusion practice is necessary. Education regarding the value of blood components and areas in which their use cannot be justified is particularly needed. Hospital transfusion committees are now being established in the five audited hospitals and we intend to encourage a further five hospitals to move in this direction in the very near future'* **[NHBT0000189_042].**

15.28 In oral evidence, Professor Contreras set out that a NLBTC consultant would sit on the HTCs, and stated that the purpose of an HTC was:

> *'…to make clinicians aware of the usage of blood and of the risks of transfusion and of their own practice of transfusion. Make clinicians aware of transfusion medicine, because it was a nonentity before, they took it like saline, you know. So, it was mostly educational and to share information at hospital level on transfusion medicine'.*

15.29 It is not clear whether Professor Contreras received a direct response to her letter: she stated that *'the ultimate responsibility lay with them, but this was our*

[1061] Written Statement of Dr Jonathan Wallis [**WITN6982001]** at [114].
[1062] Professor Contreras letter to Dr Hilary Pickles at the Department of Health, 31 May 1990

local initiative…I felt it was my duty to inform them of what we were doing…eventually it led to the CMO being interested' **[INQY1000165]**.[1063]

15.30 Elsewhere, Professor Murphy recalled that an HTC was set up at Barts in the late 1980s [**WITN0672006**].[1064] One was not set up in Trent until February 1991, but this was attributed in oral evidence to the fact that haemotologists in Trent were *'quite au fait with what was going on and were certainly kept up to date by their colleagues in the transfusion centres'* [**INQY1000175**].[1065] In Leeds they were up and running by 1992 [**NHBT0017246**]. The date in Mersey is some years prior to 1994 [**WITN4034001**].[1066]

15.31 The introduction of cross-charging (considered in more detail at section 6) coincided with teaching on appropriate use of blood, as hospitals had a financial incentive to reduce the use of blood and blood products [**INQY1000181**][1067].

15.32 Despite the flurry of activity in the early 1990s, HTCs took some time to embed nationwide. The first Better Blood Transfusion Initiative Circular in 1998 (discussed below) recommended instituting HTCs across all trusts [**NHBT0083701_002**]. The first annual report of the National Blood Transfusion Committee (**NBTC**) in 2002, which aimed to provide a toolkit for implementing the Circular, expressly stated [**RLIT0000848**]:

> *'This document is intended to help hospital transfusion committees develop a business case for the establishment of a hospital transfusion team in each trust, particularly for the role of transfusion practitioners, dedicated sessions for a lead consultant in blood transfusion, and for audit and administrative support.'*

15.33 In oral evidence, Dr Wallis explained that the importance of the Circulars was first, to measure baselines of transfusion practice to see what needed changing, and second, to provide a mandate for trusts to fund improvements, in order to comply with the Circular. He noted that the second Circular, which mandated the provision of transfusion nurses, was *'very valuable and led to big changes throughout the country'* [**INQY1000187**][1068].

[1063] Oral Evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [163]

[1064] Written Statement of Dr Gail Miflin [**WITN0672006**] at [123, 22]
[1065] Oral Evidence Dr William Wagstaff [**INQY1000175**] dated 25.01.2022 at [119, 24]
[1066] Written Statement of Dr Vanessa Martlew [**WITN4034001] [138-140]**

[1067] Oral evidence of Dr Frank Boulton on 04.02.2022
[1068] Oral evidence of Dr Jonathan Wallis dated 24.02.2022 at pages 80-83

15.34 While HTCs have not always been prioritised by stretched clinicians, and retention of attendees remains an issue, they are an *'essential forum'* which provided a conduit into hospital governance structures for issues relating to transfusion [**WITN7001001**].[1069]

B. Transfusion Practice 1970-2000

15.35 The drive for better blood transfusion came from a number of different places, including anaesthetists, which as a profession were described by witnesses as being very helpful in convincing surgeons to use blood differently.

15.36 Good transfusion practice is fundamentally focused on the core principle of the appropriate use of blood. In addition to the training described above, the blood services made efforts to drive awareness of this principle through the dissemination of various transfusion guidelines. These include:

a) In 1973, Notes on Transfusion was published [**HCDO0000861**]. This guide cautions against transfusion without a '*definite indication'* and identifies that an '*element of risk is associated with every transfusion'*. It highlights that there are limited supplies of blood and that it therefore should not be used unnecessarily. The use of transfusion to overcome '*moderate or slight degrees of anaemia that could be overcome as effectively, if more slowly, by other means seems unjustifiable unless some cogent reason for speed of recovery exists*'.

b) In oral evidence, Professor Contreras tentatively agreed that this approach towards transfusion practice was nothing new, even in 1973 [**INQY1000165**].[1070] However, the evidence from clinical haematologists training in the 70s and 80s was that they were not always taught about transfusion risks [**Prof Goldstone OE**]; **[Prof Murphy OE**].

c) In 1984, Professor McClelland and Dr Cash worked on a document to introduce concepts of clinical quality management into the blood services [**INQY1000178**][1071].

d) In 1987 a UKBTS / NISBSC Liaison Group was formed to draft guidelines on safety of blood products. This later became the Red Book [**NHBT0108865_010**]. The focus on this work was on quality assurance.

e) In 1989, The Handbook on Transfusion [**PRSE0003047**] was published: this included a *'clear recognition of the risks of transfusion-transmitted*

[1069] Written Statement of Professor Michael Murphy [**WITN7001001**] at [121].
[1070] Oral evidence of Professor Marcela Contreras [**INQY1000165**] dated 02.12.2021 at [1, 16]

[1071] Oral evidence of Dr Brian McClelland [**INQY1000178**] dated 28.01.2022 at [129/9].

infection which guided donor selection criteria at the time' [**WITN4034001**].[1072]

f) In 1989/90, colleagues, mostly from North London, but also across UK blood services, and clinicians, published the *'ABC of Transfusion'* [**RLIT0001564**], edited by Dr Contreras. It was published by the BMJ and was distributed by BPL to all hospitals for free, so they were aware of the risks of transfusion and transfusion medicine.

g) In 1989, *'New Trends in Blood Transfusion',* co-authored by Dr Contreras was published [**NHBT0057960**]**.** It covered recent changes and developments in blood transfusion and identified the factors which would determine the future use of blood and blood derivatives. It covered, specifically:

> *'The tendency towards a more rational use of blood and blood components for those patients who really need them. Education of clinicians on the proper use of blood is now becoming an accepted aspect of medical training. Responsible clinicians are re-examining the benefit-to-risk relationship of blood transfusion. However, there is a great deal of ground to be covered since many clinicians consider blood and blood components on the same level as any drug that they prescribe. In some countries, the establishment of Hospital Transfusion Committees has helped a great deal towards a more rational use of blood and it is expected that such committees will be established in more and more hospitals worldwide.'*

15.37 In 1989 the Red Book, so called for its red cover, was published setting out standards for products – [**NHBT0000013_001**]**.** It emerged as a result of the strength of the NBTS [**WITN5711001**].[1073] The initiative was started to set '*national standards for the UK Blood services. Doctors and scientists from the 4 UK National Blood Transfusion Services met to develop guidelines and standards for the blood services across the UK.'*

15.38 The quality guidelines were split into different groups such as donor selection, transfusion microbiology and immunohaematology, among others. The Red Book was published by the HMSO and covered guidelines and practice for blood transfusion medicine covering all the activities of the blood service.

15.39 Detail of the Serious Hazards of Transfusion (**SHOT**) is included at Section 16. The proposal was drafted in 1995 by Dr Williamson at Dr Robinson's request [**WITN0643001**].[1074] This accompanied a broader programme in the 1990s by

[1072] Written Statement of Dr Vanessa Martlew [**WITN4034001**] at [427]
[1073] Written Statement of Professor Contreras [**WITN5711001**] at [226].
[1074] Written Statement of Dr Lorna Williamson [**WITN0643001**]

the NBA to improve transfusion practice in hospitals, including Professor Murphy's post and the promotion of HTCs.

15.40 In 1998 the Better Blood Transfusion Initiative was launched by the DoH. The focus of the initiative was to use blood only when needed[1075]. It was an initiative which began with the blood services [**NHBT0083701_002**] and was taken up by the CMOs. The blood services spoke to the DH and the CMO to identify the '*inappropriate use of blood, of fresh frozen plasma, of red cells, of platelets. And that there was a great variation. For the same hip replacement you would have a hospital that on average used zero or one unit, and another hospital would use five or six units*' [**INQY1000165**].

15.41 Tasks under the Better Blood Transfusion Initiative included ensuring that HTCs were in place (see above), and the requirement to participate in the annual SHOT inquiry. The initiative was considered to have significantly accelerated the level of research into blood transfusion at the clinical level, with Dr Williamson's research unit producing valuable insights into the transfusion process [**INQY1000187**].[1076] Further the initiative led to transfusion being included as a risk in patient consent forms.

15.42 The blood service was not the only organisation producing guidelines on transfusion practice. There were other sources of such information including from clinical societies [**WITN6982001**].[1077]

15.43 It is essential to note that notwithstanding these guidelines, the primary decision as to whether to transfuse or not, and as to the extent of blood use, lay with the treating clinician.

15.44 In 2002, the National Blood Transfusion Committee's first annual report [**RLIT0000848**] (discussed above) addressed the issue of embedding HTCs, but also a need to develop a role for transfusion practitioners; to institute dedicated sessions for a lead consultant in blood transfusion; and for audit and administrative support.

C. The Context of Clinical Freedom

15.45 Efforts to persuade clinicians to use blood appropriately also had to contend with the culture of clinical freedom, exercised by clinicians and strongly supported by DH, as considered in the evidence of Dr Pickles **[INQY1000205]**[1078] and explored further earlier in Section 3. RTC clinicians were neither responsible for, nor in a position to, determine the approach taken by surgeons and haemophilia clinicians at the point of treatment. Such

[1075] Written Evidence of Dr Angela Robinson [**WITN6926001**] at [780(c)]
[1076] Oral Evidence of Dr Jonathan Wallis [**INQY1000187**] at [79]
[1077] Written Statement of Dr Jonathan Wallis [**WITN6982001**] at [41]
[1078] Oral Evidence of Dr Hilary Pickles [**INQY1000205**] dated 12.05.2022 at [61/10-22] and [63/2-5]

clinicians were highly trained specialists with skills and expertise relevant to decisions made [**INQY1000175**].

D. Teaching and transfusion practice today

15.46 The role of NHSBT in teaching and training today is addressed in Dr Miflin's statement [**WITN0672006**][1079] and extensively in the evidence of Professor Murphy [**WITN7001001**]; [**Prof Murphy OE**]. Dr Williamson talks about the development of SaBTO and SHOT, and the other national transfusion organisations and societies.

15.47 Developments include SPOT specialist practitioners in hospitals, the evolution of BBT into Patient Blood Management, continued audit via SHOT and governance changes including to SaBTO.

15.48 In addition, internal audit in hospitals is significant. The move in the early 2000s towards hospital blood bank staff being more assertive in response to requests for blood [**INQY1000187**][1080] meant that it was possible to determine through internal audit where patients were being transfused outside the hospital guidelines. Prior to that, some blood bank scientific staff were '*very nervous about questioning a medical request*'; a national trend that prevented pushback against the inappropriate use of blood. In our submission, this internal dialogue has advantages in terms of immediacy and responsiveness, and ability to prevent inappropriate blood use decisions, in contrast to a system in which the blood services must push to conduct a retrospective external audit on hospital practices.

15.49 As to guidelines, Professor Murphy's oral evidence suggested that the institution of guidelines has proven to be a necessary but not sufficient component of driving improvement in transfusion practice.

15.50 In addition, there were continued difficulties related to getting training across to successive intakes of large numbers of junior doctors and nurses [**WITN0672006**]. Transfusion is still not a priority for busy clinicians, as demonstrated through audits.

[1079] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1479-1490]
[1080] Oral Evidence of Dr Wallis (43/4-44/24)

16. SECTION 16: MINIMISING RISK OF TRANSFUSION TRANSMITTED INFECTIONS

A. Introduction

16.1 In this section NHSBT addresses the current understanding of Transfusion Transmitted Infections (**TTIs**) and some of the steps taken by the blood services to minimise the risks and impact of TTIs over the last decades. This covers issues such as horizon scanning for new infections, donor selection, donor education, donor testing, donor epidemiology, measures to prevent TTIs and other related issues.

16.2 This section does not repeat the detail of the blood safety initiatives taken in response to HBV and HCV, HIV or vCJD as these are dealt with in detail under the dedicated sections above.

B. The Risk of TTIs within the Blood Service

16.3 The understanding and approach towards risk within the blood services has changed over time. Factors that have driven this change include developments in science, alongside the '*loss of Crown Immunity, the introduction of Product Liability and the emphasis on Quality, Audit, and licensing by the MCA'* [**NHBT0000044_095**].[1081] European law has also been an influence as was the HCV lookback exercise[1082] which was the impetus behind the establishment of the UK haemovigilance scheme Serious Hazards of Transfusion (**SHOT**).

16.4 The role of the blood services is to provide a reliable supply of blood to satisfy clinical need, and in doing so to reduce the safety risk of such blood to the minimum practicable level. This takes place within the context of constrained budgets, as any risk reduction strategy employed by the transfusion services has to be justified or defended against cost implications. Spending on a particular area of risk reduction must always be balanced against the possible use of the same money in another area of risk reduction and patient safety.

C. Approach in the Blood Services in respect of TTIs

16.5 In her written statement [**WITN0672006**], Dr Gail Miflin, discusses current measures taken by NHSBT to ensure the safety of the blood supply. Dr Miflin has not given oral evidence but there is important information in her statement as to the current approach to TTIs and the various steps taken by NHSBT to try to reduce these to the lowest practical level, accepting that it is not possible to eradicate the risk of transmission of infection entirely. These include:

[1081] Dr Marcela Contreras and Dr John Barbara, Paper for ACTTD: Two Topics Related To Transfusion Safety dated 23.01.1992

[1082] Written statement of Dr Angela Robinson [**WITN6926001**] at [459; 491; 541; 581; 678]

a) horizon scanning for new infections,

b) donor selection (JPAC),

c) Education of donors on who is eligible to donate blood and the selection of donors according to guidelines set by JPAC.

d) donor testing,

e) donor epidemiology monitoring,

f) measures to prevent TTI,

g) Patient Blood Management ('PBM') and Appropriate Blood Use ('AUB') - discussed further below,

h) the role of the National Blood Transfusion Committee ('NBTC') – discussed further below,

i) management/investigation of potential TTI and lookback - discussed further below,

j) reporting of TTI eg haemovigilance - discussed further below,

k) patient consent (considered in Section 12.

l) The introduction of specific screening for trial markers – see Section 4H for more detail on the factors taken into consideration for the testing for viral markers.

16.6 A number of these measures are described in detail below.

16.7 This is not a new approach. The Inquiry has seen and read significant evidence of how, in the daily operations of the blood services, there were measures put in place to minimise the risk of TTIs and promote blood safety. Measures adopted in the past included:[1083]

a) Information posters were displayed at the entrance to donor session venues, emphasising the risks of TTIs [**WITN6988001**].[1084]

b) The blood service constantly revised its approach to pre-donation screening through leaflets and questionnaires as an aid to self-exclusion by high-risk donors and potential donors.

c) NLBTS had a specialist bacteriology laboratory as part of the microbiology department to identify initiatives to reduce the rate of adverse reactions and deaths due to bacterial contamination of blood components – these were adopted as standard practice.

[1083] Please not that this is a non-exhaustive list of measures taken.
[1084] Written Statement of Dr William Wagstaff [**WITN6988001**] at [480]

d) Staff were trained to treat every blood sample as though it was positive for a transfusion transmitted infection [**WITN7046001**].[1085]

e) In circumstances where infection could arise with a non-viral origin, particular attention was also paid to the exclusion of bacterial contamination by cleansing the skin at the donation site and the choice use and monitoring of equipment used. In addition, attention was given to and recording of the cold chain in the storage and transport of most blood components and of plasma for BPL, regulation checks by culture of random units of platelet concentrates stored at a higher temperature, and checking of culture of units stored at sub-zero temperatures (e.g. cryo and FFP) [**WITN6988001**].[1086]

D. Measures taken in response to specific risks

16.8 The blood services gave evidence on recent measures taken to respond to specific risks. Specific examples are listed below:

a) In relation to malaria, the blood services played a role in developments that led to improved blood safety with respect to the transmission of malaria [**WITN3101009**]. [1087] This led to the adoption of a malaria antibody assay used to screen all donors who were born in, or lived in, malaria endemic areas.

b) In 2012 a study was undertaken by a team from the Colindale Blood Centre to determine the incidence of Hepatitis E Virus ('HEV') viraemia in blood donors in south-east England by carrying out retrospective HEV screening of blood donations. The study was extended to examine the outcome of transfusion.

c) Trypanosomiasis Cruzi is a transfusion-transmissible parasitic disease. The only method of reducing the risk was to exclude all donors born, or transfused in, certain areas of South America. The blood services carried out an evaluation of the antibody screening assay [**WITN3101009**] to demonstrate that this could screen donations from those who would otherwise be excluded.

E. Evidence on the structures now involved in the safety of the blood supply

16.9 In order to understand the measures taken by the blood services, it is essential to understand the structure in which these measures are practised.

16.10 Dr Miflin explains how the responsibility to ensure that blood is safe from TTIs is shared between a number of organisations, including NHSBT, the

[1085] Written Statement of Dr Jean Harrison [**WITN7046001**] at [469]
[1086] Written Statement of Dr William Wagstaff [**WITN6988001**] at [630].
[1087] Written statement of Dr Patricia Hewitt **[WITN3101009]** at paras [97-98] and [268-269] referring to [**WITN3101013**] summarising collaborative work with two experts in malaria

Department of Health and Social Care ('**DHSC**'), Public Health England ('**PHE**') – now the UK Health Security Agency ('**UKSHA**'), the Medicine and Healthcare Products Regulatory Agency ('**MHRA**'), and the various committees and bodies such as the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee ('**JPAC**') and SaBTO - combining the expertise of various health organisations [**WITN0672006**].[1088]

16.11 The Inquiry has heard evidence from witnesses representing some of these organisations, including numerous witnesses from DHSC, Dr Susan Hopkins [**WITN7090001**] of UKSHA and her oral evidence[1089]; Dr Alison Cave of the MHRA [**WITN7477001**] and her oral evidence and Professor James Neuberger, Chair of SaBTO [**WITN7306001**] and his oral evidence.[1090]

16.12 Dr Miflin explains[1091] that JPAC, as the Joint United Kingdom Blood Transfusion Professional Advisory Committee, has two distinct functions; to prepare detailed service guidelines for the United Kingdom Blood Transfusion Service and to be an Advisory Committee to the United Kingdom Blood Transfusion Services. The 2019 United Kingdom Blood Transfusion Services' Forum ('UK Forum') constitution provides for quarterly reporting to it from JPAC. [**WITN0672041**][1092]

16.13 She further explains[1093] the role of the UK Forum. This body was established in 1999 with the objective of providing for communication and cooperation between the blood services of the UK. While the UK Forum provides for communication and collaboration, each of the blood services is still responsible for their own territories and accountable to their own Chief Executive and Director.

16.14 The UK forum meets at least four times a year. Its core membership is the four Chief Executives/Directors and the four Medical Directors of the UK Blood Services. There is an elected chair. The primary processes through which the UK Forum discharges its responsibilities are listed in the constitution as: JPAC, SHOT and the Blood Stock Management Scheme. Annual reports are also provided by the Systematic Review Group, BBTS, Quality Group, and Emerging Planning/Business Continuity. Two members of the core UK Forum Membership also attend the European Blood Alliance board meetings

16.15 NHSBT as a member of the UK Forum of Blood Services shares a memorandum of understanding with blood operators in the devolved UK nations to provide mutual aid in the event of supply challenges.

16.16 Dr Miflin's statement also covers how international blood services work closely together. NHSBT works with bodies such as the Alliance of Blood Operators,

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[1088] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1038–1057]
[1089] Oral Evidence of Dr Susan Hopkins is dated 15.11.2022.
[1090] Oral Evidence of Dr Allison Cave and Professor James Neuberger dated 16.11.2022
[1091] Written statement of Dr Gail Miflin [**WITN0672006**] at [231]
[1092] Paper on the Constitution of the United Kingdom Blood Transfusion Services' Forum
[1093] Written statement of Dr Gail Miflin [**WITN0672006**] at [235-236]

the European Blood Alliance and the International Society of Blood Transfusion to share knowledge and information to ensure that they learn from each other quickly and effectively [**WITN0672006**].[1094]

16.17 The mechanisms that underpin safety in the blood supply include clinical governance, a Quality Management System ('**QMS**'),[1095] an audit programme (which includes clinical, management of blood collection regulatory and internal audits), a risk management system and the haemovigilance programme (SHOT). The Inquiry has received written statement from Professor Mark Bellamy, [**WITN7312001**] Chair of the SHOT Working Expert Group and has heard his oral evidence.[1096] We explore SHOT in more detail below.[1097] These assurance mechanisms are overseen at NHSBT by the Executive and Board members and committees including the Board subcommittee, the Audit, Risk and Governance Committee.

16.18 The system is based on an international framework for clinical governance in blood services, described in a paper written by the ABO Medical Directors Group published in 2015 [**WITN0672072**][1098]. The components of this framework include: monitoring measures of patient and donor safety, including surveillance for emerging infections, new trends and technical developments; and the assessment of potential risks to donors and patients, at a local, regional and national level [**WITN0672006**].[1099]

16.19 Dr Miflin describes the processes for clinical audit, incident investigation and risk management. She exhibits the procedures that govern these functions. These include the documentation, mitigation and management of strategic risks, clinical risks, and organisational risks. Clinical risks include the risk of transmission of an infection. For all risks there is a score using a conventional risk scoring matrix, a list of mitigations, a mitigated score and a target score, managed on an IT system called Pentana [**WITN0672006**].[1100]

F. Evidence as to the current management of TTIs

[1094] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1056]

[1095] QMS is designed to provide the systems (and assurances) needed to meet regulatory and accreditation requirements. It is based on Good Manufacturing Practice
principles which are part of the BSQR requirements. This is to assure the quality of medicinal products, assure the safety, well-being and protection of the patient, and ensure consistent production and control of products

[1096] See Oral Evidence of Professor Mark Bellamy dated 16.11.2022 including at [21/4-180] in relation to the UK Forum: '*The UK Forum is basically the chief medical officers of the four UK blood services, together with managerial support from them. So the funding comes from the four UK blood transfusions via the UK Forum, but in terms of staff's appraisal, employment, and so on, for the people who work in the office, that's handled by the -- by NHSBT for England. All four nations fund it, NHSBT England provide the HR support and so on for the office. But all of the professional activity the office conducts is overseen by the steering group, which is independent, and whose decisions are informed, in principle, by the bodies that the members of the steering group represent: the Medical Royal Colleges, some lay members'.*

[1097] Written Statement of Dr Gail Miflin **WITN0672006**] at [1058-1147]

[1098] L Williamson at al., A clinical governance framework for blood services

[1099] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1063]

[1100] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1067]

16.20 The current general management of TTIs includes the measures listed above, many of which are described elsewhere, and some of which are summarised below in further detail.[1101]

(1) Donor Selection

16.21 The current donor selection guidelines for Whole Blood and Components are set out in the Guidelines for the Blood Transfusion Services in the United Kingdom, 8th Edition, 2013[1102]. Dr Miflin refers to the continuing importance of donor selection in her written statement [**WITN0672006**].[1103] She describes the role of the Standing Advisory Committee on the Care and Selection of Donors ('**SACCSD'**) whose remit is: to set, and update as required, guidelines for: (i) care, pre and post donation, of people who offer to donate blood and components; (ii) donor selection to identify and exclude those for whom the act of donation could be unsafe; and, (iii) donor selection to identify and exclude those whose donation could be unsafe, of inadequate quality, or contrary to relevant legislation.

16.22 SACCSD also advises on the staffing, environment, equipment and procedure for a blood donation session, in addition to coordinating with the Standing Advisory Committee on Transfusion Transmitted Infections ('**SACTTI'**) to ensure integrated advice on all aspects of microbiological safety of donors and donations.[1104]

16.23 Dr Miflin describes the remit of SACTTI[1105] which includes maintaining awareness of new or previously unrecognised microbiological threats to safety of blood and tissues and advising on the epidemiological basis for targeting or avoiding particular groups as potential donors - in respect of both recognised and emerging transfusion transmissible agents; to recommend laboratory and related procedures for detection and exclusion of donations that may pose a microbiological risk; to co-ordinate with the SACCSD and where appropriate prepare joint recommendations to JPAC that take account of all relevant aspects of microbiological safety of donors and donations.

(2) Donor Education

16.24 Dr Miflin explains[1106] NHSBT's role in the education of the general public on the importance of who can donate blood and how blood safety is one of the roles of the Donor Experience team. They provide information through

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[1101] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1083-1098]
[1102] Chapter 3 Care and selection of whole blood and component donors (including donors of pre-deposit autologous blood) available on the JPAC web-site https://www.transfusionguidelines.org/dsg/wb
[1103] For example see Written Statement of Dr Gail Miflin [**WITN0672006**] at [1040,1100]
[1104] Dr Gail Miflin [**WITN0672006**] at [1100]
[1105] https://www.transfusionguidelines.org/about/remits-of-the-jpac-standing-advisory-committee
[1106] Written statement of Dr Gail Miflin [**WITN0672006**] at [1084]

awareness and recruitment campaigns, on their website[1107] and in the leaflets given to donors prior to donating blood.

16.25 Prior to giving blood, donors are required to complete a health check. This health check consists of a comprehensive questionnaire about medical history and lifestyle. Donors are asked to read NHSBT's 'Donor Consent for Blood Donation' booklet, so they understand the importance of accurately answering the health check questionnaire. The consent booklets make it extremely clear when a donor must not or never give blood. For example, it makes clear that individuals. must never give blood or platelets if they are HIV positive, have HBV, HGV, HTLV or syphilis (or ever been treated for syphilis), or where a donor has ever injected, or been injected with, drugs. The more general Welcome booklet repeats some of this detail.[1108]

16.26 NHSBT takes various steps to keep the public informed about donation, for example the donor campaign to inform the public of the changes to selection policy, which moved to a more individualised approach. NHSBT also makes much of its information easily accessible through online publication and the use of infographics[1109]. NHSBT's move to an individualised risk approach, was based on policy developed by the For the Assessment of Individualised Risk ('**FAIR**') steering group.

16.27 FAIR involved stakeholders from public life and patient groups including Stonewall, National Aids Trust, Freedom to Donate, Sickle Cell Society and the UK Thalassaemia Society enabling public concerns about donation criteria to be taken into account. The FAIR steering group was established at the beginning of 2019 following a request by DHSC to explore an individualised approach to donor selection criteria.

G. Donor testing

16.28 Dr Miflin describes the control of bacterial infection, the difference between *testing* and *screening* and the need for confirmatory testing with screening [**WITN0672006**].[1110]

16.29 NHSBT screens all donations of blood components for several bloodborne infections, including HBV; HCV; HEV; HIV; and Treponemal (Syphilis) antibodies. Donations from first time donors are also screened for HTLV 1 and 2.

16.30 Where a donor's risk profile puts their donation at a particular risk of specific infections NHSBT also screens donors using further 'discretionary' tests. These

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[1107] www.blood.co.uk
[1108] Please see Post-donor session leaflet [**WITN0672083**]
[1109] https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/27793/annual-review-with-a4-infographics-final-accessible-features-v3.pdf
[1110] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1089]

discretionary tests include serology tests for antibodies to Malaria and Trypanosoma cruzi and Nucleic Acid Testing for West Nile Virus for travel risks. Previously NHSBT requested an additional test for HBV core antibodies where a donor declares past hepatitis of unknown origin or history of jaundice, but more recently this has been introduced on a standard basis. Additional tests were introduced for antibodies to SARS-CoV2 as part of convalescent plasma collection programme.

16.31 Certain recipients (for example babies or those immunocompromised) may require components that are negative for certain infectious markers, primarily CMV. These specialist components will have additional screening tests done.

16.32 If a donor is noted to be positive for a screening test, then the IT system generally defaults to an automatic discard and the mandatory release criteria for a blood component to be issued to hospitals will not be met.

H. Donor epidemiology and monitoring

16.33 NHSBT shares information where appropriate with stakeholders. It has obligations to make notifications of infectious diseases to PHE – now the UK Health Security Agency ('UKSHA'). This is to assess risks in relation to blood transfusion. This work feeds into SHOT and SACTTI. The blood service also receives information from those bodies which will allow investigation of possible onward transmission of infection. NHSBT has procedures for sharing information, where indicated, with other healthcare professionals such as GPs, these are described in more detail in the Consent section at 13.

I. Reporting of TTIs

16.34 NHSBT receives reports of possible TTIs on a regular basis. The reporting form is available on NHSBT's Hospital and Science website,[1111] which also hosts clinical guidelines, training, audit tools and reports of the National Comparative Audit[1112] and regional audit activity. NHSBT reviews these reports and discusses next steps, e.g. requesting more information from the hospital or requesting stored archives for further testing. Discussions and action for individual donors are recorded in their clinical file. There is a minuted review by a multi-disciplinary team.

J. The NHSBT/PHE Epidemiology Unit

16.35 Dr Miflin refers to the NHSBT/PHE Epidemiology Unit. Since 2007, the NHSBT / PHE Epidemiology Unit has as part of its surveillance function undertaken

[1111] https://hospital.blood.co.uk/epidemiology-reports/

[1112] As to which Professor Michael Murphy has provided evidence in his Written Statement [**WITN7001001**] [79-82], where he describes its establishment) and Oral Evidence of Professor Jonathan Wallis and Professor Michael Murphy [**INQY1000187**] dated 24/02/2022 at [70/8-15]; [141/12-19] and [146/1-25]

horizon scanning for infections which may affect the safety or sufficiency of the blood supply.[1113] The Unit regularly scans publications for news of emerging infections relevant to blood, tissue and organ donation safety in the UK.

16.36 The unit was established in 1995 to monitor infections in blood donors and transfusion recipients. Over time its role expanded; and it is now responsible for monitoring infections in blood, tissue and organ donors, and transfusion recipients. Data from the four UK blood services are collated and analysed by the unit to produce surveillance reports and inform/evaluate policy changes relating to infection risk. The unit collates and reports national epidemiological data on: (a) blood-borne infections among donors, and (b) the associated risk of transmission through transfusion and transplant.

16.37 The unit manages national surveillance schemes, data from which are used to assess and improve blood, tissue and organ safety. These schemes include monitoring infections in blood donors through donation testing and the collection of information about identified infected donors. Data includes that on post-transfusion infections among recipients (this forms part of SHOT) and emerging infections through the collation of relevant reports on a monthly basis. The information collected through these surveillance schemes helps to inform donor selection criteria, monitoring trends in infections, understanding the epidemiology of blood borne infections and driving follow-up of any reported post-transfusion infections. The 2021 review notes that blood donors are a well characterised low risk group with around 2 million donations screened each year for HBV, HCV, HIV, HTLV, HEV and syphilis.

16.38 Dr Miflin describes how data on the numbers of infected donations are compiled annually in the Safe Supplies joint NHSBT/PHE Epidemiology report. The Safe Supplies Annual Review for 2021, published since Dr Miflin made her statement noted that no reported transfusion-transmitted infections were confirmed during 2021. The report allows for the annual tracing of trends. The review is extremely important for blood safety, and it will continue to be conducted on an annual basis.

16.39 The findings of the report shows that the number of donor infections has decreased significantly over the past few decades and donors are safer than ever. One possible transmission of occult hepatitis B was identified. 280 donations were confirmed to be positive for one or more infection and NHSBT discarded 1 in 6,000 donations. This was an increase from 1 in 10,000 in 2020, but still low by historical standards. There were 78 HBV, 37 HCV, 9 HIV, 12 human T-cell lymphotropic virus (HTLV) and 146 syphilis positive donations in 2021 (2 dual infections) compared to 49 HBV, 33 HCV, 9 HIV, 11 HTLV and 74 syphilis positive donations in 2020.

[1113] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1051-1054]

16.40 During 2022, the UK blood services introduced hepatitis B anti-core screening to reduce the risk of non-detection of occult hepatitis B infections. In collaboration with UKHSA, NHSBT continues to monitor the risk of emerging infections with 2021 seeing some changes to travel-related donor selection criteria.

16.41 Chronic HBV was mainly identified in new donors born in countries where HBV is more common than in the UK (for example 10 born in Romania, 5 born in India, 5 born in Nigeria, 5 born in Pakistan) reflecting the diversity of new donors. All the confirmed positive donors were deferred from donating and referred for follow up care. The pre-donation selection questions reduce the chance of donors having very recent infections that screening might not detect.

16.42 UK-wide HTLV testing has evolved since beginning in 2002. 2021 marked 20 years of HTLV screening of UK blood donations. Testing began in 2002 following a successful pilot in Scotland in 2000. This decision was made due to concerns around transfusion transmitted HTLV infections following two transmissions in the 1990s.

K. Serious Hazards of Transfusion Haemovigilance Scheme ('SHOT')

16.43 The concept of haemovigilance has been described by various witnesses including Professor Bellamy [**WITN7312001**][1114] and Professor Neuberger [**WITN7306001**][1115]

16.44 The SHOT scheme is referred to by Dr Miflin at various points in her statement [**WITN0672006**][1116] and picked up in NHSBT's interim submissions on recommendations [SUBS0000018]. More detailed evidence of the scheme has been provided by Professor Mark Bellamy, Chair of the SHOT steering group in both written [**WITN7312001**] and oral evidence of Professor Mark Bellamy.[1117]

16.45 Professor Bellamy, explains the way in which haemovigilance in the UK is covered by the Medicines and Healthcare Regulatory Agency (MHRA) and SHOT, working to enhance transfusion safety. Haemovigilance reporting is through an integrated reporting portal via Serious Adverse Blood Reactions and Events ('SABRE') providing a simple electronic means of submitting reports to the MHRA and SHOT.

[1114] Written Statement of Professor Mark Bellamy [**WITN7312001**] at [18-22]
[1115] Written Statement of Professor James Neuberger [**WITN7306001**] at [3.1-3.3]
[1116] Eg [191(c)] provision of information to SHOT by NHSBT and reference to the SHOT Rule 9 response dated 23 January 2019, [206] in describing NHSBT's working relationships; [236-237] the work of the UK Forum; relevance to BSQR [252] and the relationship of SHOT to SaBTO [1042] and [1455-1462]
[1117] Oral Evidence of Professor Mark Bellamy, Professor James Neuberger of SaBTO and Dr Alison Cave of the MHRA Wednesday 16 .11.2022

16.46 SHOT was developed by a group of experts from 1994 and structured to: collect data on transfusion incidents, errors and near misses, initially through voluntary ad hoc reporting; to investigate and analyse information around these reports; draw conclusions from the trends and patterns of information alongside specific events; and to disseminate this information in an annual report, meetings, seminars and educational events, and produce recommendations for hospital trusts, some of which have become the subject of a CMO letter [**MB OE**].[1118]

16.47 Once collected, data are reviewed and interpreted by the Working Expert Group ('WEG'). The WEG is comprised of multiple teams, each typically consisting of two or three volunteer experts, drawn from a wide variety of clinical and laboratory backgrounds. It includes specialists in areas which contribute to individual chapters of the SHOT report (e.g. pulmonary and respiratory complications). The teams within the WEG are each responsible for a topic and chapter of the annual SHOT report. The entire WEG reviews the contents prior to their inclusion in the report. The WEG is chaired by the Medical Director, Dr Shruthi Narayan (who holds a shared post between SHOT and NHSBT).

16.48 SHOT has a dual governance process. The Steering Group provides overall professional guidance and is made up of representative members seconded from the medical and allied health professions, generally through their respective Royal Colleges, and includes haematology and transfusion laboratory scientists. There is also representation from other stakeholder groups, including the National Blood Transfusion Committee ('NBTC') and Royal College of Pathologists. Membership of the Steering Group is completed by lay representatives who bring a patient and public interest element to the group's deliberation. Members of the WEG are automatically part of the Steering Group.

16.49 In oral evidence, Professor Bellamy described the difficulties in ensuring that the SHOT recommendations, which are professionally mandated, are implemented and discussed various ways these issues might be addressed [**MB OE**].[1119] In November, December each year, SHOT conducts surveys on the implementation of recommended measures. The response rates and extent to which those measures are implemented is variable. [**WITN7312001**][1120] The statement also covered the role of transfusion specialists in reporting incidents, implementing transfusion education, maintaining standards, the role and importance of properly staffed and trained hospital laboratories[1121] and SHOT

[1118] Oral Evidence of Professor Mark Bellamy, Professor James Neuberger and Dr Alison Cave 16.11.2022
[1119] Oral Evidence of Professor Mark Bellamy, Professor James Neuberger and Dr Alison Cave 16 .11.2022 at [27,1-23; 65, 23-25; [66] [1-14] [111] [8-25], [119] and [1-25]
[1120] Written Statement of Professor Mark Bellamy WITN7312001 at [38]
[1121] Written Statement of Professor Mark Bellamy WITN7312001 at [39]

findings on TTIs and how these fit in the overall context of the adverse effects of transfusion.[1122]

16.50 Dr Miflin's written statement covers the 2020 SHOT report [**WITN0672006**][1123] and notes that for that year there were 3214 events reported in total of which 1130 were near-miss events. Of the other 2084 errors or adverse events there were no TTIs; in the years from 2015-20 there had been four and from 2010-20 there had been 16 across the UK.[1124]

16.51 Some of the issues identified in this evidence are picked up in NHSBT's submissions on recommendations contained at Section 17. Dr Miflin notes that NHSBT would like to institute a system whereby the outcomes of all transfusions could be known rather than a system of just reporting adverse events [**WITN0672006**],[1125] This would offer NHSBT new ways of auditing blood use and auditing against clinical guidelines, benchmarking between hospitals and performing research. Such a system has never been set up in this country and is very uncommon worldwide. The Scandinavian Donation and Transfusion ('**SCANDAT**') is considered the best example of it. In England this would involve significant datasets and NHSBT is of the view that this could be achieved through data linkage with the ability to audit practice regularly and to use the information obtained to inform research and development. A paper-based system or one that involves someone in a hospital registering the outcome with NHSBT is not considered feasible. NHSBT recently agreed funding to start working out how this could be best done in England[1126].

L. Patient Blood Management ('PBM') and Appropriate Blood Use ('AUB')

16.52 The Inquiry has received evidence on efforts made by the blood services to improve clinical practice on the use of whole blood and blood components.[1127]

16.53 Best practice dictates that blood, plasma, cell and tissue products should only be given when they are essential to the quality of life, health or survival of the patient, and where there is patient consent [**WITN0672006**][1128] UK Blood

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[1122] Written Statement of Professor Mark Bellamy [**WITN312001**] at [27]
[1123] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1456]
[1124] The 2021 report has since been published – [**SHOT0000032**]. Chapter 20 is on TTIs and includes Table 20.5 – the Number and type of implicated components from confirmed TTI recipients, by year of transfusion in the UK, reported to SHOT between October 1996 and December 2021 (Scotland included from October 1998). The number for 2021 is also 0.
[1125] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1462]
[1126] The SCRIPT project referred to in [SUBS0000018] https://www.shotuk.org/resources/current-resources/script/ and in the written statement of Professor Mark Bellamy [WITN7312001] (42-46) and which is part of the Blood and Transplant Research Unit in data driven transfusion: Using data to improve transfusion practice — University of Oxford, Medical Sciences Division gives more information
[1127] Written statement of Dr Gail Miflin [**WITN0672006**] and for example the evidence of Professor Contreras in her written statement in educating clinicians that 'blood can kill': Written Statement of Professor Marcela Contreras [**WITN5711001**] at [278]
[1128] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1130]

Services' clinicians continue to work with colleagues throughout the NHS to establish and implement guidelines for the appropriate use of blood and tissue.

16.54 It is a priority for the UK CMOs and the medical community in the UK to ensure that patients are treated with blood or tissue products only when there is real clinical need. SaBTO recommends[1129] that patients be offered the opportunity to give informed consent to blood transfusion whenever practicable and a series of information leaflets are available explaining the potential benefits and risks including those relating to vCJD.

16.55 Professor Murphy describes the purpose and origins of the Better Blood Transfusion ('BBT') and Patient Blood Management ('PBM') schemes.[1130] Patient Blood Management PBM is a multidisciplinary, evidence-based approach to optimising the care of patients who might need a blood transfusion, with the aim of putting the patient at the heart of decisions made about blood transfusion to ensure they receive the best treatment and of reducing the avoidable, inappropriate use of blood and blood components.

16.56 PBM represents an international initiative in best practice for transfusion medicine. NHSBT continues to work together with the DH and devolved governments and the National Blood Transfusion Committee (NBTC) to support NHS Trusts to manage their blood use effectively.

M. The National Blood Transfusion Committee ('NBTC')

16.57 Dr Miflin discusses the work of the NBTC:

> *'…Reporting to NHS England/Improvement, the NBTC provides national advice on initiatives to optimise the prescribing and safe delivery of blood components. Additionally, appropriate use of blood components and the minimisation of wastage of components is also within the remit of this body. The NBTC and its Regional Transfusion Committees comprise a structure that provides education, audit and advice to hospitals and their transfusion committees on best transfusion practice. NHSBT provides data and resources to enable this work to be carried out, and for hospitals to act on NBTC's advice'.* [**WITN0672006**] [1131]

16.58 Professor Murphy described the work of the NBTC [**WITN7001026**][1132] and its remit [**INQY1000187**]:[1133]

[1129] And Professor Neuberger gave oral evidence as to SaBTO's work on consent 16/11/2022 [15/22-16/7]; [101/3-103/12]
[1130] Written Statement of Professor Mike Murphy [**WITN7001001**] at [116-123; 135-137]
[1131] Written Statement of Dr Gail Miflin [**WITN0672006**] (primarily at [825-827] but also [243]; [244]; [246]; [814])- further discussed in Section 15 – Liaison with Hospitals.
[1132] Written Statement of Professor Mike Murphy [**WITN7001001**] at [116-123]; [135-137]
[1133] Oral evidence of Professor Mike Murphy [**INQY1000187**] dated 24.02.2022 at [149/5-150/7]

'2.1. The overall objective is to promote good transfusion practice by providing a framework to:-

2.1.1. 'Channel information and advice to hospitals and Blood Services on best practice and performance monitoring with the aims of:- "- Improving the safety of blood transfusion practice "- Improving the appropriateness of clinical blood transfusion "- Exploring and facilitating the implementation of methods to reduce the need for allogeneic blood transfusion "- Listening to and informing patient concerns about blood transfusion "- Promote the highest quality and consistency in transfusion practice'

2.1.2. Consult with national groups developing guidelines in transfusion medicine in order to determine best practice "

2.1.3. Review the performance of the services provided by the National Blood Service

2.1.4. Identify service development needs, and provide assistance, as required, with the work of the …(sic)

2.1.5. Identify and respond to patients' perceptions about the provision of transfusion services

2.1.6. Provide advice to the CMO on transfusion practice.'

N. Use of Tranexamic Acid

16.59 Professor Murphy[1134] and Professor Roberts[1135] have also provided evidence to the Inquiry on the value of using tranexamic acid to minimise blood loss during surgery, thus considerably reducing the risk of needing a transfusion and on the consequences of failure to follow NICE Guidelines in this respect.[1136]

O. Transfusion transmitted infections (TTI) and lookback investigations, UK 2021

16.60 TTI investigations are initiated in blood components when transfusion recipients have shown to be positive for a blood-borne infection and no other

[1134] Written Statement of Professor Mike Murphy [**WITN7001001**] at [36]; Oral Evidence of Professor Jonathan Wallis and Professor Michael Murphy [**INQY1000187**] dated 24.02.2022
[1135] Oral evidence of Professor Ian Roberts Professor Derek Manas dated [**INQY1000259**] dated 10.11.2022 at [72/12-16]; [76/6-14]; [77/ 9-16]; [78/3-25] and [79/6-16]
[1136] Oral evidence of Professor Ian Roberts Professor Derek Manas [**INQY1000259**] dated 10.11.2022 at [86/5-13] and [16/25] and [87/1-4] and Oral Evidence of Professor Jonathan Wallis and Professor Michael Murphy [**INQY1000187**] dated 24.02.2022 at [145/15-16]

more likely risks have been identified.[1137] In the case of bacterial transmission, this is following a significant transfusion reaction. The risk of a TTI in the UK remains extremely low. During 2021, 125 cases were investigated including 115 suspected bacterial incidents and 10 suspected viral incidents. The viral incidents included three cytomegalovirus (CMV), three HBV, two HCV and two HEV. [1138] Based on Safe Supplies investigations, none of these infections was acquired via blood transfusion and hence no bacterial or viral transmissions were reported in 2021.

P. Lookback investigations

16.61 The 2021 review notesthat lookback investigations are considered when markers of infection are identified in a donation from a repeat blood donor, which initiates an investigation into their previous donations. [1139] Lookback investigations may also be used when a new screening test is introduced. Archive samples of previous donations are identified and tested for evidence of infection. For NHSBT, where donors are identified with occult HBV infection, donations given during the last three years are considered in lookback investigations due to archive availability. Investigations may be extended depending on the outcome of lookback regardless of the screening results.

16.62 Any recipients identified as part of lookback are offered information about lookback, asked for consent for testing and followed up depending on the outcome of tests.

16.63 In 2021, NHSBT and SNBTS identified 10 donors who required lookback investigation of previous donations. This included one donor with occult HBV, two with HEV and seven with syphilis infections. A total of 26 components were transfused from the 10 donors, 13 of the recipients were alive and tested for markers of infection, the remaining recipients were deceased. One recipient was found to be positive for markers of HBV infection, this was identified as a possible occult HBV transmission as the recipient had markers of past HBV infection which could have been due to another source. Lookback investigations are ongoing. All investigations and outcomes are reported to SHOT. The reports are available on the SHOT website.[1140]

Q. Horizon scanning of emerging infections, UK 2021

[1137] Page 12 - Annual Review - Safe supplies 2021: FAIRer donor selection Joint working between NHS Blood and Transplant and UK Health Security Agency, available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/27793/annual-review-with-a4-infographics-final-accessible-features-v3.pdf
[1138] As reported in Safe Supplies (above) and in SHOT and MHRA Annual Report 2021 [**SHOT0000032**]
[1139] SHOT and MHRA Annual Report 2021 at [pg21]
[1140] https://www.shotuk.org/

16.64 The 2021 review notesthat scanning for emerging infections takes place daily.[1141] The Epidemiology unit produces the Emerging Infectious Agents Report ('**EIAR**'), a monthly horizon scanning list of emerging infections with potential to affect the UK blood and tissue supply. This relies on a range of national and international evidence sources which are reviewed annually. Sources include: UKHSA daily emerging infections horizon scanning results and monthly summaries; European Centre for Disease Prevention and Control ('**ECDC**') communicable disease threat reports, Program for Monitoring Emerging Diseases ('**ProMED**') outbreak and news alerts and peer-reviewed literature.

16.65 The monthly EIAR is passed to SACTTI for risk-assessment and where urgent, items are sent directly. SACTTI highlights whether further action is required by the JPAC and its Standing Advisory Committees.

16.66 The remit of SACTTI is broad [**WITN0672006**].[1142] It includes requirements to:

a) maintain awareness of new or previously unrecognised microbiological threats to safety of blood and tissues; to advise on the epidemiological basis for targeting or avoiding particular groups as potential donors – in respect of both recognised and emerging transfusion transmissible agents;

b) recommend laboratory and related procedures for detection and exclusion of donations that may pose a microbiological risk;

c) co-ordinate with the Standing Advisory Committee on Care and Selection of Donors 'SACCSD' and where appropriate prepare joint recommendations to JPAC that take account of all relevant aspects of microbiological safety of donors and donations; and

d) coordinate with the SACBC and Standing Advisory Committee on Tissues and Cellular Therapy Products ('**SACTCTP**') on guidance to improve microbiological safety of donations.

SACTTI also conducts regular risk assessments on any infection related transfusion risks, using a standardised form.[1143]

16.67 Selected items included in the EIAR in 2021 from North America included dengue acquired in Florida; Powassan virus likely acquired through blood transfusion and a tuberculosis outbreak linked to a contaminated bone graft. From South America items included evidence of West Nile virus ('**WNV**') in Brazil; malaria transmission in Costa Rica while El Salvador was declared malaria-free. In Europe items included WNV in humans and horses, malaria,

[1141] Written Statement of Dr Gail Miflin [**WITN0672006**] at [pg16-17]
[1142] Written Statement of Dr Gail Miflin [**WITN0672006**] at [1103]
[1143] Written Statement of Dr Gail Miflin [**WITN0672006**] at [exhibit 79]

and Crimean-Congo Haemorrhagic Fever ('**CCHF**'), all reported in Spain while a Dengue case was acquired in Var, France.

16.68 A family cluster of three cases of monkeypox in the UK was associated with travel from Nigeria. No further spread was identified, all 38 contacts were traced and care workers remained negative aided by the Covid-19 control measures in place. At this point, human-to-human transmission was thought less common with the main source of transmission presumed to be direct or indirect contact with live or dead animals. Outside of Africa, cases of human monkeypox infections had only been documented in four countries, including four cases in the UK in 2018/2019. A larger outbreak in the US in 2003 of 47 cases had been linked to imported pet rodents but more recent cases had all been associated with travel from Nigeria. Monkeypox is still closely monitored. In Asia there were reports of new viruses, Manych virus in Russia and Tamdy virus in China.

16.69 During 2021 SACTTI action included: monitoring arboviruses in Europe, risk assessment for Yellow Fever in Asia, discussion of babesia risk to UK and review of CCHF risk assessment. No change to policy was required. Changes made to travel deferrals in 2021 included: updates to tropical virus risk in Africa, malaria risk areas amended for India and South Africa, removal of malaria deferral for various countries including El Salvador. The JPAC website gives the full list of change notification.[1144]

16.70 In 2021, the horizon scanning for emerging infections was audited by the Government Internal Audit Agency, who found with 'substantial assurance' that the framework of governance, risk management and control was adequate and effective. This information is used to evaluate any further action required and will contribute towards the position statements produced by SACTTI and published by JPAC. These position statements are all publicly available.

R. Conclusion

16.71 The Inquiry has heard from numerous blood service witnesses as to historical and current practices aimed at minimising TTIs. These include Professor Murphy who showed in his statement [**WITN7001001**];[1145] oral evidence [**INQY1000187**][11461147] and subsequent letters[1148] to the Chair the lack of complacency and ongoing work of the blood services to improve the safety of transfusion practice. Professor Bellamy explained his desire and determination

[1144] See: https://www.transfusionguidelines.org/document-library/ change-notifications
[1145] Written Statement of Professor Mike Murphy [**WITN700100**1]
[1146] Oral evidence of Professor Mike Murphy **[INQY1000187]** dated 24.02.2022 at [171/2-21]
[1147] Letters of dated 22 September (enclosing paper URN Tranexamic Acid for Safer Surgery, the Time is now ; British Journal of Surgery 2022 1-2) and 16 November 2022, including the work of the and the work of the National Comparative Audit of Blood Transfusion (NCABT) programme

to drive improvement and safety in blood transfusion. This evidence forms the basis of several of NHSBT's submissions on recommendations.

17. SECTION 17: RECOMMENDATIONS BY THE INQUIRY

A. Introduction

17.1 The Inquiry provides an important opportunity to advance the safety of blood and blood transfusion in the UK.

17.2 In this section we make submissions on recommendations that NHSBT considers would achieve this. We confine ourselves to these issues as this is the domain within which NHSBT is expert.

17.3 These submissions build on those made at the interim stage [SUBS0000018]. As stated above, while we do comment to some extent on submissions made at the interim stage by other core participants, we cannot (for obvious reasons) comment on their final submissions and will do so as necessary in oral submissions.

B. Recommendations advanced by NHSBT

(1) Risk-based decision-making

Suggested recommendation

That the approach to blood safety policy making in the UK by those concerned with blood policy is based on risk-based decision-making in accordance with international best practice.

That the appropriate international practice is the risk-based decision-making framework developed by the Alliance of Blood Operators.

That the levels of appropriate risk tolerability and cost-effectiveness parameters are defined for transfusion safety policy-making by an expert body independent from the UK Governments and the UK blood services. That body should advise the UK Governments, which will make the ultimate decision on risk tolerability.

Rationale

17.4 The risk-based approach to the complications of blood transfusion is premised on the basis that not all risk can be eliminated. Risk tolerability must be a feature of blood transfusion policy and a decision-making framework is a tool by which a risk-based approach can be properly and transparently applied.

17.5 The Alliance of Blood Operators (ABO) Risk-Based Decision-Making Framework for Blood Safety (RBDMF) is the internationally recognised framework for risk-based decision-making. It was built out of an international consensus on such decision-making which began at the International

Consensus Conference on Risk-Based Decision-Making in Blood Safety in Toronto in 2010.[1149]

17.6 The consensus statement that emerged from these discussions acknowledged that:

a) Though blood transfusion is an integral component of medical practice, risk is inherent from 'vein-to-vein'.

b) Achieving zero risk is unattainable, and the well-being of transfusion recipients is central to any recommendation to improve blood safety decision-making.

c) Product safety and supply responsibilities reside with blood operators.

17.7 From this consensus statement, it was decided that an integrated risk framework must be developed to improve decision-making, facilitate proportional responses to risk, ensure decisions are evidence-based, increase trust in investment decisions, and allow for the re-direction of resources to improve effectiveness.

17.8 Following the identification and characterisation of the risk, a structured process is undertaken to assess the magnitude of the risk and the level of risk reduction that can reasonably be achieved in the context of the complexity of the risk management action proposed and its cost.

17.9 NHSBT employs this risk-based decision-making framework for blood safety in line with the ABO RBDMF [**WITN0672100**].[1150] The framework has also been adopted by both JPAC and SaBTO. This is a departure from the more informal and opaque approach to risk-based decision-making which the Inquiry has considered in the 20th Century. In this way the blood services nationally and internationally have progressed to remedy the defects of historic approaches to decision-making concerning the complications of blood transfusion.

17.10 A recommendation that departs from the ABO RBDMF would be one which departs from international consensus.

17.11 The ABO RBDMF requires that users define risk tolerability as part of the framework and decision-making process. This is necessary because tolerability will be set at different standards depending on the jurisdiction, local conditions and different scenarios. This is a strength of the framework as it places risk squarely in the mind of the decision-maker, in the relevant context, and provides for transparent consideration of how that risk will be approached in

[1149] See the following open access peer-reviewed paper: - Risk-based decision-making in transfusion medicine - Leach Bennett - 2018 - Vox Sanguinis - Wiley Online Library (accessible here)
[1150] Board paper for a meeting of the NHSBT board on 26 November 2015 to approve the replacement of the previous safety framework with that adopted by the ABO.

any decision as well as stakeholders being a fundamental part of decision-making and having account taken of their views.

17.12 The appropriate body for the defining of risk tolerability is an expert body independent of the UK Governments and the UK blood services advising DH. Ultimately, the level of risk that can be tolerated within the system is a political consideration which properly sits with DH (and, where appropriate, can be delegated by DH). At this time SaBTO is the appropriate body to provide that advice, and NHSBT has requested that it undertake this work on risk tolerability in the context of the ABO RBDMF.

17.13 It should be noted that the ABO RBDMF does not preclude use of the precautionary principle. The use of the precautionary principle would be a very sensible output from the framework were the review of the risk assessment to suggest there is insufficient evidence to make a risk-based decision using the framework. The two approaches are not mutually exclusive.

17.14 We submit that the Inquiry should not make recommendations directed to how that balance should be struck, either generally or with specific reference to the precautionary principle. As to the latter, the expert evidence heard by the Inquiry was ultimately to the effect that the precautionary principle has neither a clear and precise definition nor a clear and precise application. In the circumstances, in NHSBT's view, a recommendation that such a principle should have primacy would be confusing, would inappropriately fetter – or risk usurping - SaBTO's work here, and in any event would achieve little in real terms. At most, the Inquiry should recommend factors which SaBTO should consider in the process of advising the UK Governments.

17.15 As to specific instances in which a risk-based assessment must currently be made (for example, in respect of donor exclusion and the FAIR initiative), this is a matter for expert bodies applying the RBDMF and the levels of risk tolerability advised by SaBTO and accepted by ministers. Such individual cases require a holistic decision in the current context of the health services. SaBTO serves as an independent and expert body reviewing matters of blood safety.

17.16 The RBDMF was explored in the evidence of Dr Miflin in her statement [**WITN0672006**] at paragraph 1030. It is also addressed in detail in Section 16 of this closing statement

(2) Future lookback

Suggested recommendation

That an independent expert body advise the UK Governments on whether a lookback exercise should be undertaken across the UK in respect of a transfusion-transmitted infection.

That an independent expert body advise on the appropriate approach to such a lookback exercise.

Such advice would be specifically helpful in the context of a large national lookback (as opposed to a small specific patient-related lookback). In such cases the principles to govern the approach to lookback including issues such as when donors no longer attend blood services, lookback beyond the donations where samples are kept, and identifying the roles and responsibilities of parties involved[1151] would be helpful.

Rationale

17.17 Lookback is an important feature of ensuring the reliability of the blood supply, protecting the health of recipients, and maintaining the confidence of the public in the blood services.

17.18 The Inquiry has heard evidence focused on the HIV and HCV lookbacks, both of which faced difficulties in execution. NHSBT is of the view that lookbacks undertaken in the future must be of an appropriate scope to achieve their aims without overburdening the blood service such that its normal operations are compromised.

17.19 An expert body independent of the Government is the appropriate forum in which advice can be formulated on whether, and if so how, a lookback should be undertaken. Such recommendations should be submitted to the UK Governments for decisions on implementation to be made as appropriate.

17.20 If the Inquiry is minded to make a recommendation along these lines, then the appropriate body to undertake this role is SaBTO as it has the requisite skill and knowledge.[1152] SaBTO has established a working party chaired by Professor Susan Brailsford that is currently undertaking a review of national lookbacks. This is an appropriate next step for the management of lookbacks in the UK.[1153]

17.21 In this event the SaBTO working group should have regard to the findings of this Inquiry and take learning from it in producing its recommendations.

(3) Consent to transfusion

[1151] Including DHSC and other national bodies, regulators, Blood Services, hospitals, primary care providers and patient organisations and associated resources.
[1152] As the independent advisory committee that advises UK ministers and health departments on the '*safety of blood, cells, tissues and organs for transfusion/transplantation*'. See the terms of reference of SaBTO at **[RLIT0000686]**.
[1153] See the Written Statement of Professor Neuberger in section 4 [**WITN7306001**], specifically '*it is hoped that all four nations will agree to a common approach, although that decision will be with the relevant minister.*'

Suggested recommendation

That patients receiving blood transfusions are properly consented in compliance with NICE, SaBTO and professional regulator guidelines.

Rationale

17.22 Consent is a necessary part of the transfusion process. The Inquiry has heard evidence of the shortcomings of the consenting process and the proper recording of consent.

17.23 NICE, SaBTO and professional regulators each represent a different but important source of guidelines on ensuring proper consenting as part of the transfusion process.

17.24 In respect of NICE, Professor Murphy gave evidence to the Inquiry as to the findings of the recent audit: 2021 National Comparative Audit of NICE Quality Standard QS138; National Comparative Audit of Blood Transfusion [**WITN7001061**]. This included the evidence that only 64% of transfused patients had evidence of receiving written or verbal information about risks, benefits and alternatives to transfusion. Only 26% received both written and verbal information.

17.25 The recommendations of the National Comparative Audit include that hospitals should examine their procedures for implementing the NICE Quality Statements for Blood Transfusion and explore the barriers to their implementation, work to overcome them and take advantage of regular repeats of this audit to monitor effectiveness of interventions.

17.26 In respect of SaBTO, on 17 December 2020 the Committee issued updated recommendations to NHS Trusts and Health Boards on patient consent to transfusion [**WITN7001004**]. These include a shift of emphasis on healthcare organisations employing mechanisms to self-monitor compliance with the recommendations, with subsequent improvement plans, rather than specifically recommending external monitoring and regulation.

17.27 In respect of professional regulators, the GMC has produced relevant guidance on decision-making and consent [**WITN3365040**]. While directed more generally to medical treatment, this provides a further source of guidance on securing effective consent.

17.28 In his evidence Professor Murphy noted that there is no shortage of guidance in this field, and that the difficulty is ensuring implementation. He discussed the Commissioning for Quality and Innovation (CQUIN) payment framework as one mechanism (applicable in England) for securing implementation. This tool provides a financial incentive to hospitals to secure a certain standard of care. Professor Murphy also gave evidence about an electronic alert system used at

Oxford which provides a prompt when a prescription of blood is made to secure compliance [**WITN7001001**].[1154] If the Inquiry is minded to make practical recommendations on securing compliance with consenting guidelines, these two tools may be of assistance.

(4) The Serious Hazards of Transfusion (SHOT) scheme

Suggested recommendation

That all NHS organisations have a mechanism in place for implementing recommendations of the SHOT reports and for monitoring such implementation.

Rationale

17.29 Haemovigilance in the UK is covered by both the work of the MHRA and SHOT. Recommendations on haemovigilance are produced by these bodies, and by the National Blood Transfusion Committee (NBTC).

17.30 In contrast to the historic position explored by the Inquiry, these bodies provide a complete picture on haemovigilance in the UK.

17.31 In respect of transfusion-transmitted infections, SHOT is supported by the joint NHSBT/UKHSA Epidemiology Unit which acts as the national infections coordinator. The role and work of SHOT has been set out in evidence by Professor Bellamy [**WITN7312001**]. SHOT is a professionally independent body making recommendations to improve blood safety to all organisations involved in blood transfusion.

17.32 Professor Bellamy gave evidence that reporting to SHOT is '*professionally mandated''* [**MB OE**].[1155] Thus, among other mechanisms, the regulatory framework operating around clinicians (e.g.good practice enforced by the GMC) acts to require such reporting.

17.33 Implementation of SHOT report recommendations should similarly be professionally mandated and monitored by healthcare regulators. This will produce a requirement for implementation within a system which has an in-built monitoring framework. This must not absolve healthcare providers of a separate obligation to monitor the implementation of the recommendations.

17.34 Professor Bellamy gave evidence that tasking SHOT with making mandatory recommendations '*changes the dynamic of the organisation itself and it may impair its ability to come up with the right recommendations. So, I think there is*

[1154] Written Statement of Professor Michael Murphy **[WITN7001001]** at [314-315]
[1155] Oral Evidence of Professor Bellamy dated 16.11.2022, at [71/8] and also see oral evidence at [64/14]

a trade-off to be had…' [**MB OE**].[1156] Making recommendations professionally mandated strikes the right balance and is in line with other guidance which is produced to improve NHS services. This also permits appropriate flexibility, in that a healthcare provider can choose to depart from a recommendation with good reasons and an appropriate risk assessment.

17.35 It must be remembered that the work of haemovigilance extends beyond transfusion-transmitted infections, the incidence of which is now thankfully rare. Thus, any recommendation on haemovigilance must consider the range of transfusion issues upon which it focuses.

(5) Staffing levels in clinical haematology and laboratory areas within NHS trusts

Suggested recommendation

That transfusion laboratories are staffed (and resourced) adequately to meet the requirements of their functions.

Rationale

17.36 Recent SHOT reports indicate that most transfusion-related complications arise in hospital transfusion laboratories. For example, in 2021, there were 266 cases of incorrect blood component transfusion **[SHOT0000032]**.

17.37 Clinical and laboratory teams can function optimally only if adequately staffed and resourced. Staffing levels have been a common feature of other inquiries into NHS incidents including: the Mid-Staffordshire Inquiry [**RLIT0001925**], the Paterson Inquiry [**RLIT0001926**], the Ockenden Review [**RLIT0001927**], and 'No One's Listening' (an inquiry into avoidable deaths and failures of care in sickle cell patients – further information is available [**RLIT0001928**]).

17.38 In 2006 an initiative was launched in conjunction with the IBMS, SHOT, RCPath, BBTS, UK NEQAS, NSHE, NBTC and the equivalents in Scotland, Wales and Northern Ireland that led to the formation of the UK Transfusion Laboratory Collaborative (UKTLC).

17.39 The UKTLC, in considering the nature and spread of the errors documented by SHOT, concluded that a significant proportion of these errors was most likely to be related to either the use of information technology or staff education, staffing levels, skill mix, training and competency issues. In the absence of any formal guidance on these matters, the UKTLC developed a series of recommendations using the results of two laboratory surveys conducted in 2007 and 2008. The most recent survey, undertaken in 2019, and all other surveys are available online. is available. A link to all the surveys and related

[1156] Oral Evidence of Professor Bellamy dated 16.11.2022 at [182/13]

documents is available. In addition, the RCPath haemotology workforce survey is available online[1157].

17.40 Compliance with the UK TLC standards has been accepted by both the United Kingdom Accreditation Service (UKAS) / Clinical Pathology Accreditation (UK) Ltd (CPA) and the MHRA as evidence to support their inspection programmes for laboratories.

(6) Education of healthcare professionals in the field of transfusion medicine

Suggested recommendation

That people working in the NHS are adequately trained in transfusion and that accountability for this is defined.

Rationale

17.41 The Inquiry has heard evidence that clinicians, particularly those without expertise in the blood transfusion field, lack sufficient training. Historically, this has led to inappropriate use of transfusion; most notably transfusion where it is unnecessary. In a context where risks inherent in blood and blood components can never be nil, it is important that inappropriate use of transfusion is avoided. In addition, avoidable errors in relation to blood transfusion remain (see the 2021 SHOT report).

17.42 All staff likely to be involved in blood transfusions need to have basic knowledge of blood components, indications for use, alternative options where available, risks, benefits, possible reactions, and management. In addition, such staff need to have the skills to improve patient outcomes in respect of transfusion and reduce health inequalities by involving patients in their own care and ensuring that any care takes into account individual patient need.

17.43 Such a recommendation should be made at both the undergraduate and postgraduate level.[1158] This should include haematology training, transfusion, training, and education on the Better Blood Transfusion initiative.

(7) Transfusion and governance

Suggested recommendation

That NHS Trusts have appropriate structures and governance for delivering safe transfusion practice. These are originally defined in Health Service Circular 2002/009 Better Blood Transfusion but are now part of the work

[1157] The links for which were provided with our interim submissions **[SUBS0000018]**.
[1158] In her Written Statement [**WITN0672006**] at [1480-1488] Dr Miflin has described some of the work that NHSBT already does in respect of training in blood transfusion at the postgraduate level.

of the NHS England National Blood Transfusion Committee with further guidance contained in the document Transfusion 2024.[1159]

Rationale

17.44 Everyone involved in blood transfusion needs to take responsibility for ensuring it is used appropriately. PBM needs leadership and support at every level, from national and regional leaders to trust management, health professionals and their colleagues within the hospitals.

17.45 Patient Blood Management (PBM) is a multidisciplinary, evidence-based approach to optimising the care of patients who might need a blood transfusion. PBM puts the patient at the heart of decisions made about blood transfusion to ensure they receive the best treatment and avoidable, inappropriate use of blood and blood components is reduced.

17.46 It is important to discuss the risks, benefits and alternatives with the patient in order to gain informed consent.

17.47 PBM represents an international initiative in best practice for transfusion medicine. NHSBT continues to work together with the DHSC and the National Blood Transfusion Committee (NBTC) to support NHS Trusts to manage their blood use effectively.

17.48 Following the Future of Blood Transfusion Conference in 2012. The recommendations are supported by NHS England and NHSBT.

17.49 It is important that appropriate governance structures are in place to ensure that hospital transfusion committees are functioning, effective, report into the patient safety group or equivalent, and are reviewed at Board level.

17.50 Various recommendations which may further transfusion practice in this respect are open to the Inquiry, including:

- Continuing training for healthcare professionals in transfusion medicine.
- Proper dissemination of transfusion guidelines.
- Appropriate routes for reporting matters of patient safety to committees.
- Protected learning time for clinical leads with sufficient funding.
- Representation of all relevant clinical specialities on hospital transfusion committees.
- Monitoring of hospital transfusion committees to ensure they are operational and effective.

[1159] See for example information from JPAC on this: https://www.transfusionguidelines.org/uk-transfusion-committees/national-blood-transfusion-committee/patient-blood-management

- Board level responsibility for the implementation of these structures.
- Audit by an appropriate authority to ensure compliance.

17.51 In considering these issues, the Inquiry will have the benefit of the evidence that it has heard in 2022 and previously from current experts in relevant fields. NHSBT does not repeat their evidence here as much of it is relevant to the above.

(8) Information technology

Recommendation suggested

That information technology is adopted where it has been shown to improve patient safety in relation to transfusion, including that relevant NHS bodies implement electronic systems for identification, blood sample collection and labelling.

Rationale

17.52 The Inquiry has heard evidence on the use of IT in the transfusion context from Professor Mike Murphy and Dr Jonathan Wallis. Such evidence has related to the use of electronic blood ordering, and the use of electronic records to include prescribing blood and components.

17.53 In his statement Professor Murphy exhibited a journal article from the 2021 volume of Transfusion Medicine pp.1-9 titled: 'Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England [**WITN7001031**].[1160]

17.54 That five-year strategy includes various recommendations on IT and the development of a blueprint for hospitals to improve the safety of laboratory IT.

17.55 The five-year strategy paper notes that, despite the evidence of the effectiveness of IT in clinical settings, NHS Trusts have been slow to implement new technology to support clinical transfusion practice. Investment has been lacking. In the paper there is a reference to the Healthcare Safety Investigation Branch's (HSIB) recommendation that NHSX (now the NHS Transformation Directorate) take steps to ensure the adoption and ongoing use of electronic systems for identification, blood sample collection, and labelling.

17.56 Similarly, electronic clinical decision support and information on the use and implementation of such support is discussed by Professor Murphy and exhibited to his statement at [**WITN7001016**].

17.57 Evidence is already available to Inquiry on various IT systems which are in place. The reality is that even with these systems the outcomes of recipients of blood components is not easily known without a national or audit clinical audit.

[1160] Shubha Allard, Jon Cort, Catherine Howell, Louise Sherliker, Gail Miflin and Cheng Hock Toh

Transfusion 2024 also includes development of a system of 'vein-to-vein' tracking. The plan notes that implementation of these significant schemes would be subject to finding a funding solution. However, it seems a reasonable recommendation that robust systems to understand the outcomes of people undergoing transfusion of blood components together with one that allows clinical audit and research should be an aim of the NHS. This is likely to be best achieved using IT systems that have appropriate interfaces between existing systems. Simply trying to take data out of many existing systems into a new registry would be fraught with data transfer risks and potential errors and would be extremely difficult to set up and costly to maintain. Furthermore, if this was done correctly it should allow NHSBT to manage the blood stocks throughout the system and for experts to audit the appropriate use of blood components using simple analysis tools rather than large complex timely audits.

(9) Monitoring outcomes for recipients of blood and blood components

Recommendation suggested

That a framework be established for recording outcomes for recipients of blood components. That those records be used by NHS bodies to improve transfusion practice (including by providing such information to haemovigilance bodies).

Rationale

17.58 The recording of, and access to, information concerning transfusion is currently difficult in the NHS. The lack of integration between various records is an important limitation which hampers patient access to information, and limits the ability of the blood service to undertake tracing, audit and root cause analysis. Thus, a framework within existing systems should be established for proper recording of outcomes for recipients of blood components. (Some of the rationale for the previous recommendation is also relevant to this one.)

(10) Principles applying to the allocation of livers for transplantation

Suggested recommendation

That the principles and protocols currently applicable to the allocation of livers for transplantation in respect of patients with a history including infection with a TTI through blood, blood components, or blood products are appropriate and be maintained.

Rationale

17.59 The evidence of Professor Manas explained the systems used in approaching an allocation decision for a given liver and a given recipient. The matter is a complex one imbued with clinical decision-making. Having been based on clinical observation and advanced by experts in the field, NHSBT say that any recommendation should not seek to upset the balance that has been reached in that analysis. Any such recommendation may have negative knock on clinical effects for individual patients and the donation waiting list as a whole which can only be seen by an expert clinical decision maker.

17.60 In respect of those recipients infected as a result of infected blood and focusing on liver transplantation, Professor Manas explained the following in his oral evidence [**INQY1000259**]:[1161]

> *'What I suggested in my report was, if we were going to look at a way of trying to give some advantage, then the system has the variant syndrome list, or they could say: well, every centre could use the DCDs that they have that are allocated to them, and in their list, that they give to us, they could itemise which patients have been co-infected and why they're on the list and why they're getting priority.*
>
> *But I think the NLOS system gives – it's much safer because it monitors them all the time and they will – every time there's an offer, they'll be in the system. And when they decompensate, they get it. They're not disadvantaged at all. The system makes sure of that.'*

17.61 In NHSBT's submission, the current approach to transplantation decisions for this class is the appropriate one. It has been made based on expect clinical knowledge; it is a much safer route which ensures a transplant is given at the appropriate time. Insofar as any recommendation is going to be made on this issue, it should be one to endorse the current approach.

17.62 Of course, if the Inquiry concludes, in the light of the evidence, and in accordance with these submissions, that no change to the system is necessary, it could say that without expressly making any recommendation to that effect and allow the expert groups to consider this further.

C. Comments on other recommendations

17.63 We anticipate that our response to submissions on recommendations by other core participants will be quite limited, and where relevant this will be picked up in oral submissions.

[1161] Oral Evidence of Professor Derek Manas [**INQY1000259**] dated 10.11.2022 at [51/7]

CONCLUDING STATEMENT

Introduction

1. NHSBT has set out, within these submissions, its impression of the conclusions that should be drawn from the evidence the Inquiry has heard, whether on events or on other more individual aspects of that evidence. As necessary, we will expand on these at the oral hearings, and we do not intend to repeat them here. However, there is, in concluding, a small number of points NHSBT wishes to emphasise. We do so simply because they might otherwise remain unstated in the submissions heard by the Inquiry.

2. We stress that nothing that we say here is intended to detract from what we have said already, and what we say in the final paragraph of these submissions below, as to the terrible suffering caused by the events that have prompted this Inquiry. Nor is it intended to excuse any conduct of anyone which caused or contributed to such suffering.

Structure and funding

3. The first is that the evidence made available throughout the Inquiry makes it plain that NHSBT's predecessors were significantly hampered in their response to the infected blood tragedy because of the funding and the structure of the blood service. Both of these factors are fundamental context to the actions of the service (i.e. what it did and what it did not do). They weighed heavily as limitations upon the response that could be mustered to avoid and mitigate infections.

4. While the resolution of problems with structure and funding would not have been the complete answer to the questions of the blood services posed by this Inquiry, NHSBT maintains that they were significant frustrating factors, amounting to a common theme that appears throughout the story of blood in England and Wales. (As such NHSBT wishes to recognise the service of the clinicians, scientists, and other staff concerned, past and present, and undertaken in difficult circumstances, and without the tools that we take for granted today, with their duty to recipients and donors in their minds.)

The Blood Service's role

5. Secondly, the evidence also makes it plain that the position of NHSBT's predecessors, essentially occupying a place behind treating clinicians, was one into which it had little or no input, let alone control over, treatment decisions. The requirement for the service was to provide a safe and sufficient supply of blood to meet clinical needs. By definition, it had very little control over how that supply of blood was used. This was an inevitable corollary to the overall position of the blood service in the structure, and of its focus upon providing a reliable supply of blood.

Lessons learned

6. Thirdly, NHSBT hopes that the information it has provided to the Inquiry demonstrates the learning that has already been taken from this tragedy. The service in England and Wales has been transformed from a loose federation of RTCs to a special health authority which ensures high standards across its practice. Its response to vCJD, and the creation of SHOT, were responses informed by the experiences of the past, and ones which show the evolution of the service to its modern state. Today, all the services in the UK operate an internationally recognised risk-based decision-making framework which appropriately and transparently manages risk with the benefit of expert clinical advice. NHSBT looks forward to the report of the Inquiry and will study it carefully to take forward learning and recommendations to further improve the service that it provides.

Donors

7. Fourthly, NHSBT wishes to recognise the work of donors who over the years have given tens of millions of donations and made a blood service possible. Without their trust and goodwill, it would not have been (and would not now be) possible to provide a supply of blood to meet clinical needs.

NHSBT and this Inquiry

8. Fifthly, we express the hope on behalf of NHSBT that it has been able to deliver on its promise to assist in the Inquiry's endeavour in every way that it can, and that it is obvious to the Inquiry, and to all others concerned, that that approach was shared by the witnesses who have given evidence on behalf of NHSBT.

The Infected and Affected

9. Finally, we return to where we began: with the Infected and Affected, many of whom have suffered for decades without acknowledgment or recognition of what happened to them. It is impossible to imagine the hurt and suffering caused and compounded by these events and the failures to respond to them. NHSBT wishes to recognise each individual tragedy, and we hope that the Inquiry, and the report soon to be issued, will bring answers that have not been provided in all the decades that have gone before. We also recognise the part the blood services have played in that harm and suffering. So, we would like to say again, to all those infected and affected, for all they have had to endure, we are deeply and truly sorry.

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39 ESSEX CHAMBERS
16.12.22

TABLE OF ACRONYMS

1. Table of Acronyms that appear in the Statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 26 February 2021 of Gail Miflin.

Term	Acronym
Acquired Immunodeficiency Syndrome	AIDS
ABO blood group system	ABO
Alliance of Blood Operators	ABO
Advisory Committee for Transfusion Transmitted Diseases	ACCTD
Advisory Committee on Dangerous Pathogens	ACDP
Advisory Committee on Transfusion Transmitted Infections	ACTTI
Advisory Committee on Virological Safety of Blood	ACVSB
anti-human globulin	AHG
Arm's Length Bodies	ALBs
Antimicrobial Resistance and Healthcare Associated Infections Reference Unit	AMRHAI
hepatitis B core antibody	anti-HBc
Audit, Risk and Governance Committee	ARGC
Advisory Committee of the Safety of Blood	AVSCB
British Blood Transfusion Society	BBTS
Blood Centres	BC
Blood Group Reference Laboratory	BGRL
Blood Products Laboratory (later Bio Products Laboratory)	BPL
Blood Products Laboratory Diagnostics	BPLD
Blood Supply CARE committee	BSCARE
bovine spongioform encephalopathy	BSE
British Society of Haematology	BSH
Blood Safety and Quality Regulations (SI 2005-50)	BSQR
Central Blood Laboratory Authority	CBLA
Centers for Disease Control and Prevention	CDC

Communicable Disease Surveillance Centre	CDSD
Component Development Laboratory	CDL
European Committee on Blood Transfusion	CD-P-TS
Commission on Human Medicines	CHM
Creutzfeldt–Jakob disease	CJD
Chief Medical Officer	CMO
cytomegalovirus	CMV
change and safety notifications	CNs
Central Planning Team	CPT
Care Quality Commission	CQC
Donor Experience Team	DET
Donor Health Checks	DHC
Department of Health and Social Care	DHSC
Department of Health and Social Security	DHSS
Department of Health	DoH
Department of Health	DH
Data Protection Impact Assessment	DPIA
Expert Advisory Group on AIDS	EAGA
European Blood Alliance	EBA
England Infected Blood Support Scheme	EIBSS
Emerging Infections Report	EIR
Enzyme-linked Immunosorbent Assay	ELISA
For the Assessment of Individualised Risk	FAIR
Food and Drug Administration	FDA
Fresh Frozen Plasma	FFP
Factor IX (nine)	FIX
Factor IX Concentrate	FIX
Fellowship exams of the Royal College of Pathology	FRCPath
Factor VIII	FVIII
Factor VIII Concentrate	FVIII
Gastrointestinal Bacteria Reference Unit	GBRU
Hepatitis A (Infectious Hepatitis)	HAV
hepatitis A Virus	HAV

Hepatitis B Core Antigen	HBc
Hepatitis B Surface Antigen	HBsAg
Hepatitis B (Serum Hepatitis)	HBV
Haemophilia Centre Director	HCD
Hepatitis C Virus	HCV
hepatitis E Virus	HEV
Human Immunodeficiency Virus	HIV
human leukocyte antigen	HLA
Her Majesty's Stationery Office	HMSO
Health Protection Agency	HPA
Human Platelet Antigens	HPA
Human T-cell lymphotropic Virus	HTLV
Human T-cell lymphotropic Virus-III	HTLV-III
International Blood Group Reference Laboratory	IBGRL
immunoglobulin	Ig
International Society of Blood Transfusion	ISBT
Integrated Supply Planning	ISP
intravenous	IV
Intravenous immunoglobulin	IVIg
Joint Management Committee	JMC
Joint UKBTS Professional Advisory Committee	JPAC
Multi-disciplinary team	MDT
Medicines and Healthcare Products Regulatory Agency	MHRA
Minimum Inhibitory Concentration	MIC
Medical Laboratory Scientific Officer	MLSO
Management Process Descriptions	MPD
Medical Research Council	MRC
Specialist exam for membership to RCPath	MRCPath
Microbiological Safety of Blood and Tissues for Transplantation	MSBT
Microbiology Services Laboratory	MSL
Non A Non B Hepatitis	NANBH
National Blood Authority	NBA
National Blood Authority (Establishment and Constitution)	NBA (Amendment)

Amendment Order 1994 SI No 589	Order 1994
National Blood Authority (Establishment and Constitution) Order 1993 SI No 585	NBA Order 1993
National Blood Transfusion Committee	NBTC
National Blood Transfusion Service	NBTS
Welsh Blood Services	NBTS (Wales)
National Blood Transfusion Service / Central Blood Laboratory Authority	NBTS/CBLA
Non Clinical Issue	NCI
National CJD Research & Surveillance Unit	NCJDRSU
National External Quality Assessment Service	NEQAS
National Health Service (NHS) Blood and Transplant	NHSBT
NHSBT National Clinical Governance, Audit, Risk and Effectiveness group	NHSBT CARE
NHSBT (Establishment and Constitution) Order (SI 2005 No. 2529)	NHSBT Order 2005
NHSBT (Establishment and Constitution) Regulations (SI 2005 No. 2531)	NHSBT Regulations 2005
NHSCord Blood Bank	NHS-CBB
NHS England	NHSE
National Institute for Biological Standards & Control	NIBSC
Northern Ireland Blood Transfusion Service	NIBTS
National Institute for Health Research	NIHR
National Management Committee	NMC
Notification of infectious diseases	NOID
Organ Donation and Transplant	ODT
Principal Accounting Officer	PAO
Polymerase Chain Reaction	PCR
Personal Development and Performance Review	PDPR
Plasma Fractionation Centre	PFC
Scottish Protein Fractionation Centre	PFC
Plasma Fractionation Laboratory	PFL
Public Health England	PHE

Public Health Laboratory Service	PHLS
Publlic Health Laboratory	PHLS
population, intervention, control, and outcomes	PICO
Plasma Protein Solution	PPS
Quality Management System	QMS
Royal College of Pathologists	RCPath
Regional General Manager	RGM
Regional Health Authority	RHA
Regional Health Board	RHB
radioimmunoassay	RIA
Blood test for HCV	RIBA
ribonucleic acid	RNA
Regional Transfusion Centre	RTC
Regional Transfusion Director	RTD
Respiratory and Vaccine Preventable Bacteria Reference Unit	RVPBRU
Serious Adverse Blood Reactions and Events	SABRE
Advisory Committee on the Safety of Blood, Tissues and Organs	SaBTO
Standing Advisory Committee on Blood Components	SACBC
Standing Advisory Committee on Care and Selection of Donors	SACCSD
Standing Advisory Committee on Clinical Transfusions Medicine	SACCTM
Standing Advisory Committee on Immunohaematology	SACIH
Standing Advisory Committee on Information Technology	SACIT
Standing Advisory Committee on Tissues and Cellular Therapy Products	SACTCTP
UK Standing Advisory Committee on Transfusion Transmitted Infection	SACTTI
saline-adenine-glucose-mannitol	SAGM
Senior Departmental Sponsor	SDS
Special Health Authority	SHA
Serious Hazards of Transfusion	SHOT
Scottish National Blood Transfusion Service	SNBTS
Scheme of Delegation	SoD

Standard Operating Procedure	SOP
Single Plasma Pack	SPP
?	SPSS
Secretary of State for Health and Social Care	SSHSC
Transport Development Group	TDG
Transfusion Medicine Epidemiology Review	TMER
Transfusion-transmitted Infections	TTI
transfusion education talks	TxED
University College London Hospital	UCLH
UK Blood and Transfusion Service	UKBTS
UK Haemophilia Centre Directors (now Doctors) Organisation	UKHCDO
UK Health Security Agency	UKHSA
variant Creutzfeldt–Jakob disease	vCJD
Von Willebrand's Disease	vWD
Von Willebrand's Factor	vWF
World Health Organization	WHO