Tuesday, 24 January 2023

(10.00 am)

SIR BRIAN LANGSTAFF: Yes, Mr Cory-Wright.

Closing Statement by MR CORY-WRIGHT KC

On behalf of NHS Blood and Transplant

MR CORY-WRIGHT: Thank you, sir. My name is Charlie Cory-Wright and, as part of a small team of solicitors and barristers, I represent NHS Blood and Transplant in this Inquiry.

It feels a bit strange to be introducing myself to everyone when we've worked together in the same room for nearly four years, but that's the way the Inquiry process works, and, I'm sure to everyone's relief, I've not said much publicly since 2018 in relation to this.

I should explain what I propose to do in my two-and-a-half or so hours. Five things, I hope. First, I'm going to make some opening remarks about the Inquiry itself, about NHBT's role in it, and about the infected and affected. I'm going to explain what we did in our written submissions, and, given that this is a separate exercise, essentially what I'm doing just now: explaining the purpose of these submissions.

I'm going to cover in this first section, and indeed amplify, a fair bit of the ground that we covered in the early part of our written submissions, which was

intended specifically for Core Participants as well as for Sir Brian, and that may take a bit of time.

Secondly, I want to deal with some of the detailed past historical matters, in order to cover some topics that have been discussed in the written submissions but we think should be addressed by us orally as well, sometimes because they've been picked up by others in their submissions and we need to respond to that.

Thirdly, and importantly as well, I'm going to explain about the present position: what's changed, what's in place now. It's really important for us to be clear about that because the Inquiry can only make recommendations as to the future with full knowledge of the current position. And it's apparent to us that some of the present position isn't necessarily widely known. And that may be in part because much of it was based on evidence provided by Dr Miflin to the Inquiry, which evidence was given in writing but to which she was never asked to speak.

A good example of this, perhaps I can just explain what I'm talking about, we've had number of suggestions from others that haemovigilance was something that needed to be adopted in the UK, by us. It is something that we've been doing for many years and that's all set out in that statement, but I'm going to deal with that

when we come to it because it is integral to current approaches to safety.

Fourthly, I'm going to describe NHBT's position in relation to the future in the context of the recommendations that we have suggested for Sir Brian to make, and indeed that others have suggested.

And finally, to make some concluding remarks.

First of all, then, some thanks.

It's important, even though this has already been done by others and no doubt will continue to be done by more others, to pay tribute and to say thank you to the Inquiry and to all involved in it over the last four years while we've been here. Thanks and such tribute to the chair, to Counsel to the Inquiry, to all the Inquiry staff, and by that I mean Rhys, George and Sam, as well as Laura, Aemon, Angela and David, and all the others, who have looked after us while we've been here.

Quite apart from their work for us all, day-to-day, that last cohort, Laura and her team have been crucial in dealing with witnesses, many of whom were elderly and vulnerable, and without the assistance given to them to put them at their ease, the quality of the evidence given to the Inquiry would have been much less. So a really big thank you to them.

Thanks to all the other participants, but most particularly, of course, thanks to the infected and affected cohort who have been here throughout and alongside whom we have immersed ourselves in the Inquiry process. I will pay a proper tribute to them in a moment.

At the preliminary hearing on 26 September 2018, I gave, on behalf of NHSBT, a commitment to the Inquiry and to the infected and affected. I hope no one will mind if I remind us all what that commitment was. I said this:

"It goes, we hope, without saying that NHSBT fully supports the Inquiry in all of its terms of reference. Our primary concern is for those who were given infected blood or infected blood products, and for their families and others who have been affected by this. We do know that we can never truly understand the impact this has had on the infected, their families and loved ones, however we do of course know that impact has been devastating. One only has to have paid attention to what's been said over the last three days ..."

This was on the final day of that preliminary hearing.

"... to be aware of that.

"We understand that our job is to provide the

Inquiry team with all the help that we can in fulfilling its terms of reference. We will do whatever we can to assist the Inquiry in order that answers can be provided to the questions asked by those infected and those affected. We will be open, constructive and honest. Our motivation is to get to the truth for those infected and affected to the best of our abilities.

"In that sense we share, we hope, the same approach as the Inquiry itself. Indeed, we understand that this Inquiry is above all things a search after truth, the unvarnished truth about all of the many disquieting things that we have been hearing about over the last three days. We do get it, that if the Inquiry is able to do that job properly then that is likely to include the uncovering of facts that are seriously unpalatable.

"Whatever those truths may be, we want to say, loud and clear at the outset, that we too are very sorry for what happened to all those infected, all those affected, all who are victims.

"We also understand that actions speak louder than words. We hope that we are demonstrating that in our co-operation with the Inquiry, both thus far and as it continues, as well as in the terms of the safety measures we now apply in screening protocols and the like, which I will outline in a moment.

"We do understand and embrace the need for the Inquiry to apply current clinical science and current standards and norms to its scrutiny of what went wrong. It's only by doing that that the lessons that need to be learnt will be clear.

"Finally, I hope I can help by mentioning this morning's invitation by Steven Snowden QC, who raised Bishop Jones' six-point charter for public bodies and invited those here involved to sign up to that charter. That question having been raised, NHSBT has considered the charter and its six points. We do not see these six points as any different to the commitment we were already making to the Inquiry, and in those circumstances we confirm our intention to be guided by and to strive to follow those principles."

I do very much hope that we've demonstrated by our actions since then that we meant it when we gave that commitment and that we've sought to honour our pledge throughout.

Now turning to the Inquiry and its task, it is an important discipline in all significant and long-term endeavours for those involved to be able on occasion to step away from what's being dealt with in the moment so as to be able to review the exercise as a whole. We as a team obviously had to do that when we were reviewing

all the evidence for the purposes of writing our written submissions. It was very worthwhile. It was also, frankly, a humbling exercise. It's easy to lose sight of the Inquiry's achievement over these years of present gathering and presentation at hearings when one has been deep in the Inquiry process throughout that. That achievement has been remarkable.

First and foremost, it's 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 unheard or ignored, are now woven into the fabric of all of the evidence the Inquiry 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 who have given evidence to it.

It goes without saying that many have said it already, and I say it again: that the evidence the Inquiry has heard over its five years from the infected and affected has been particularly and profoundly moving. Witnesses have given detailed accounts of great suffering. They've 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 have had to face the world isolated.

For those who have attended over the five years, it's been moving and humbling to hear and to read that evidence.

We did not, in our written submissions, wish to identify any particular individual account or any particular witness in seeking to pay tribute to the infected and affected. That was because we thought it might suggest we were valuing one person or a few people's experiences over those of others. But having thought about this a bit more, we think that's wrong, because it might seem -- or feel like -- we were maintaining a distance or being indifferent to what we've heard. So we do want to mention a couple of individuals in the hope that this can be seen as a proper medium by which we can express our feelings about, if that's not too awkward a phrase, and pay tribute to, the wider cohort of all the many infected and affected from whom or about whom we've heard.

We've chosen these ones because they're striking, but also particularly given that they've been specifically singled out by their own representatives already.

At the conclusion of his closing submissions, Steven Snowden KC referred to Lee Turton, born with haemophilia A, diagnosed at the age of 4 with HIV after treatment with a contaminated batch of Factor VIII, and died in January 1992 at the age of 10. I know that that terrible summary won't remotely do justice to him, but those were the raw facts. We watched a series of video clips relating to Lee, concluding, I think, with a clip taken at Christmas just one month before he died. No one who watched that video will ever forget it.

I don't think I need to, or I ought to, say more than that, save only to say thank you to Lee's family for being able to share those deeply private and poignant moments with the world. And, as I say, I hope that tribute can stand as a thank you to everyone else who has shared in some way in order to shed light on these terrible events.

Brian Cummins, Steven Snowden's colleague in the team, made specific mention of the evidence of John Peach.

Mr Peach and his first wife Susan, who died in the early 1980s, had two sons: Leigh and Jason, born in 1966 and 1969. Both had haemophilia A. Both went to Treloar's. Mr Peach told the Inquiry how they thought Lister concentrate was a godsend. They had no idea when

the boys left Treloar's that they had tested positive for HTLV-III and they found out both were infected at the same time. He told us how, after their diagnosis, their world fell apart. He told us how they tried to make the best of things and how they died just five months apart, at the ages of 23 and 27, and of how he misses them every day. All he wants now is the truth.

Once again, no one who heard his evidence and saw the courage it took for him to give it will ever forget it. Once again, I hope that it's appropriate to make mention of him, to pay tribute to him and his family, and to use that memory as a symbol for the suffering of others that we all ought to recognise.

All those who shared their stories gave to all of those of us who have been at the Inquiry day-to-day or followed it online an invaluable insight into the suffering of the infected and affected, into their grief, and as to how their lives have been transformed from what they were entitled to expect. We've heard of the impact of stigma and discrimination and the difficulties faced by those living with HIV and HCV in many cases alongside haemophilia.

It's against this backdrop that we must acknowledge the strength of those who brought this Inquiry into

being: the patients' groups, whose efforts ensured that the Inquiry has taken place. It has taken too long. We hope that this Inquiry has been, and we hope it will continue to be, an important trigger for collective efforts to ensure the quality of care offered across the whole services. We hope that this Inquiry delivers answers that the infected and affected have campaigned for and deserve.

These experiences have been with us throughout, and it's 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.

What's also really striking, to those who have had the opportunity to attend the hearings throughout, is that 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 tried throughout to deliver on its own promise of fulsome engagement and assistance. It's also so, we detect, across the range of Core Participants, whether infected and affected or not.

The seeds and indeed shoots of this sense of

collective endeavour have been there all along. They were evident even at that preliminary hearing 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 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 institutional CPs, such as myself, once those CPs had demonstrably committed themselves to the Inquiry's task.

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 the 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 experiences of those who have suffered is woven into its proceedings in the way described above.

Now, NHSBT has throughout both understood and welcomed the fact that this scrutiny of past events has 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 that is the approach, it is, we submit, vital for the Inquiry to bear in mind the extent here of the potential consequences, unless guarded against, of seeing only through this lens.

This applies particularly to the examination with hindsight of the events as they took place in real time and, in that context, to any explanations given to the Inquiry of why things were done the way they were or why they were not done differently. I'll come on to deal with that more fully in a moment.

I'd like to say more, a little more, about the infected and affected themselves. They have been the touchstone of this Inquiry. All with individual stories that come together to map a tragedy that has run for many decades and, as we have said, we cannot do justice to all the individual stories here but we have no doubt that the Inquiry can and will be able to do so. Without their evidence, the depth of the experiences of the infected and affected would have been obscured or lost. Thus, again, NHSBT wishes to express its gratitude 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

given.

I would add that we heard loud and clear what Roanna Maharaj said in her submissions on behalf of The Thalassaemia Society on Friday. I include that now because what she says is equally something important for us to acknowledge and act on. Although her own role is a very specific one, it seems to us to have a resonance that goes back beyond that of the thalassemia sufferers. I will come back to that when we deal with recommendations below.

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 that they supplied was the cause of that suffering to any person, we apologise unreservedly.

Now, I would like to say something about reviewing the past and the Inquiry's approach to that. The approach of seeing things through the lens of the infected and affected has made the task of NHSBT and its representatives that much easier to undertake in terms of 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's important nonetheless for all, for NHSBT, other CPs and, most of all, the Inquiry and its team to bear in mind the ramifications of this approach on the mindset of all concerned.

The starting point is, of course, that these matters have all to be considered in the context, ever present in the mind of all involved in the Inquiry, that we are largely dealing with matters between 50 and 30 years ago, and it's 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.

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, and we've heard much about that, 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 the precise chronology or the detail of what happened.

As to more public events, it's not difficult for us to summon up their general historical sweep: in the

1970s, 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 1980s, HIV and AIDS; the Falklands War; the Iran-Iraq and Soviet-Afghan Wars; and the beginning 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 relying upon the archives for that.

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 in this Inquiry. We get a slight jolt of surprise when we're 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 separate, of projecting the present along with all its assumptions back into the past.

Both the sweep of underlying societal and technological changes, and their practical day-to-day manifestations are important to the Inquiry for all

sorts of reasons: they're relevant to society, they're relevant to governments, to the NHS and other public health services in the UK; they're relevant to the practice of medicine which has changed fundamentally, because of progress in medicine itself, in science, in the 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.

First of all, societal differences. It's necessary to bear in mind the wide social and legal transformations of the last 40 years. As well as the landmark events referred to above, there are major differences between expectations and habits, then and now, and between attitudes then and now.

First of all, expectations and habits, day to day. It's 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. 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. 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.

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

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.

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

Attitudes. 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 we mention this now not in any way to excuse them; it's rather to identify them as factors that would have represented obstacles to relevant action or change at the time.

In particular, there was very commonly a real discomfort with any honest or serious discussion about sex. This was present in most households and even extended, as the Inquiry has heard, to some clinicians.

It's 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 unfair stigma and abuse. It's a discomfort which constrained public consciousness and discourse, and possibly for many in private as well, in a strange hinterland between comedy -- the Carry On shows and Dick Emery -- prurience, and, hidden behind those things and most relevant to this Inquiry, simple disapproval, for some, shading into disgust, if not at the idea of sex itself, at least at the idea of discussions about it.

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 it. Even, when the need arose, apart possibly in academia and medical circles. This feature of the times, ignorance, combined with socially-enforced silence about sex was inevitably a fertile breeding ground for homophobia: widespread, 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 it or accept it. It's 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.

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 of a particular sort or not would have been unthinkable during the '70s and '80s and such discussion would have run a high risk of being counterproductive.

This was essentially for two reasons. First, because of a squeamishness in addressing it on part of decision-makers but, secondly, also because of a real and probably justified concern on the part of decision-makers that addressing these matters directly with the public would not achieve the desired result: sections of the public would recoil rather than take in the evidence.

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

Changes over the years. We've already said on some of the technological advances -- talked about some of the technological advances since the '70s and '80s. As well as their general societal impact, those advances have changed the management and operation systems of the health services, 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 information services, and have increased the speed of adaptation to new changes.

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

There have been transformations in the practice of medicine. These include changes in the doctor-patient relationship in respect of sharing information, views on medical paternalism and consent, 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.

This effect was something that the ethics experts recognised as part of their oral evidence. As Professor Savulescu said, 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 you don't have some universal or moral objectivity -- objectively principles in both of them -- sorry, that doesn't mean you don't have some universal or moral objectively true principles in both of them. It means that the facts are different.

And Professor Kerridge. In medicine, as in many other spheres of life, we can see examples in 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 these are just not acceptable and were actually never acceptable.

The importance of context specificity means it's 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.

The changes in the organisation of the Blood Service during this period are described in the written submissions that we provided and I'll touch on those in the next section. These changes transformed the organisation capabilities and practice of the Blood Service. 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 the 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 the systems within which they were working.

Detailed accounts of the history of the English Blood Services, 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 and Dr Gail Miflin. It was explored in our written submissions in detail in the section "The Blood Service and its Role", and "Running the Blood Service". It may be an obvious point but it is only so once identified that the context here also includes all the

other important life-enhancing and life-saving services and functions being provided by the Blood Services.

I'd like now to turn from contextual changes since those times to other factors relevant to our own consideration of the past, relating more to us than to the events that we're assessing. Nothing, can I stress, that I'm about to say is intended to be taken as undermining the lived experience of the infected and affected as described by them or suggesting that the accounts that they've given are in any way not correct. That is not the purpose of these submissions.

What we say we do simply because these are relevant factors which the Inquiry, we say, should bear in mind when weighing the evidence it's heard from others as well.

So, first of all, reliance upon memory of recent events. Much of the evidence heard by the Inquiry consists simply of personal recollection, often assisted by relevant documentary recorded itself, often incomplete. When I say "simply" there, I don't mean "merely", I mean unassisted by other things.

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 30 or 40 years ago, however that evidence is, by definition, difficult to test now.

Furthermore, the timescales involved mean that there are important limitations as to its reliability. Those limitations should be considered when the Inquiry assesses this evidence. There are number of distinct points here. First, what is encoded in a witness's memory is determined by what they attend to and what they've stored as important and, one might add, in relation to the accounts given by infected and affected, often what is seared on to their memory in the way described by Ms Monaghan in her submissions late last week. As I say, I am not in any sense seeking to undermine that.

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 of many years before. That process of presenting witnesses with selected contemporaneous written documentation after a significant period has elapsed, would itself have had an impact on the evidence to the Inquiry. Invariably, in refreshing witnesses' memories, looking at these documents may also itself alter the witnesses' memories.

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 own understanding of events has developed organically. That's inevitable. The questions posed and the answers given reflect the developing nature of this undertaking.

Finally, there's 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 the other priorities that were part of the picture back then, but are no longer part of the picture, are not remembered.

We have no doubt at all that all concerned in the Inquiry are well aware of these points. Once again, none of them is intended to represent criticism of the way in which the Inquiry has performed its function. They're 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 the events.

Hindsight. There are a number of points here. I've already dealt with the question of the review of past events being seen through the lens of 21st century thinking and norms, and I'm not going to go back over that now.

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

We know that we know many of the answers to the questions that were back in the day unanswered. For example: what was the nature of NANB? How serious was it? In relation to HIV/AIDS: what is the nature of this infection? Is it a virus? Is it one or a number of viruses? We can attempt to put ourselves in the position of those who did not know the answers to those questions. In doing so, we can imagine not knowing them. But it's much harder to give due colour or weight to the significance back then of what we now know to be wrong answers but didn't know then, or wrong lines of inquiry that led nowhere, scientific blind alleys or worse.

This applies most particularly in the context of the cutting edges of scientific progress. Why did it take so long to discover X or Y? But it's equally important in steps dependent to and subsequent to that scientific endeavour which are necessary to make practical progress

in the real world in the light of it. Thus, it can be acutely relevant to understanding, for example, the explanations for delays in the implementation of scientific or other steps, which steps have been subsequently proved obviously sensible.

The danger, put shortly, at these steps may seem with hindsight always to have been obviously sensible when, at the time, they were not.

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

A useful analogy for the review, now, of such situations is the challenge of the cryptic crossword puzzle. We don't know the answer to a clue until we have solved it. Similarly, we don't know until then how long it's going to take to do so. Once we have solved it, it often seems to us that it was completely obvious, and that it's 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.

That reaction, understandable but in fact often wrongheaded, 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 with finding answers back in the day, or deciding on strategy, we are distracted by our hindsight, our knowledge of those answers. We're distracted 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.

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

I'm going to mention very briefly the contents of our written submissions in case anyone hasn't had a chance to look at them and would like to know the topics that are covered in there. The specific topics with which we deal, in relation to the Blood Service and the blood supply, there's a topic on the Blood Service and its role, decision making and reliability of the blood supply, running the Blood Service, self-sufficiency. Dealing with particular infections and responses to them. Sections on hepatitis generally,

HIV, non-A, non-B (hepatitis C), HIV look-back, HCV look-back and vCJD. Other related matters, a section dealing with consent, a section dealing with recordkeeping, a section dealing with teaching and transfusion practice, and a section dealing with minimising the risk of transfusion-transmitted infection. And then concluding section on recommendations that the Inquiry might make.

So now I turn to the historical section. This is dealing with only a very few topics which seem to us particularly important to raise now, either because they weren't covered in our written submissions, because they've been raised since then by others, or because we feel they need to be emphasised in particular.

The central role of the Blood Service has been and remains to obtain a reliable supply of blood from voluntary, unremunerated donors and to make that supply available for transfusion and for use in blood products. When we say reliable, we mean a supply which is safe for all recipients, including prospective recipients, and a supply which is sufficient for all recipients, including prospective recipients.

At the outset of our oral submissions we began with an apology. That apology is because we failed in this role. Numerous of our witnesses have recognised

failings in what we did in the past, and we apologise for those wholeheartedly. We deal with those apologies in detail in our written submissions, and I certainly don't want to go through the task of listing what we've said sorry for in the written submissions. They're there for people to see.

I will give one example now, and that is the taking of donations of blood from prisons and other correctional institutions. Simply put, the Blood Service made the wrong decision.

Once it was recognised that the blood of those donors was at highest risk than those of the general population, those donations should have ended. In not ending those donations, people will have been infected by blood that we took. We sincerely apologise for that.

In making our written submissions and these oral submissions, we don't seek to row back from any of these apologies for the things that we got wrong. We've also made apologies for making decisions that were the wrong decisions to make, often difficult decisions which had complex, competing circumstances. However, where we took the wrong decision, we are sorry.

The purpose of these submissions, I hope it's clear already, is not to avoid blame. It's to assist the Inquiry and the infected and affected in understanding

what the Blood Service did and why. We've hoped throughout that that is so, and we continue to do so.

We've said a lot in our written submissions on the historical matters, as I've said, but there are three topics that I want to deal with orally: structure and function of the Blood Service, donors, and testing.

Now, first of all, structure and function of the Blood Service. From its inception in around '93, '94, the Blood Service operated as a loose federation of independent Regional Transfusion Centres. Instead of being bound together as an organisation, they were bound to their Regional Hospital Boards, later regional health authorities. There was no -- sorry, Health Boards. There was no executive control within the Blood Service, nor over those who received our blood, be that fractionation laboratories, hospital blood banks, or clinicians.

While the Advisory Committee in the early 1980s and the National Directorate from the late 1980s gave some internal direction, it was only in '93/'94 that centralised and executive control was established in the National Blood Authority.

This was not for a lack of desire on the part of the Regional Transfusion Directors to be a centralised service. The CTI team has produced a very helpful

presentation -- that's INQY0000307 -- which sets out the various requests made and the views expressed of Regional Transfusion Directors. We've referred to this, and indeed relied upon it in our written submissions at paragraphs 5.4 to 5.8.

Neither was it for a lack of perceived benefit from a centralised service. Such would have provided hope for a unified approach to policy internal to the Service, for a unified approach with the fractionation laboratories, centralised funding, which was not regionally determined by RHAs, executive authority to issue directions to other healthcare providers. Indeed, this is what eventuated when the NBA was established.

The result of the lack of this centralisation and executive control is set out in detail in our closing submissions.

Two things to highlight just for present purposes. In respect of self-sufficiency, the situation is a complex one. The CTI have again produced a helpful analysis which goes through the issue in detail, and this is INQY0000333, and we have made submissions in this in detail at our section 6.

At this stage we wish simply to say that a centralised service had significant benefits over a diffuse one, and that a centralised service would have

made significant difference in achieving self-sufficiency at an earlier stage.

In respect of executive control -- that's the second topic -- over other practitioners, the Inquiry has heard about the weight placed on clinical freedom for practitioners. The remit of the Blood Service did not include direction of clinicians outside the service. Indeed, even when the service direction was diffuse between RTCs.

We did issue guidelines, including *Notes on Transfusion* in the 1960s, through to the 1980s. The 1973 *Notes on Transfusion*, if anyone wants to look at it, are at HCDO0000861. The Red Book was issued after that.

A number of our witnesses also spoke of being involved in teaching. Whether in the context of the times and in our state, with a diffuse set of RTCs with no executive authority nor centralised funding, going beyond this would have been possible or feasible is unclear. We say it was a great difficulty, considering our status.

The second topic was donors. The Blood Service would not be able to fulfil its core role without donors. We know that all are aware of that fact. Without sufficient donors to meet the demand for blood

components, including specific components such as the immunoglobulins and rarer blood groups, sufficiency of supply would be compromised. Such a failure of supply would itself be a significant safety risk.

The question of supply in each RTC, over the decades focused on by this Inquiry, is a complex one. Shortages occurred and the risk of shortages was an ever-present consideration. Indeed, where the introduction or not of a new policy potentially impacted sufficiency of supply, then that consideration was a risk which had to be understood and accounted for in any analysis of whether to introduce the policy.

Furthermore, the extent of the risk of a novel policy to the donation numbers was by its nature unknown. In those circumstances, the question then arose as to whether a cautious approach to quantifying that risk should have been taken before factoring in the risk to supply into the overall decision to adopt the new policy. Might have militated against that.

We deal with much of the matter of donors in section 3 of our written submissions and section 5, that's "The Blood Service and its role" and "Running the Blood Service". However, to assist specifically on the issue of donors and donor shortages, it's worthwhile looking at two specific topics: blood shortages and

donor goodwill, and the reluctance or potential reluctance of donors to donate.

First, on blood shortages. A number of witnesses in the blood services spoke of shortages of blood. To take one example, in late 1984, in her oral evidence Professor Contreras spoke to blood shortages being quite common when she took up her role as director in North London. That's INQY1000165, at 71/19. She spoke of importing O groups from Oxford, with whom they had a contract. Correspondence from Dr Cash also indicates Scotland was providing blood to North London at this time and that numerous elective operations were being postponed in London because of the chronic shortage of blood. That's PRSE0002549.

Now, at this point I'm going to refer to the first of seven documents. I'm only proposing -- with Lawrence's -- and I'm very grateful to Lawrence for this, his help -- to refer to seven documents during these submissions. And the first one is a discussion paper for the meeting in November 1984 of the Advisory Committee on the NBTS. The reference is CBLA0001914.

Now, in this paper is a useful pen portrait of blood use, donor sensitivities and approaches to managing shortages and I'm just going to -- this the only document I'm actually going to read out in full but I am

going to read this document out in full because it is useful for this very purpose throughout.

So it's not for publication, "Advisory Committee on the [NBTS] Service, Blood Shortages", that's the heading:

"Background

"Reports have been reaching the Department over the past few months, and from a variety of sources, that regular blood donors are not attending sessions in the usual numbers. In the London area in particular this has resulted in shortages in blood supply, and on two separate occasions recently the shortage of Group O has reached critical levels. On the first occasion no other Region was able to offer help and London RDOs had to resort to publicity in the London 'Evening Standard' and via Capital Radio etc; this publicity found its way into other daily papers also. One London hospital cancelled elective surgery as a result of the shortages.

"On the second occasion London Regions accepted an offer from the Daily Express to run a front page article, and Mr Dawson, RDO at Brentwood, appeared on the 'Jimmy Young Show' on BBC Radio 2 to promote the same message via that medium.

"Blood Handling Charges.

"The Department received a number of letters of

complaint about the introduction of Blood Handling Charges, and letters to provincial newspapers reflect an equally critical reaction by donors. Some Directors and RDOs have fielded criticism locally by appearances on local radio etc.

"More recently there was adverse publicity connected with the imposition of blood handling charges for a hospice in South Western Region. A Dear Administrator Letter ... was issued on 31st October, drawing health authorities' attention to their discretionary powers to make [Section 64] grants. It is hoped that the DA letter will help diffuse this particular criticism."

Just to be clear, the perception on the part of the donors who were critical of this appears to have been, wrongly, that what these blood handling charges represented was a desire on the part of the Blood Services to make a profit out of the gift that had been made by the donors. That is not what was happening. It was more a question of accounting, as between services. But it's understandable that that false impression could have arisen in the circumstances.

"Other factors

"A decline in the number of industrial sessions, because of the economic recession, has exacerbated the situation; to a lesser extent so too has the adverse

publicity attracted by the recent Old Bailey convictions. The ever present problem of holiday absences of donors no doubt precipitated the recent crisis in London.

"Consultation on publicity

"There has been some criticism of London RTCs for having used national publicity to overcome local shortages. Unless carefully orchestrated, this can result in embarrassingly large numbers of donors turning up at sessions and having to be turned way. This too reached the Press and produced adverse comment.

"Such locally initiated publicity can also reduce the effectiveness of organised campaigns produced by the Publicity Subcommittee and could leave few practical options in the event of a national shortage of major proportions. Accordingly the matter will be discussed by the Subcommittee on the 7 November, and an oral report will be made to the Advisory Committee members at the meeting. The Subcommittee will consider the need for an enlarged publicity campaign.

"Members may have to consider what further steps might be taken to improve donor attendance."

So that minute shows the delicate balancing act that has to be made between too much publicity about shortages, which can result in unbalanced provision, but

the main point being identified is that there were shortages and that they had to be managed and prevented.

In the meeting itself, a 20 per cent uptick in demand was also attributed to cardiac surgery, and it was noted that media publicity required to restore London supplies had caused problems in the provinces. That's the same point again.

Secondly, on donor goodwill and the reluctance of donors to donate. This is relevant generally but also important as part of the understanding of the impact of non-specific testing. Donor perception of donation was an important feature of ensuring sufficiency. The example of 1984 is pertinent, as blood handling fees had an impact on donor attendance. In essence, donor perception of the meaning of blood handling fees undermined the goodwill of donors to donate.

Aside from blood handling fees, another example of donor perception was the persistent belief that donation could lead to infection with HIV. A study from Newcastle of 1991 of college, university and polytechnic students at three higher education institutions provides an example of this. In 1991, 20.9 per cent perceived a risk of acquiring HIV on giving a blood donation. The report concluded that these findings call for a new educational initiative to help safeguard the efficient

gathering and use of blood. That's NHSBT0015573.

Donor goodwill was and is built on donors' understanding, correct or mistaken, of the safety, ethics and probity of the donation process. Professor Tedder commented on this in his oral evidence on 14 October 2022 at 59/25 -- that's the reference in the transcript -- in the context of HCV testing, and the reference is INQY1000256:

"Well, everything is a balance of risk and benefit, and I don't in any way step back from the sadness that people may have been infected with HCV during that time. The introduction of a screening test, when you're uncertain of its specificity and its sensitivity, could do more harm. It could reduce -- it could reduce 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 services not to risk introducing something which could do more harm through rendering blood unavailable for use, rather than making people safer in the sense of removing people out of the donor panel that you don't want."

We comment on this from paragraph 5.20 in our written submissions.

It's important to recognise that a shortage of

donors due to a drop in goodwill is different in nature to one due to merely an increase in demand. When demand increases, this does nothing to dissuade donors from responding to calls for additional donations. Indeed, if anything, as we learnt last year it has the opposite effect.

When a drop in goodwill is the cause of the shortage, that is also a factor which dissuades donors from responding to calls for additional donations. If the drop in goodwill is large enough, say because donors are concerned about the unsubstantiated threat of being infected with HIV from a donation or indeed a false positive test for such a TTI on a donation, there is a real risk to there being sufficiency of supply -- there being a sufficiency of supply. Indeed, we submit the relationship between donor goodwill and specificity of testing is an important aspect of a decision to introduce a test.

To bring together these ideas in 1984/1985, it's useful finally to consider the answer to some Parliamentary Questions from 16 April 1985. This takes me to my second document, which is CBLA0000042. If we go through, please, to page 7 of that document, and this is questions in the House. At -- left-hand column under "Blood Donors (AIDS)", so --

SIR BRIAN LANGSTAFF: It's 00003, _00003. _057_00003, third page.

MR CORY-WRIGHT: I've got a different reference.

SIR BRIAN LANGSTAFF: It's not on the screen at the moment, what you're looking for.

MR CORY-WRIGHT: Yes.

SIR BRIAN LANGSTAFF: I think you're looking, are you, for a --

MR CORY-WRIGHT: I see --

SIR BRIAN LANGSTAFF: -- question by Sir --

MR CORY-WRIGHT: -- what's happened and the bit immediately above has been extracted. I'm very grateful.

"Mr Dubs asked the Secretary of State for Social Services what has been the change in the number of blood donors since the recent publicity about [AIDS]."

John Patten responds:

"Figures for recent months on the number of donations are not yet available. However, inquiries suggest that there has been some reduction in donations in the past few months. It is not possible to distinguish how much of this is due to publicity on AIDS and how much to other factors such as the bad weather experienced earlier this year.

"Our revised leaflet for blood donors concerning AIDS was of course deliberately designed to cause those

in the high risk groups to refrain from donation. I should like to take this opportunity to reassure all members of the public there is absolutely no risk of contracting AIDS through donating blood.

"Mr Dubs: Does the Minister agree that there is an acute shortage of blood for the transfusion services and that at least some of the shortage is caused by people's reluctance to go to blood transfusion centres for fear of being refused the chance to donate blood because of AIDS? Does the [honourable] Gentleman agree that he should take further action to encourage more people to give blood?

"Mr Patten: Preliminary figures show a drop in donations of 5 or 6 per cent in the first three months of this year. People should not be inhibited from donating blood, because there is no risk of contracting AIDS. All the equipment is sterile and it is all disposed of immediately after use; it is used once. We are spending £250,000 in the current financial year to encourage people to be blood donors.

"Mr Key: Does my [honourable] Friend agree that those of us who are blood donors have the responsibility to give a lead? Can he assure us that the HTLV 3 test, which is promised for July, is still on target, because that will give great hope to the regional blood

transfusion service authorities.

"Mr Patten: Yes, we hope to have a screening test within a few weeks."

That's all I wanted to take you to.

Shortages and their relevance to decision making continued in the 1990s. In 1998 and 2001 the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation noticed in the context of managing vCJD that proposed deferral of all those who had been transfused in the past would remove in the region of 15 per cent of donors. The 1998 paper said 15 to 17 per cent would be impacted, the 2001 paper said up to 14.5 per cent of donors. The reference there is NHSBT0008129.

Shortages also remain a concern today. In our written submissions at paragraph 5.42 we address the amber alert declared between 12 October and 8 November. Attached to Dr Miflin's statement are the current policy on red cell shortages and platelet shortages.

This is absolutely not to disregard or take weight away from the duty that the Blood Service has always owed to recipients. However, we add this to generally explained approaches to decision making in the Blood Service and because it's specifically relevant to the issue of the introduction of testing, to which we now

turn.

Many of the Core Participants have made submissions on the introduction of testing. We have written on this in detail in our submissions and we don't think it would be sensible to restate the detail of those submissions orally as well. However, we did think it would be useful to draw together some of the common threads as to what goes into a decision, whether in introduce a test or not. This is not with the intention of making submissions about whether steps taken historically were right or wrong. It is more fundamentally because it might be of assistance to restate how the Blood Service makes a testing decision, and also to provide an overview of this topic to those who may not have had an opportunity to review our closing in detail.

The decision to introduce the test has many factors, often in competition, and often uncertain. Fundamentally, however, the decision is one of ensuring that it produces a safe outcome for all recipients now and in the future. As a starting point, the transfusion of blood components is not, and is unlikely ever to be, risk free. Thus, of all the factors in the analysis, the safety of the individual recipient from a risk is of the most weight. NHSBT has had a longstanding responsibility, as we've said throughout, for the safety

and supply of blood, organs, stem cells and tissues. These responsibilities all relate back to the service's operational function and the need to maintain the reliability of the blood supply.

To do that, when introducing a test, the Blood Service must ensure that the supply is reliable through: safety in quality, that is it's free from TTIs; and safety in quantity, that is that there must be a sufficient supply; and that the recipient and donor impacts must be balanced.

Therefore, there is a multiple stage process which, is to be considered, prior to the introduction of a test. These include the following stages:

Step 1: determination of whether the virus or disease warrants a test. This decision might be whether to introduce generally or for specific diseases -- I'm so sorry -- or for specific classes of recipient. There are diseases, the Inquiry has heard, whose effect is so mild that it may not be necessary to test for them.

Step 2: whether a test exists.

Step 3: whether a test is sufficiently reliable for use. Crucial here is the issue of sensitivity and specificity, which I'll turn to in just a moment.

Step 4: whether a step can be scaled for high throughput, in other words, in respect of vCJD, brain

biopsy as a test was not viable for this reason.

Step 5: whether there is a confirmatory test.

Focusing on step 3, that's whether a test is sufficiently reliable for use, and sensitivity and specificity. 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 of a test is the extent to which the test correctly identifies those without a disease. This is known as the true negative rate. The sensitivity of a test operates as a function of the population of individuals truly positive for a disease. In other words, you compare it with the numbers of the population who are truly positive. So for a test that is 80 per cent sensitive, 10 per cent 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 per cent specific, 10 per cent of the entire population tested will receive false positives.

The proportion of false negatives or positives to true negatives or positives for a given test will depend on the underlying incidence of a disease in the population. And this is a crucial point which we do want to stress. The performance of a test in

a particular population is shown by the positive and negative predictive value of the test. This is a technically difficult area, and we go into it in slightly more detail -- much more detail, actually -- in our written submissions, and we didn't think it was sensible to try to go through it all in detail now, because it's there already and in writing and people can read it slowly and I won't mess it up, with any luck.

But in that section, paragraph 4.82 to 4.87, in that section we have addressed the idea of the positive predictive value -- that is the percentage chance that a positive test result correctly identifies an infected person -- and the negative predicted value, that is the percentage chance that a negative test result correctly identifies an uninfected person.

We commend that section to you, sir, because it's key to understanding the effectiveness of a screening test from our point of view. The key point, however, is this: generally, as the prevalence of a disease in a population increases, the likelihood that a positive result on a screening test is correct likewise increases. This means that the proportion of true positives increases when compared with false positives. Thus, for populations with low prevalence of a disease, the likelihood that a positive result on a test is

incorrect is higher.

That is the key point, because false positives are a proportion of the overall population. Thus the number of incorrect results is, as a starting point, much higher. In contrast, false negatives are a proportion of the infected population and thus, as a starting point, much lower. However, for completeness, it's worth recognising that, generally, as the prevalence of a disease in a population increases, the likelihood that a negative result on a screening test is incorrect increases.

In this way the underlying incidence of a disease is key to understanding the effectiveness of a test. Indeed, omitting to consider prevalence in the general population is often called the base rate fallacy. This is because a consideration without the prevalence in the general population fails to consider the positive and negative predictive values of a test. This is a key reason why a decision concerning the introduction of a test may vary between countries. Variance in base rate can significantly change the positive and negative predictive value of a test.

So, looking at specific situations, the explanation, is, we think, important in understanding one aspect of a decision to introduce a test. It also reflects why

it's important to assess a test generally. That is, to identify its sensitivity and specificity and any steps that can be taken to improve these by changing cut-off points on an assay, and, in the specific population, to ensure positive and negative predictive values are satisfactory, and to ensure that the test works in the field with low human error.

In our submission, these considerations are relevant to all of the decisions on testing that you, sir, have to consider over the decades.

Further, we would note the following: the paper on the assessment of the HIV test by PHLS is available at DHSC0000486, and the assessment by the blood services is at DHSC0001607.

For HCV screening the timeline is more confused but assessment of both first and second generation tests did occur. Examples of such assessments are available at NHBTS5073 and 0000 -- sorry, NHBT000044, although there are others on HCV tests. We would invite you, Sir Brian, to consider these in detail as we say they provide important analysis of whether tests generally and some specific models of tests produced by companies were appropriate to be introduced.

Overall decisions. And sir, I'm coming to the end of this section, and I will then be moving on to dealing

with the present, and that will, I hope, be after another minute or so. That will be a suitable moment for a break with your approval.

SIR BRIAN LANGSTAFF: Yes.

MR CORY-WRIGHT: Overall decisions. Sensitivity and specificity are important parts of a decision to introduce a test. They're key to ensuring the safety of the recipient. They're also key to ensuring the goodwill of donors, including their mental wellbeing. However, they were not the only factors that go to the decision whether to introduce a test. These are factors we address at sections 4 and 5 of our written submissions. But the establishment document for the NBA gives a good précis of some of the considerations involved derived from its statutory aims:

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

service.

These principles flow through the statutory underpinnings of NHSBT today. They are also factors which ministers, both historically and still today, take into account in making their decisions.

While we provide this to assist the Inquiry, Core Participants and the infected and affected in understanding testing decisions made by the Blood Service, we do wish to make clear the following: we do not row back from our position that the Blood Service should have introduced HCV testing earlier than it did and that the criticisms advanced toward Dr Lloyd at the time were incorrect. We apologise unreservedly for that.

That concludes the first half of my submissions, sir, and I have now to come onto the present position and recommendations, and I hope that's a convenient moment to pause.

SIR BRIAN LANGSTAFF: Yes. Well, we'll take a break until 11.50. 11.50.

(11.19 am)

(A short break)

(11.50 am)

SIR BRIAN LANGSTAFF: Yes.

MR CORY-WRIGHT: Thank you, sir.

So, having dealt with those few but important historical points, I now move to the present position: how things have changed and how things -- they are now.

It's particularly important to do this for perhaps obvious reasons, so that everyone is aware of the current position before we go on to consider what recommendations you, sir, might wish to make and what suggestions and submissions we make about them.

The NBA was established in 1993, when the Regional Transfusion Centres all came under its control in 1994. From that point, to today, the Blood Service in England has been a combined and centralised service.

I leave to one side just for a moment the question of the relationship with Wales, which is somewhat complex in terms of the history and how responsibilities have been allocated as between them.

But today, as NHSBT, it also has UK-wide control of transplant.

Many witnesses have provided evidence on aspects of all this. Most notably for the Blood Services, live evidence was given by: Professor Neuberger, on the Advisory Committee on the Safety of Blood, Tissues and Organs, that's SaBTO for short; Professor Mark Bellamy on the Serious Hazards of Transfusion, that's SHOT for short, and the haemovigilance scheme; and Professor

Derek Manas on transplant practice.

Critically, someone who gave extensive evidence on the current position but wasn't called to give oral evidence, so some may be unaware of her evidence, is Dr Gail Miflin, medical director of NHSBT, and Dr Miflin is here in this room today.

Given the importance of some of her evidence and its relevance to the present position, and therefore also to possible recommendations, as I've said, we think it is important to summarise some of it very briefly now. And obviously, if anyone wants to look more closely at these questions, they're all there in the written submissions. They're also all there in her witness statement.

The topics which I would like to look at now are -- there are four of them: decision making and the risk-based decision making framework; haemovigilance, horizon scanning; and recipient-directed focus.

Now, first of all, decision making and the risk-based decision making framework. I begin with how decision making within the Blood Service has changed to the way it is today. It is addressed in Dr Miflin's statement and in our suggestions for recommendations. We draw attention to the Alliance of Blood Operators' -- that's ABO for short -- risk-based decision making framework.

The ABO is a network of over 90 blood operators from North America, Europe and Australia. It aims to be a high performing international collaboration of blood operators which drives local performance improvement, knowledge exchange, and resolution of global strategic issues for the benefit of patients and health systems served by its members. The membership includes the American Red Cross, the Australian Red Cross, Lifeblood, the Canadian Blood Services, and NHSBT.

A useful explanation of this framework for blood safety is given in a minute to the NHSBT board attached to Dr Miflin's statement. This document was produced by Dr Williamson, from whom the Inquiry heard, recommending the framework to the board.

This is at document WITN0672100, and it's the next document I'm asking Lawrence kindly to put up on the screen. It's only five pages and I'm going to be looking at only -- well, actually, only four of them. Four of them, but only very briefly.

This is a minute for a board meeting in 2015, November 26, 2015, prepared by Dr Williamson, and it's headed "A risk-based decision making framework for blood safety". And I'm going to read out the first paragraph because it summarises it -- it does what it says on the tin, a summary:

"The ... (ABO) has developed a new framework for decision making on blood safety issues, which was approved by the ABO Chief Executives in spring 2015. A web-based tool to enable use of the framework is now available. This contains all the elements within our current safety framework, being suitable for both implementation and removal of safety steps. It places more emphasis on stakeholder engagement and links better with overall risk assessment processes, and therefore offices improvements to the current framework.

"If approved, its first 'live' use will be in the platelet bacterial screening/pathogen inactivation project. Once we have experience with its use for blood safety decision, we will also wish to assess its suitability for decision taking on organ safety.

"JPAC will also consider this framework for suitability, as well as SaBTO, which plans to review the current framework in 2016."

If we then go down the page to "Background" please, 5.1:

"Blood transfusions in the 1980s and 1990 resulted in many transmissions of HIV and hepatitis C. These had profound impacts, not only on affected patients, but on public and government confidence in blood services internationally. Public inquiries were held in several

countries, and blood services reorganised to provide more central decision making and stronger links to government.

"In the 1990s/early 2000s, much more sensitive tests became available for blood screening, along with techniques for inactivation of viruses and bacteria in plasma and platelets. These advances led to a belief that blood could one day become a 'zero risk' product, and led to adoption of safety steps with very low cost-effectiveness compared to other parts of healthcare.

"5.3. In 2010, the Canadian Blood Services (CBS) held an international Consensus Conference on Risk-Based Decision Making ..."

And that's the start date for the development of this framework.

If we go down to 5.6, describing the framework, which as you'll see at 5.5 is actually 80 pages long:

"The objective of such a framework is to provide Blood Services with a structured, rigorous process by which decisions affecting blood safety can be taken. This is considered to be important in achieving transparency, consistency between decisions, involvement of stakeholders, and evidence for regulators, government and, if appropriate, suppliers. Although different

jurisdictions may reach different decisions on the same issue, a consistent framework across countries will add weight to its validity.

"The framework is designed to operate in situations of incomplete evidence, and a 'small-scale' assessment process is included for low impact decisions."

Then the "Proposal for its use by NHSBT" is section 6. If we go over the page to 6.4, please, Lawrence, page 3, "Risk management principles". That's the focus I want to try to achieve for now:

"Our corporate risk management processes do not currently define underlying principles. However, the suggested principles of beneficence, fairness, transparency, consultation, practicality, proportionality, vigilance and continuous improvement underpin much of our activities already, and are expressed in various strategies and assurance documents.

"6.5 Risk communication and stakeholder participation. We have a strong programme of stakeholder engagement and good processes for consultation on service reconfigurations. It is recommended that each project involving a safety decision produces at its outset a plan for stakeholder engagement. This is lacking in the current safety framework.

"Assessment principles. The proposed principles underpinning safety assessments are sensible: assessments should be proportional to the risk, timely, based on as good quality of evidence as possible, document any uncertainties, be transparent and appropriately confidential. Care should be taken to integrate assessments with other safety decisions with which there are cross-impacts.

"Risk tolerability. This is defined in our risk management processes using the standard 5 x 5 matrix of probability versus impact."

Then over the page at 4:

"Points for consideration.

"It should be noted that the framework is not a 'black box' which automatically generates a clear answer from a series of inputs. Blood safety decision-making will continue to require considerable internal and external discussion, involving judgement in terms of proportionality.

"It is recognised that major recommendations/decisions on blood safety are taken by SaBTO/health ministers, and I have presented this framework to members of the DH Blood Policy Team and the Health Protection Analytical Team. The SaBTO framework is due for renewal in 2016."

Now, I'm going to leave that document there but I am going to come back to a couple of pages within the framework itself when we deal with recommendations, because it's important to see the extent to which what we in the Inquiry, all of us, have been aware of as the precautionary principle -- which can mean a number of different things to different people, but leave that aside for a moment -- is itself enshrined within this risk management policy.

So what that framework does is to make systematic the identification of relevant risks and the exclusion of irrelevant risks; provides for an approach to engagement and identification of stakeholders; provides a toolkit of principles to be applied, including the precautionary principle to which we'll come, as I say. It's not a black box from which decisions emanate, rather it is, as it says on the tin, an internationally recognised structure for decision making.

The full framework, if anyone wants to look at it, is on RLIT0001989.

The second topic is haemovigilance. Haemovigilance is, of course, a topic referred to in evidence, recommendations are also made by many of the Core Participants on this in their submissions. The Inquiry has documents on the history of haemovigilance in the

UK, also from the documents, from the Council of Europe and the SHOT steering group. We can map how the haemovigilance was also developing across Europe in the 1990s in response to the events focused on by this Inquiry.

Certainly, in our submission, a big positive step towards establishing SHOT was, as we say, the establishing of the NBA. Similarly, the mandatory haemovigilance scheme in France arose around the time that its new national agency was established. Certainly, sir, you'll be able to look at how the idea of haemovigilance developed in the early 1990s and became a number of the schemes that we can see around the world today. In these circumstances, whether a defined haemovigilance scheme was a realistic prospect prior to the early 1990s and should have been advanced by the Blood Service in the UK, as some have suggested, is, we would submit, doubtful.

Considering SHOT itself, the first steering group was held on 21 December 1994. SHOT was launched in November 1996, with the first report being for the 1996-1997 year. Both Professor Bellamy and Dr Miflin commented on the SHOT scheme in their written statements, with Professor Bellamy also giving oral evidence to the Inquiry about it. A key function of the

SHOT scheme is to record the wide range of transfusion hazards which present, including newly identified TTIs.

It might assist briefly to go to the most recent 2021 report, which is at SHOT0000032. The first -- again, there's the tin, and that's what it is. It's the "Annual SHOT Report" for 2021. If we go to the next page, please, Lawrence.

Now, this -- I'm sorry -- and I say the next page, it's the next page in my file but of course it's page 9 of this document, because I've only got the ones I'm referring to. My apologies.

So this is a page that was referred to by Professor Bellamy, one of the questions that has been raised by Core Participants in their submissions was the extent to which there was cross-reporting between haemovigilance schemes, et cetera, and this is a helpful diagram showing the reporting relationship between SHOT and the MHRA. There is a combined reporting scheme.

If we then go forward to page 15, please, Lawrence.

Now, it's the first paragraph on this page that I wanted to draw attention to. This is "Key SHOT messages":

"Transfusion in the UK continues to be safe and SHOT data for the last 10 years show the risk of death from transfusion as 0.92 per 100,000 components issued. This

includes all deaths reported with imputabilities ranging from possible, probable or confirmed."

What that shows, therefore, if my mathematics is correct, and I hope it is, is that the risk of death in relation to all transfusion risks over the course of that 10-year period is 0.00092 per cent.

One then goes, Lawrence, please, to page 21. Thank you.

Now, because these charts are in black and white, not colour, it's slightly less easy to navigate one's way around them but I'm going to give it a go.

These show the summary data for the top -- the top chart is for the last year. The lower chart is for the period since SHOT commenced. So it's a cumulative chart. And it shows a whole series of different things, near misses, et cetera, et cetera, et cetera.

The particular thing I wanted to draw attention to, for reassurance really, is the extent of TTIs (transfusion-transmitted infections) which appears -- it's the third last on the top chart and it's nought. So in the last year there have been no reported examples of TTIs. That's not just deaths, that's no reported examples of TTIs there.

And the second chart, the equivalent is the third one down, this is reports since SHOT started, so in

1994, '95, '96, and we see the third one down, "TTI: Transfusion-transmitted infection", and the figure -- I haven't got my ruler out, but my guess is that that looks like around somewhere between 100 and 150 in the whole of that period.

That is cumulative data for SHOT categories -- sorry -- I think I gave the wrong date just a moment ago, 1996 to 2021. So that's a 5-year period there.

We would also note --

SIR BRIAN LANGSTAFF: Sorry, what's a 5-year period?

MR CORY-WRIGHT: I'm so sorry. I knew I shouldn't go off my track. It's not a five-year period; it's a 20 --

SIR BRIAN LANGSTAFF: Five?

MR CORY-WRIGHT: Yes, thank you. 26-year period, I think, 1996 to 2021, 25 years. Absolutely right.

SIR BRIAN LANGSTAFF: If we just go back to the previous page that you had up, I was puzzling to myself why the last three items on the list were ordered as they are, why it is that TTIs are first, which might suggest they were regarded as a potentially greater risk. The answer might be perhaps on the next page, if you go back, that compared with PTP, post-transfusion purpura, it's a greater --

MR CORY-WRIGHT: They had been greater in the past --

SIR BRIAN LANGSTAFF: -- incidence. So potentially it's

a bigger risk but it's still of a low incidence in the year leading up to the report in 2021.

MR CORY-WRIGHT: Yes.

SIR BRIAN LANGSTAFF: Thank you.

MR CORY-WRIGHT: Thank you. I shouldn't have said anything about my mathematics earlier on. But anyway apologies for that.

What this report demonstrates is the combined approach to reporting between SHOT and SABRE, which is the Serious Adverse Blood Reactions and Events body that's referred to on page 9, and we've looked at the data for '21 and cumulative.

It's important, we respectfully suggest, sir, that these data are borne in mind when you consider the extent to which recommendations may be necessary that might change the way this operates. But I'll come back to that in a moment.

There's much evidence in Dr Miflin's statement. NHSBT has processes broader than SHOT reporting alone and we draw your attention to the management process description for serious incident management, among other documents, at WITN0672074.

That paper also provides important information about NHSBT's approach to the duty of candour, which is a crucial aspect to any response to a serious incident.

Now I turn to horizon scanning. Forward-looking scanning, identification of upcoming risks, is an important part of the Blood Service's roles. It's key in JPAC. You may have heard that acronym before. Just to be clear, what it's short for is Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee. So it's a useful acronym because it saves a lot of time.

The key high policy documents provided in Dr Miflin's statement are the JPAC position statement, arrangements in place for monitoring threats to the UK blood supply from new emerging infectious agents -- that's at WITN0672141 -- and the JPAC management process description on preparedness for emerging infectious agents. That's at WITN0672070.

The approach is a joined-up one which takes information monthly from the NHSBT, PHE (Public Health England) epidemiology unit emerging infectious agents report and other sources from the EU rapid alert system.

There is then an assessment of emerging risks undertaken by the Joint UK Blood Transfusion Service -- JPAC, and its Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI).

Once a recommendation is agreed through JPAC, these issues are taken through to the individual blood

services.

In respect of horizon scanning, you may also be assisted by a further document attached to Dr Miflin's statement. In August 2021 the Government Internal Audit Agency produced a report on NHSBT, on blood safety and detecting emerging infections. That report makes a recommendation in respect of the current approach of the Blood Service concerning formal processes to review the effectiveness and efficiency of the horizon scanning process. However, the overall conclusion reached by the report was that there was a finding that substantial assurance that the framework of governance, risk management and control in respect of detecting emerging infections is adequate and effective.

This document is provided, reference WITN0672071.

Finally, the question of recipient focus. That is, focus by NHSBT on recipients as opposed simply to donors.

We've already addressed above the point that recipient involvement is a key part of the decision making by the Blood Service. The ABO framework provides for such key stakeholder involvement in decision making, which is something that was recently undertaken in NHSBT's work on the FAIR initiative: for the individualised assessment of risk initiative concerning

a more individualised approach to donor selection and you may recall the FAIR initiative was touched upon a little by Ms Maharaj in her closing statement on Friday.

However, recipients also have an important place in some of the structural aspects of the Blood Service. Particularly pertinent is the NHSBT Therapeutic Product Safety Group, one of a large number of groups which reports to NHSBT CARE Committee, upon which I'll comment in a moment.

The role of the NHSBT Therapeutic Product Safety Group is important because of its key position on patient safety, and it's useful to consider the first page of the terms of reference in full, and that's at WITN0672102.

Here we have the terms of reference for NHSBT Therapeutic Product Safety Group:

"Aims of the TPSG

"To ensure that NHSBT is coherently engaged in the developing safety agenda within and beyond NHSBT; including 1) shaping the safety agendas of external bodies (eg SaBTO and JPAC); 2) responding to emerging threats to safety; 3) providing advice to CARE and external stakeholders on safety matters; 4) communicating safety matters to stakeholders and the

public; 5) proactively seeking and considering safety measures relevant to NHSBT."

And the "Remit of TPSG":

"The remit of the Group is limited to products manufactured by NHSBT (blood components, stem cells and tissues). It includes the safety of the donor only where this could impact upon patient safety; donor safety is a specific responsibility of the CARE groups and the clinical governance arrangements in blood, tissue and stem cell donation.

So the point about that is that this group is specifically focused on patient safety, and is not concerned with donor safety except to the extent that donor safety itself is something that impacts upon patient safety.

And the group reports to CARE. As we see from the bottom of the page:

"Accountability

"The group is accountable to the NHSBT CARE committee ...

"The group will meet two monthly in advance of the NHSBT CARE committee."

If you go over the page, you see the membership, medical and research director, that's Dr Miflin.

These terms of reference are important and, we say,

speak for themselves but they do however prompt a point worth repeating. Products manufactured by NHSBT here is directed to blood components, stem cells and tissues. As has been repeated many times during this Inquiry, sir, the role of the Blood Service has been distinct in respect of blood product, on the one hand, and blood components, on the other. Indeed, with the advent of recombinant products, this distinction is more acute as many products are no longer derived from blood. This is not expressed to excuse, but merely to flag once again how this distinction can be relevant to recommendations, for example, the fact that, broadly speaking, NHSBT is self-sufficient in components.

The TPSG reports to NHSBT Clinical Audit Risk and Effectiveness Committee -- that's CARE, we've dealt with that -- and NHSBT recognise the setting out of the terms of reference is not determinative of the conduct of an institution. Some of that current conduct is addressed through Dr Miflin's statement, in those sections addressing the current position. However, we do say that these committees play an important role in ensuring the safety of recipients and ensuring that recipients are in the core of any decision making on clinical audit, risk and effectiveness.

Now, sir, I turn to the question of your

recommendations, what suggestions we make for those recommendations and any comments we have on the recommendations suggested by others.

Having considered some of the current work of NHSBT and the bodies associated with it we now turn to recommendations. But we begin by thanking all the Core Participants for their recommendations in respect of -- insofar as they concern the Blood Service. These have been read and considered by Dr Miflin and others within the service. This process provides a valuable opportunity for the Blood Service to continue to improve and meet its core aims.

As I say, I'm going to start by the recommendations suggested by NHSBT itself. That was, of course, as part of the process -- we started this in May or June last year when we put in interim submissions on this and those interim submissions were then swept up into our written submissions that we provided back in December.

Now, some of these recommendations, which I'm going to read out, I'm not going to add very much more to but I think it's important publicly to state what it is that we suggest the recommendations might be.

The first relates to risk-based decision making. We've been talking about that just now in the context of the ABO framework. The suggested recommendation is

this: that the approach to blood safety policy making in the UK by those concerned with blood policy is based on the 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 ABO, 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 UK Blood Services. That body should advise the UK Governments which will make the ultimate decision on risk tolerability.

This suggestion broadly reflects current practice in the involvement of SaBTO as an independent advisory body which applies the ABO framework referred to earlier and gives advice to ministers who then make final decisions.

As we've already stated, the ABO framework is an internationally recognised framework used across the globe. The risk -- this framework includes many principles which are relevant to decisions, one such principle, which has been an important part of the evidence in the Inquiry is the precautionary principle and the proper approach to unknown or poorly defined risk.

The ABO framework deals with this at two important

sections, and could we go Lawrence, please, to RLIT0001989. Now, I've already said that this document -- there's the front page -- is 80 pages long and I'm only going to be referring to two of those pages but, of course, anyone who wants to examine this framework in more detail can do so by reference to the reference I've just given.

So if we could possibly go first to page 44, please, Lawrence, thank you, "Guiding Principles".

I don't want to read through all of these, but the principles are -- I should say, this section, just to be absolutely clear, is headed "Chapter 7, Health, Economics and Outcomes Assessment", and the "Guiding Principles" are in accordance with that heading. So number 1:

"Health economic analysis is not static ...

"2. Societal perspective ..."

Over the page to 45:

"3.context ...

"4. Transparency and best practice ...

"5. Estimation ...

"6. Precaution ..."

This is what's said at this stage about precaution:

"While precaution remains a strong force in blood safety, health economic analyses support concepts of

proportionality and consideration of the impact of actions to reduce risk and increase overall safety because of the presence of a wide diversity of risks."

If we then go over to page 49, please -- I'm sorry, perhaps we should go to 48 first, which I -- thank you.

So as part of step number 3, "Conduct the analysis", remember this is a systematic slightly mechanistic approach to ensure consistency across decision-makers. This is conducting the analysis. So this is the heart of the process and, over the page, under "Considerations":

"Models are simplified representations of a broad range of possible outcomes. The best model for a given question should be only as complex as is necessary to answer the question it was designed to address. Overly complex models are difficult to work with and even more difficult to find appropriate data for entering into the model."

So that is advice about the way to undertake this analysis. But the important bit is by the magnifying glass or whatever it is, immediately below that in italics:

"The use of these techniques can lead to insights that may support precaution. In situations where uncertainty is very high, it may be appropriate to adopt

an intervention that favours precaution rather than a proportional intervention."

Now, that is the precautionary principle in practice. Where you are uncertain about some aspect of a proposed decision or step that you might take, or something of that sort, and that uncertainty carries with it risks which you don't know the extent of, then you should apply a precautionary approach to it as opposed to what's referred to here as simply a proportional intervention.

That is the precautionary principle in practice, and that's embedded within this framework.

The position remains, as stated before, that the framework is not a black box into which information is put and an answer provided. Decisions in respect of risk tolerability, cost effectiveness and the whole range of other relevant considerations are all taken into account.

Thus, on the setting of risk tolerability and what represents the lowest practical level of risk, NHSBT's submission is that an expert body with remit to advise ministers is appropriate. That role is currently fulfilled by SaBTO and thus NHSBT suggests any recommendations maintain that body as the appropriate body to advise ministers and blood services as

appropriate on these issues. The evidence of Professor Neuberger is -- I'm sorry, he was Neuberger, in fact, thank you -- is particularly important in understanding how SaBTO is properly placed to undertake that role and his evidence is commended to the Inquiry.

The framework is an important document. We are aware that the Inquiry may feel it does not have all the information it requires on it. For one reason or another we're not entirely sure about, we're not certain that the full framework document got onto the Inquiry system in the way we thought it had when we submitted Dr Miflin's statement. There was a link that went with it and the link may not have worked, we don't know. But the point I'm making now is, quite simply, that NHSBT would be happy to respond to further Rule 9 requests if that seems appropriate in relation to this framework.

We also submit that for major recommendations, SaBTO, which applies the framework and then provides recommendation to ministers, may be helpful as well.

The second recommendation concerns future look-back. An independent expert body advised the UK Governments on whether a look-back exercise should be undertaken across the UK in respect of a transfusion transmitted infection. That an independent expert body advised on the appropriate approach to look-back exercise, such

advice would be specifically helpful in the context of large national look-back, as opposed to a small specific patient related look-back. In such cases, the principles to govern the approach to look-back, including issues such as when donors no longer attend blood services, look-back beyond the donations where samples are kept identifying the roles and responsibilities of parties involved would be helpful.

As a starting point, the current policies on look-back are provided for in Dr Miflin's statement at WITN0672126 and WITN0672132. As Professor Neuberger also explained, the issue of look-back is something which has been before SaBTO and is currently being considered by a working party led by Dr Sue Brailsford, who is also in the room today.

As with our last recommendation, concerning the ABO framework, NHSBT is of the view that SaBTO is the appropriate expert body with experience of this field to be able to make meaningfully forward-looking recommendations on future look-back.

It is important to recognise, particularly in respect of new or emerging diseases, that look-back may well take a different form dependent on the specific characteristics of the disease. That's important in recognising the role of the expert body to advise

prospectively, considering the importance of the context of any new disease.

The third suggestion for recommendation is consent to transfusion, and the recommendation that we suggest is that patients receiving blood transfusions are properly consented in compliance with NICE, SaBTO and professional regulator guidelines.

As a starting point, NICE, SaBTO and professional regulators each represent a different but important source of guidelines on ensuring proper consenting as part of the transfusion process. Professor Murphy noted in his written evidence that there is no shortage of guidance on this issue. The problem is with its implementation. There is still much work to be done to achieve proper implementation of guidelines.

The 2021 national comparative audit of NICE Quality Standard, QS138, demonstrated that only 64 per cent of transfused patients had evidence of receiving written or verbal information about risks, benefits and alternatives to transfusion.

Professor Murphy pointed to two tools which might drive further improvements to implementation. First, the Commissioning for Quality and Innovation -- that's CQUIN -- patient framework which provide a financial incentive to hospitals to provide a certain standard of

care, and, second, an electronic alert system which provides a prompt when a prescription of blood is made to secure compliance. That's WITN7001001.

NHSBT is of the view that Professor Murphy's evidence is overall key in this area and commends it to the Inquiry. It's been recommended that NHSBT be given a role in ensuring consent for blood transfusion. By that, I mean it's been suggested as part of the suggested recommendations.

This may be freestanding or part of its obligation pursuant to NHSBT directions issued by the Secretary of State to promote the appropriate use of blood. In NHSBT's submission the appropriate use-off blood is an important part of NHSBT's role in transfusion expertise. It's centred on giving blood only when necessary and only to the extent necessary. On the other hand, the issue of consenting is broader matter based on regulatory guidelines, including GMC, *Good medical practice*.

NHSBT's submission is that clinicians must ensure they undertake consenting in line with their regulatory and ethical obligations and as imposed by their own professional bodies, including those mechanisms identified by Professor Murphy to progress consenting.

It's those bodies which have the appropriate

management, regulatory and ethical control positively to achieve positive change for patients. NHSBT has limited mechanisms through which to implement the kind of recommendations Professor Murphy suggests, thus placing this in the remit of NHSBT would not be an effective way to secure an improvement in proper consenting.

So the recommendations are good, Professor Murphy's suggestions are good suggestions but there's a limited amount that NHSBT itself can do about them, or some of them.

SHOT. The SHOT scheme, Serious Hazards of Transfusion. The suggested recommendation is that all NHS organisations have a mechanism in place for implementing recommendations of the SHOT reports and for monitoring such implementation.

The position about implementing recommendations is a complex one. Professor Bellamy gave evidence that reporting to SHOT is professionally mandated, thus, among other mechanisms, the regulatory framework operating around clinicians, ie good practice enforced by the GMC, acts to require such reporting. We submit that 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 that has an inbuilt monitoring framework. This must not absolve healthcare providers of a separate obligation to monitor the implementation of the recommendations.

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's a trade-off to be had", he said. Making recommendations professionally mandated strikes the right balance and it 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.

The next five recommendations, that's at 5, 6, 7, 8 and 9 -- I'm being really careful to get my maths right now -- are all based on a particular document, which I'd like to turn to now, this is a document called "Transfusion 2024", it was exhibited to Professor Murphy's witness statement. It's an important paper of which Dr Miflin is one of the authors and it's at WITN001031.

Thank you, Lawrence.

This, you'll be glad to hear, is the last document

to which I am going to be asking Lawrence to take you.

So just again, looking at it from the top. This is "A 5-year plan for clinical and laboratory transfusion in England". You'll see that Dr Miflin, Gail Miflin, is one of the authors. It's essentially an NHSBT supported document. It isn't -- it doesn't have the force of -- it isn't practically implemented in full but it is the plan that NHSBT wishes to see implemented.

This document is a summary of the full Transfusion 2024 document. As you'll see, it's an article about that document. Sorry I didn't make that clear.

The abstract says this:

"The Transfusion 2024 plan outlines key priorities for clinical and laboratory transfusion practice for safe patient care across the NHS for the next 5 years. It's based on the outcomes of a multi-professional symposium held in March 2019, organised by the [NBTC] and NHS Blood and Transplant ... attended and supported by Professor Keith Willet, Dame Sue Hill on behalf of NHS England and Improvement. This best practice guidance contained within this publication will facilitate the necessary change in pathway design to meet the transfusion challenges and pressures for the restoration of a cohesive, and functional healthcare system across the NHS following the COVID-19 pandemic."

So that's the context. What I want to take you to is the table that appears on page 2 and following. That's table 1, which covers the next three pages. I'm only actually going to take you to it over the first two of those pages. In short, this table sets out the Blood Service's own freestanding recommendations, which it adopts for the purposes of suggesting to Sir Brian what his recommendations might be.

As you see, "Table 1, Summary of transfusion 2024 recommendations", section A, "Patient blood management", and there are three items under that. Under 2:

"Resources to support clinical transfusion practice

"(a) Strengthen support within hospitals and NHSBT for clinical transfusion practice.

"(b) Develop and implement a national competency framework for transfusion practitioners.£

There's then a column that deals with how deliverable this is, and then importantly, we would submit, there is a column for "Key responsibility, other stakeholders", and who might be responsible for delivery, therefore.

These recommendations here are also developed in Dr Miflin's witness statement -- I'm sorry, these are the basis for the written submissions that we make about recommendations.

So then 3:

"Inclusion of transfusion in national patient quality and safety initiatives

"Aim to include where feasible transfusion data in national databases of diseases/outcomes for which transfusion is regularly used."

Then there's a section under "Transfusion laboratory safety", a section under "Laboratory staffing" over the page, and then, at the bottom of the page, a section under "Information technology": "Transfusion IT", "Vein-to-vein electronic tracking", and "Recommendations for further research and development".

Having looked at that, I'll briefly, therefore, refer to those recommendations as they appear in our written submissions that I've just referred to.

Staffing levels -- this is recommendation 5, relating to staffing levels in clinical haematology and laboratory areas within NHS Trusts. The suggested recommendation is that transfusion laboratories are staffed and resourced adequately to meet the requirements of their functions.

Just to make it clear, we're talking about hospital transfusion laboratories.

Recommendation 6: education of healthcare professionals in the field of transfusion medicine.

That people working in the NHS are adequately trained in transfusion and that accountability for this is defined.

Recommendation 7: transfusion and governance.

That NHS Trusts have appropriate structures in governance for delivering safe blood transfusion practice. These are originally defined in Health Service Circular 2002, No. 9, Better Blood Transfusion, but are now part of the work of NHS England National Blood Transfusion Committee, with further guidance contained in the document *Transfusion 2024*.

That's obviously the document to which I've been referring.

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.

In relation to that, we would note that this derives from *Transfusion 2024* and is in accordance with the NHS long-term plan. We ought to add one comment, though, on the question of vein-to-vein tracking:

Transfusion 2024 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 and blood components, together with one that allowed 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 the 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 were 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 complex timely audits.

Then, 9, the recommendation is -- this is monitoring outcomes for recipients of blood and blood components -- that a framework be established for recording outcomes for recipients of blood components, that these records be used by NHS bosses to improve transfusion practice, including by providing such information to haemovigilance bodies.

Having dealt with these recommendations arising out of *Transfusion 2024*, we make a brief comment on the

question of accountability and responsibility. For a framework of those things, which function successfully, it's key that the body invested with accountability and responsibility have the necessary powers and expertise properly to ensure implementation of rules and policy. Clearly, in some situations, this will be NHSBT. Indeed, of particular note is the ongoing role for NHSBT in collaborating with the National Blood Transfusion Committee to develop guidance and influence best practice and the role of NHSBT supporting clinical transfusion and patient blood management initiatives across the NHS.

Transfusion 2024 provides important guidance on the key responsibilities for the recommendations and stakeholders necessarily involved in taking actions forward. In considering your recommendations, sir, we would suggest that this document provides guiding context when you consider accountability and responsibility.

However, we would also flag the importance of any such recommendations being informed by the expertise and powers of bodies currently and whether as part of the recommendation the extension of powers should similarly be recommended.

Finally, the question of allocation of livers for

transplantation. The suggested recommendation is this: 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.

Our final recommendation was to suggest the affirmation of the principles and protocols currently applicable to the allocation of livers for transplantation. The Inquiry heard evidence on this from Professor Manas. In respect of those recipients infected as a result of infected blood and focusing on liver transplantation he explained the following in his oral evidence, and this was at INQY1000259.

"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 you 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."

In NHSBT's submission, the current approach to transplantation decisions for this class is the appropriate one. It's been made based on expert clinical knowledge. It's 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, we would respectfully suggest.

It's been suggested that the current framework omits to consider the curative element of liver transplantation and that this matter should be recognised as a positive in favour of the transplantation.

NHSBT's position is that this argument is difficult. While it may possibly be curative, there are significant risks associated with transplantation, including the ongoing need to suppress the immune system. We maintain the appropriate approach is that advanced by Professor Manas.

Insofar as you, sir, are of the view that the current framework does not properly consider the matter of the curative infect of liver transplantation, we

would suggest obtaining further evidence of competing benefits and risks of such an approach from Professor Manas or another appropriate specialist.

Finally on this, recommendations of others. I'm not going to deal with all the recommendations that have been suggested that have relevance to the Blood Services, but I'm going to deal with a few of them.

We've responded to a number of the recommendations already advanced by Core Participants. We hope that our views on our recommendations, including those in the written submissions, are of assistance. In addition, we hope that the current practice section of our written and oral submissions, along with the evidence particularly of Dr Miflin, is of some assistance in setting out how many of the recommendations are already met by the Blood Service. We do, however, comment on this small number of recommendations now.

We hope this doesn't in any way appear to detract from the recommendations we don't comment on. It's not our intention and instead we hope reflects the position we've already addressed.

First of all, quality of recordkeeping.

NHSBT agrees that inadequate recordkeeping has hampered look-back exercises and hampered the ability of the infected to understand the pathogens to which they

have been exposed and to seek justice and recompense. It has been a regulatory and legal requirement since 2005 to have full traceability, which clearly is important and beneficial.

However, many trusts still use the manual record, which are labour intensive. NHSBT is of the view that the best way to resolving this matter is to achieve the introduction of vein-to-vein software in trusts, as was already commented on in respect of recommendation 8. This would allow an integrated approach which would provide more benefit to patient safety, understanding and traceability than, for example, a separate registry of transfusions.

In respect of the proposed recommendation that blood, tissue and organs should never again be collected in prisons, borstals and other such correctional institutions, NHSBT agrees, and is of the view it would not do so.

A number of Core Participants have commented on the current position concerning self-sufficiency in England and Wales. In respect of blood components, which the core of NHSBT's role, we are self-sufficient.

Finally, as we noted at the beginning, we've heard loud and clear what Roanna Maharaj said in her submissions on behalf of the Thalassaemia Society on

Friday, which seemed to us to have a pertinence that went more widely than simply those whose interests she was formally representing. What she said -- and I'm going to read it all out if I may -- this part of it:

"I think that a recommendation should be given to the NHS Blood and Transplant, I think more people -- and donors for example -- I feel sometimes they don't understand the risks that they bring to the recipient. It is great to donate blood. I'm alive because of the blood I have received throughout my life. But I think when people donate blood they don't understand really that, while you are giving this great gift, we can't deal with any more health conditions because it is really difficult to deal with the one that we were born with.

"So I think there needs to be more emphasis on the communication to the general public, to donors, about how important it is to protect the recipients and to take that responsibility in filling out and answering correctly, honestly on the questionnaires, disclosing information. I do think there needs to be more emphasis on that and I don't think that the communications that I have been seeing is sufficient, and it is a worry to me every time I have a transfusion: am I going to be protected?"

Now, those of us sitting in the room when she said that -- I mean, it rang loud and clear as a concern which was emblematic of the concern of many infected and affected at this Inquiry, even though they weren't thalassemia sufferers or requiring regular or frequent transfusions of the sort that she was describing.

We've heard this. We understand the point. The issue of messaging to donors on the safety of blood and its impact on recipients is an important one. NHSBT will continue to consider how best to improve our messaging and communication with donors.

Before I come very briefly to my concluding remarks, there's one matter I want to raise on behalf of the Welsh Blood Service and, for this purpose, I'm speaking on their behalf and not just that of NHSBT.

I'm asked to say the following on their behalf: as traversed in the evidence received by the Inquiry, there's historically been no neat separation between the Blood Services in England and Wales for the periods the Inquiry has been considering. For much of it, the Welsh service was, in effect, operating as a region of the English service. The Welsh Blood Service has put in brief written submissions which endorse the submissions and recommendations advanced by NHSBT, and has therefore taken the decision not to add to those submissions in

closing, on the basis it endorses the position taken by NHSBT.

The Welsh Blood Service has also confirmed that, in collaboration with the other UK Blood Services through the Blood Services UK Forum, which is the vehicle for coordination and promotion of consistency and collaboration between UK services, it looks forward to reviewing and working on any recommendations made by the Inquiry.

I know, sir, that the motivation for asking us to say that was to ensure that no inadvertent offence was given by the fact that they weren't making oral submissions themselves.

Some concluding remarks on behalf of NHSBT, then.

We have set out in written submissions the impression that we have 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. Some of that has been expanded upon today. There are a small number of overarching conclusions that we do wish now finally to emphasise. We do so simply because they might otherwise remain unstated in the submissions heard by the Inquiry stated in this room.

We stress that nothing we say here is intended to

detract from what we've said already 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.

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, ie 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.

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 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 we take for granted today, with their duty to recipients and donors in their

minds.

It also wishes to pay tribute to those of its own staff, past and present, many of them very elderly, who responded to Rule 9 requests and, in many cases, gave evidence orally to the Inquiry.

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. Specifically, 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. That 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.

Thirdly, lessons learned. NHSBT hopes that the information it has provided to the Inquiry demonstrates the learning that has already been taken from these terrible events. 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 I've described, 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 further to improve the service that it provides.

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.

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. It seems so to us, we hope it was to everyone else.

Finally, we return to where we began. To the infected and affected, many of whom have suffered for decades without acknowledgement or recognition of what

happened to them. It's impossible to imagine the hurt and suffering caused and compounded by these events and the failures to respond to them. NHSBT repeats that it wishes to acknowledge 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.

Perhaps most importantly of all, and unequivocally and without caveat, 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.

Thank you, Sir Brian.

SIR BRIAN LANGSTAFF: Now, just a question, if I may. The predecessor of NHSBT, the National Blood Authority, was a party to the *A v NBA* case, which Mr Justice Burton decided. He made various findings of fact. One of the findings he did not have to make was by way of concession from NBA, as I understand it, that screening for HCV should, at the latest, have been introduced by the 1 April 1991. Your submissions on paper take a different and later date. Why?

MR CORY-WRIGHT: The simple answer -- and I hope this doesn't seem mean spirited in some way or to go against

what I've been saying all morning -- the simple answer is that we, looking at the evidence now, we don't accept that there was fault in going right the way back to that date; we take a later date. The fact that that concession was made, I think, in evidence doesn't necessarily mean that that is the correct answer and what we would say to you, sir, is that when you're examining this issue, it wouldn't be right for you simply to say "Well, that concession was made, then, that's an end to the matter". What you would need to do, we respectfully submit, is to look at all that evidence, and come to your own conclusion about it.

You've heard many, many submissions about that which are based on a range of factors, a range of bits of evidence, all we're saying is we would respectfully ask that you come to your own conclusion about it, rather than simply adopting it because it was adopted by Mr Justice Burton in that case.

SIR BRIAN LANGSTAFF: So if I haven't misread the judgment, it was a concession made by counsel, then instructed, that, be that as it may, you're not telling me there's anything specific that you had in mind, just the general considerations that you've made reference to.

MR CORY-WRIGHT: That, sir, and the factor relevant to that case, which is that, in order -- what was relevant in

terms of strict liability in that case was the nature of the cause of action for product liability, which did not itself depend upon fault. So it's -- again, this is the last thing I want to say last, if you see what I mean, but there are complexities from a strict liability point of view and in terms of the fault, which I think is what you're putting to me.

SIR BRIAN LANGSTAFF: Well, I'm simply putting to you the date at which he said it should have been introduced. Now, that, the judgment was saying, was an agreement or rather a concession formally made during the course of the hearing, no doubt looking at the evidence before him -- and of course the evidence was different from the evidence which there has been here -- as to the pros and cons of the situation in that context.

So in the context in which as you point out, fault was to be assumed on a certain basis, the date was as it was.

MR CORY-WRIGHT: May I speak to the organ grinders for a moment?

SIR BRIAN LANGSTAFF: Yes, of course. Of course.

MR CORY-WRIGHT: The answer to your question, sir, is -- sorry.

The answer to your question is there's nothing else now that I wish to draw to your attention in this

hearing room as a factor which would explain why that's all wrong and we're taking this position. We have set out our case on this in detail in the written submissions and there's a range of factors referred to in there and I would comment them to you, and that's all I can say.

SIR BRIAN LANGSTAFF: Well, thank you very much and thank you for your submissions.

Now, I think we have to hear from Ms Richards in a moment as to what is in store for us not tomorrow, but on Thursday.

MS RICHARDS: Yes. So we are no longer sitting tomorrow. I hope that's a message that everyone has received and for unavoidable reasons. So we will resume on Thursday at 10.00 when we hear, first of all, from Mr Johnston KC on behalf of the Scottish Government, and then a closing statement by Nicola Leahey, an unrepresented Core Participant.

Can I just invite people to keep an eye on the timetable and any updates because I have been informed by Mr Johnston in the course of this morning that he does not think he'll be in the whole morning. So it may be that we make some adjustments to the timetable, but it may not. But if people just keep an eye on the website in that regard. But we should be starting at

10.

SIR BRIAN LANGSTAFF: We were due to hear tomorrow from Ms Scolding KC on behalf of the Leigh Day clients -- Leigh Day cohort. That is now going to be heard next week.

MS RICHARDS: That's correct.

SIR BRIAN LANGSTAFF: And the date for that for those who might be interested?

MS RICHARDS: It's next Tuesday afternoon and then running on, if necessary, to ensure that she has the full time that was originally scheduled, into Wednesday morning.

SIR BRIAN LANGSTAFF: Very well. So, if you hadn't picked that up, there you have it. Thank you very much.

Until tomorrow -- Thursday, there you go -- Thursday at 10.00.

(1.06 pm)

(The hearing adjourned until Thursday at 10.00 am)

I N D E X

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