Friday, 27 January 2023

(10.00 am)

SIR BRIAN LANGSTAFF: Yes, Mr Aldworth.

Closing Statement by MR ALDWORTH KC

On behalf of the Belfast Health and Social Care Trust

MR ALDWORTH: Good morning, Sir Brian. Good morning, everyone. My name is Philip Aldworth and I appear with Mr Mark Robinson, who is behind me, on behalf of three Northern Ireland Core Participants.

They are, first of all, the Belfast Health and Social Care Trust, and for the most part I will simply refer to them as "the Trust". The second is the Northern Ireland Blood Transfusion Service, and the third is the Department of Health in Northern Ireland.

I will be dealing with the closing submissions on behalf of the Trust. Mr Robinson will deal with the closing submission on behalf of the Northern Ireland Blood Transfusion Service.

I will also read a short statement on behalf of the Department of Health in Northern Ireland, which sets out its position in relation to making a substantive submission to the Inquiry.

For those who may not be familiar with the organisational history and the structure of the Trust, I will give a very brief outline. I hope you will

forgive me if it is a little convoluted, but it is important that I am clear who the present Trust's predecessor bodies were, given their involvement in the provision of haemophilia care at various times relevant to the Inquiry.

The present trust came into existence in 2007. It represents the amalgamation of six former healthcare trusts. These trusts were created in the early 1990s. They included the Royal Group of Hospitals Trust, which administered the Royal Victoria Hospital. They also included the Belfast City Hospital Trust, which administered the Belfast City Hospital.

Prior to the establishment of these trusts, both the Royal Victoria Hospital and the Belfast City Hospital were administered by the Eastern Health and Social Services Board. The Eastern Health and Social Services Board was one of four health and social care boards that administered hospitals in Northern Ireland. So when I refer to "legacy organisations" the term includes the various bodies that I have just mentioned.

The Belfast Trust is currently responsible for the regional adult Haemophilia Comprehensive Care Centre, which I will shorten to "the Belfast Centre". It is located on the Belfast City Hospital site.

The Trust is also responsible for the paediatric

haemophilia clinic which is located in the Royal Hospital for Sick Children, known locally as the Children's Hospital. The Children's Hospital is on the Royal Victoria Hospital site. The adult haemophilia centre was located in the Royal Victoria Hospital until 2002, when it moved to its current location on the City Hospital site.

I would like, just briefly, to outline the scope of my submissions, sir. As with our written submissions, our oral submissions on behalf of the Trust and the Blood Transfusion Service are relatively brief. They are intended primarily to assist the Inquiry by giving further context and background to some of the issues considered by the Inquiry as they arose in Northern Ireland.

We will confine our submissions to aspects on which we hope we can make a useful contribution. The fact that we cover only a limited number of issues does not in any way indicate that the Trust considers other issues less important or not important. It is simply recognition of the extent to which we feel we can usefully contribute to the Inquiry's task of assessing evidence and making findings.

Stated shortly, our submissions today comprise five main elements. First and foremost, an apology.

Secondly, some reflections on evidence generally. Thirdly, some observations on historical issues at the Belfast Centre. Fourthly, present-day care at the Belfast Centre. And lastly, some very brief concluding remarks.

An apology.

Sir Brian, with your permission, I would like to speak directly to the infected and affected community, particularly those infected and affected in Northern Ireland. I want to read publicly a section of the Trust's written submission provided to the Inquiry in December 2022. The section reads as follows:

"The Inquiry has shone a light on aspects of patient care and patient experience that make uncomfortable reading and difficult listening for any healthcare provider. The Trust recognises the harm ... hurt and the distress that the contaminated blood tragedy has caused to the infected and affected community. It is a matter of deep regret that any of this should ever have happened. It has been stated already by other core participants' representatives that the tragedy should not have happened and that things should and could have been done differently. The Trust adopts those statements without qualification. The infected and affected community in Northern Ireland is entitled

to an apology. For the part played by it and by its legacy organisations, Belfast Health & Social Care Trust says to each and every one of that community - we are sorry. Some may feel that an apology is long overdue, but it is no less sincere because of the passage of time."

We are aware that the apology I have just read references wording used by Ms Grey, King's Counsel, for the Department of Health and Social Care. We are also aware that that wording was the subject of some comment. Having listened to the evidence given to the Inquiry, the Trust considers it is entirely appropriate at this juncture to accept that things went wrong and that things should and could have been done differently. However, the Trust considers that it should not pre-empt specific findings that the Inquiry may make.

That said, in offering the apology I have just read, the Trust takes full account of the evidence the Inquiry has received from the infected and affected community in Northern Ireland.

I turn now to some reflections on evidence. One of the Inquiry's tasks will be to provide a comprehensive and definitive factual narrative in relation to the infected blood tragedy. As part of that process, the Inquiry has obtained evidence from a wide range of

individuals and organisations. In his opening statement the trust's solicitor, Mr Alphy Magennis, gave a commitment to engage fully with the Inquiry.

The substantial volume of documentation and significant number of Rule 9 statements that the Trust has provided to the Inquiry over the last four years hopefully demonstrates that that commitment has been fully honoured.

The Rule 9 statements include those from former and present clinicians and from senior administrative staff from the Trust. Quite properly, the questions contained within the Rule 9 requests have included detailed and searching questions. Answering those questions has proved challenging for some of the recipients. Some of the clinicians in post during key periods are now advanced in years and have a range of health problems. It has been difficult for them to recollect events stretching back over 30, 40 or even 50 years with the detail and clarity that the Inquiry would wish, that you would wish, and indeed they would wish.

There are examples of responses that might be viewed as incomplete or vague or otherwise deficient or unsatisfactory. In our experience, such deficiencies are not due to lack of effort or want of trying. Fixing events within a specific time period or to a specific

point in time is just one example of situations in which witnesses have encountered particular difficulty.

It has been suggested on behalf of Core Participants, again quite properly, that problems of fading memory, age or infirmity, should not confer forensic advantage on clinicians. In our respectful submission, Sir Brian, it is not a matter of seeking forensic advantage. These have been real and significant problems for several of the former clinicians when dealing with Rule 9 requests. Answers that may appear deficient or answers that can be shown even to be demonstrably wrong are not necessarily attributable to a selective memory, to evasion or worse. Where allowances are made, it is for reasons of fairness not forensic advantage.

Moreover, that applies to all witnesses, not just a specific group. We have no doubt, sir, that you are and will be fully mindful of that reality when assessing the evidence presented and when making findings based on that evidence.

In our December 2022 written submission we touch upon what we describe as the potentially distorting effect of hindsight when assessing what was known or what ought to have been known 30, 40 or 50 years ago. We do not seek to overplay hindsight or to use it as

a convenient refuge from inconvenient facts. However, when evaluating decision making retrospectively, knowing the outcome does represent an advantage that those making decisions at the time did not have.

The jigsaw analogy has been used on various occasions during the Inquiry. Much of the focus, understandably, has been on the challenge of finding the pieces of the jigsaw. Another aspect of the analogy might be that, even if the pieces are available, the task of fitting them together is much more difficult without a picture of what they should look like once assembled.

We respectfully submit that at various key periods, although clinicians may have had some pieces of the jigsaw, they did not have the full picture of how those pieces fitted together. Whether and when they ought to have had sufficient information to enable them to realise what the full picture might look like is a matter we leave to the Inquiry.

Some observations on historical issues at the Belfast Centre, and I want to preface this section of my submissions by saying that these are intended as contextual observations. The first point I would like to address, sir, is the state of knowledge in relation to the risks associated with hepatitis. Clinicians in

Belfast were aware that hepatitis B could be transmitted by blood and blood products essentially from the outset. Hepatitis B was not common in Northern Ireland in the 1970s. This may be explained by low prevalence in the population at large and the screening of blood donors from 1972.

In the 1970s, clinicians in Belfast were also aware of non-A, non-B hepatitis and that it could be transmitted by blood and blood products. Liver function tests undertaken as part of routine blood tests indicated abnormal results in patients treated with factor concentrates. However, patients generally remained well.

During this period, clinicians in Belfast believed that non-A, non-B hepatitis was essentially a benign condition with no long-term consequences in the great majority of cases. This understanding of the apparently benign nature of non-A, non-B hepatitis was not limited to clinicians in Belfast. Simply by way of example, the Inquiry will recall the eighth edition of Professor Dame Sheila Sherlock's book, *Diseases of the Liver and Biliary System*, published in 1981, which stated:

"Non-A, non-B hepatitis often progresses to a mild/chronic hepatitis. The prognosis of this is at the moment uncertain but probably benign."

Just for the transcript, sir, the relevant reference is WITN4032023, at page 259.

The Inquiry has considered in detail papers and research that appeared from the late 1970s and early 1980s indicating that non-A, non-B hepatitis was not, as had been widely believed, a benign condition, but which was one which would have very serious long-term consequences.

In our respectful submission, it would have taken time for the belief that non-A, non-B hepatitis was a benign condition to be displaced, especially at a time before the Internet, when the exchange of information and sharing of knowledge took place at a much slower pace than it does today. Mr Cory-Wright covered this point in his closing submissions on Tuesday, and we respectfully adopt what he said in that regard.

However, the further one gets into the 1980s, we accept the more difficult it is to resist the conclusion that the serious nature of non-A, non-B hepatitis was known or ought to have been known by clinicians. The point we would make is that general recognition that non-A, non-B hepatitis was a serious condition represented a significant change in the state of knowledge and, like many significant changes, it took place over a period of years.

It is against that background of significant and evolving change that evidence of deficiencies or failures to provide patients with information about the risks of non-A, non-B hepatitis has to be considered. We submit genuine uncertainty and lack of full understanding of the condition were major factors in the approach taken by clinicians. Another factor which may also have contributed to the situation was a well-intentioned, albeit misguided, desire to avoid causing patients distress and anxiety in relation to risks about which there was much uncertainty.

That, of course, raises questions about clinical practice in the past, and paternalism. Suffice to say there are multiple factors in play when considering the issue of provision of information to patients about the risks of non-A, non-B hepatitis.

HIV and AIDS. The Inquiry has looked in detail at how the state of knowledge in relation to AIDS developed from reports of opportunistic infections in the United States in 1981 and 1982 to increasing evidence during 1983 that it was probably caused by an infectious agent transmissible by blood and blood products. The Inquiry has also looked in detail at the response of the UKHCDO and Government, including their assessment of the risk that AIDS posed to recipients of blood products.

The Inquiry is familiar with the HCDO guidance issued in June 1983. This included advice that there was insufficient evidence to warrant restricting the use of imported concentrates in view "of the immense benefits of therapy".

The one qualification was that the supply of NHS concentrates should be retained for children and mildly affected patients. That remained HCDO guidance until December 1984, when heat-treated products first became available in -- I think it was the -- PFC first introduced the heat-treated products at that time.

The June 1983 guidance has been subject to close scrutiny by the Inquiry and no doubt it will be addressed in your findings, sir. In Belfast, Dr Mayne followed the HCDO guidance and it appears to have influenced her treatment policy to a significant degree. Although the amount of NHS concentrate used in Belfast increased markedly after 1983, following the agreement with PFC to fractionate Northern Ireland plasma -- and I'll say more about that in a moment -- the annual returns indicate that significant amounts of commercial concentrate continued to be used.

One factor contributing to the amount of commercial concentrate used appears to have been the number of patients with inhibitors. Northern Ireland appears to

have had a relatively high number of such patients. The returns show examples of various commercial products such as porcine Factor VIII being used to treat patients with inhibitors.

Against that background, it is, however, worth noting that Northern Ireland had proportionately fewer patients treated with factor concentrates who seroconverted with HIV compared to other parts of the United Kingdom.

In Northern Ireland, 25 per cent of severely affected patients seroconverted compared against 59 per cent across the UK as a whole. As for all patients, the percentage in Northern Ireland was 16.5 per cent as opposed to 41 per cent across the UK as a whole.

I take those statistics, sir, from the article in the Ulster Medical Journal from April 1989 entitled *HIV Infection in Northern Ireland 1980-1989*, and the reference for the record is WITN3082020.

Supply of factor concentrates in Northern Ireland. Northern Ireland was able to produce its own cryoprecipitate from plasma collected locally. There is no evidence of any supply difficulties in relation to cryoprecipitate. The situation in relation to freeze-dried factor concentrates was very different.

Northern Ireland had no fractionation facility. This was never a realistic proposition because of geography, population and economies of scale. All factor concentrates, whether NHS or commercial, had to be sourced from outside.

Northern Ireland did not have access to NHS concentrates in the quantities required, and was of course in direct competition with Haemophilia Centres in England and Wales for a limited supply of concentrates. The annual returns until 1984 show small amounts of NHS concentrate from BPL and Oxford PFL, and occasionally some from Edinburgh PFC. It is estimated that this would have been in the region of 10 per cent of the total used during that period and, to a large extent, relied on goodwill of fractionators in England and Scotland.

That lack of NHS concentrate appears to have led to reliance on imported commercial concentrates. Use of commercial concentrates in the Belfast Centre became established at an early stage.

I mentioned Dr Mayne's policy of limiting patients to a single product so far as possible. The annual returns indicate that she was reasonably successful in maintaining that policy until the late 1970s. Subsequent annual returns indicate that she was unable

to adhere to that policy for all patients. It is not clear why this happened.

In 1982 the Department of Health in Northern Ireland and the Scottish Home and Health Department agreed an arrangement whereby plasma collected in Northern Ireland would be fractionated at PFC. In return, Northern Ireland would receive Scottish NHS concentrate on a pro rata basis. As I have stated, the HCDO returns show a marked increase in the use of Scottish NHS concentrate in Northern Ireland from 1984 onwards.

Stated shortly, Belfast's historical reliance on commercial concentrates prior to 1983 may well have shaped or influenced product selection to a significant degree.

In our written submission we say something about death certificates, and I believe this may have a particular resonance in Northern Ireland. We note that on death certificates of patients who died from HIV or HCV infections in the 1980s and 1990s as a result of infected blood products -- I beg your pardon, I would like to start that again.

We would make those observations, and we accept that recording of HIV or HCV on death certificates was avoided so far as possible. It was not uncommon for bereaved families to request that these conditions were

not included as a cause of death because of the stigma attaching to them. It is difficult at this distance and time to convey how much additional distress might be caused to a grieving family, were it to be known within their community that a loved one had died of HIV or HCV.

Northern Ireland is a small place. Communities tend to be close knit. In many instances, that is and was a positive feature of our society. Support networks are strong. The downside, however, can be maintaining privacy. In the 1980s and 1990s stigma sounding HIV and HCV was very real. Families could be ostracised with devastating consequences. To spare them the prospect of that additional pain and anguish, not mentioning HIV or HCV on a death certificate was, as Dr McNulty described it in her written statement, seen as an act of humanity to a grieving family. It was not done to conceal the fact that those conditions had been caused by infected blood or blood products.

And the reference for Dr McNulty's written statement is WITN0921001 at paragraph 3.19.

We also say something about patient records, and the provision of documentation generally. While there were some issues about the provision of patient records in the early stages of the Inquiry, these were largely overcome as staff became more familiar with the process

of searching for and retrieving historical records.

The Trust cannot and does not claim to have been able to produce every record. Some had been destroyed in accordance with retention and destruction policies in place at various times, including policies which were those of the legacy organisations. However, throughout the life of the Inquiry, the Trust has made determined efforts to locate and provide documents requested by the Inquiry and by individual members of the infected and affected community. For the most part, it has been successful.

The point we wish to highlight, sir, is that in undertaking that task, the Trust has not identified evidence of deliberate, wrongful destruction or alteration of patient records.

I now turn to present-day care at the Belfast Centre. In the Trust's June 2022 submissions, we focused mainly on the present and how the provision of care for inherited bleeding disorders had changed, particularly over the last ten years or so. The Trust took this approach for three reasons. First, to assist the Inquiry when considering recommendations by highlighting changes that had already been introduced. Secondly, to provide patients and families with reassurance and tangible evidence that the Trust is

committed to providing care that is focused on the needs of patients. And thirdly, to share with the Inquiry and other Core Participants some initiatives and ideas that may be of interest beyond Northern Ireland.

One thing the Trust is anxious to stress is that this approach should not be seen as indicating complacency. The Trust continues to listen and to learn, not least from the evidence that has been given to the Inquiry.

Details of the current position are set out in the June 2022 submission. I don't propose to rehearse them all. I would, however, like to mention, just by way of example, some of the developments in haemophilia care in Northern Ireland in recent years.

The first one is psychological support. And I think we can claim to have been at the forefront of providing psychological support in response to the Inquiry.

A dedicated clinical psychologist was appointed for the duration of the Inquiry. That post will continue beyond the life of the Inquiry. And the response of patients and of their families has been generally positive, so it does appear to be doing beneficial work to help patients and their families.

The second aspect which I would highlight is initiatives to reach out to patients. The Belfast

Centre has undertaken several of these initiatives directed towards patients who tend not to attend the routine clinics. The largest group of such patients are those with mild haemophilia. The Trust has used telephone contact and remote review, coupled with invitations to patients, to discuss how the Centre could assist them, and the focus has been the Centre is asking the patients how can they assist them, what could they do. And that is very much at the forefront of the thinking within the Centre at this time.

Another aspect of what might be described as reaching out is a satellite clinic. A satellite clinic operates at Altnagelvin Hospital. Every two months, the whole team, medical, nursing, physiotherapy, social work, occupational therapy, travel to the northwest to offer full multi-disciplinary clinical consultations for patients living in that area, which saves them a 70-mile trip in each direction in many instances, and again, seems to have been successful and well received.

The fourth point I would like to highlight is perhaps a more abstract point, but in some respects it might be the most important of all the points that I have highlighted, and it is putting good communication at the centre of patient care. At the Belfast Centre, good communication is seen as a core objective. Central

to good communication is information flowing in both directions; that is, staff to patients, and patients to staff.

The Inquiry will recall the evidence of Dr Benson, the current director of the Haemophilia Centre, and he described how staff actively encourage both formal and informal exchanges of information with patients. That exchange of information, that partnership, is embedded as the model of care at the Centre.

And building on that last point, if the Trust had to identify a single aspect at the core of lessons to be learnt from the evidence received by the Infected Blood Inquiry, it is that the provision of healthcare must be approached as a genuine partnership between patient and healthcare professional. Patient safety, patient autonomy, informed consent, provision of information, informed decision making about treatment -- all fall within that fundamental principle.

Indeed, that idea of partnership and exchange of information seems to resonate with some of what Ms Leahey said yesterday in her suggestions for recommendations.

I now, sir, come to my concluding remarks.

Earlier in these submissions I referred to the commitment to fully engage with the Inquiry given by the

Trust's solicitor in his opening statement. That commitment will not end with the publication of the Inquiry's findings and recommendations. On the contrary, the Trust will use the Inquiry's findings and recommendations to inform and shape the delivery of healthcare at the Belfast Haemophilia Centre, and the use of blood and blood products generally in the years ahead.

The Trust gives that commitment not only to the Inquiry, but to the infected and affected community in Northern Ireland who have suffered so much.

Thank you.

SIR BRIAN LANGSTAFF: Thank you very much.

There is one particular matter you can help me with which arises out of the way in which your written submissions have been written, and I want to understand properly what is being said.

It's paragraph 5.2. Let me read it out so that those who are here and listening can understand what is said as it appears on the page. This is talking about the growth of AIDS and the growing understanding, and what you say is this:

"From the end of 1982 there was growing concern that AIDS was caused by infectious agent that could be transmitted by blood. By the end of 1983, concern had

become wide acceptance. Looking back, the risk to people with haemophilia and other patient groups in receipt of blood or blood products seems clear."

Then you say this:

"Having regard to the evidence presented to the Inquiry it would be difficult to argue credibly that clinicians and government should and could have recognised sooner the implications for recipients of blood and blood products and, perhaps, more importantly, the seriousness of the risk."

You go on to describe a fundamental error which you say was made in the approach, which was to look at the number of reported cases and take that as an indication that the risk was small. Well, it plainly, had you analysed it properly, wasn't.

I just wonder about that sentence:

"Having regard to the evidence ... it would be difficult to argue credibly that clinicians and government should and could ..."

Is there a negative which is missing? That it "should and could" -- or to argue credibly that they shouldn't have recognised sooner or couldn't have recognised sooner?

MR ALDWORTH: Yes, clearly what I'm saying is, having had the benefit, sir, of the evidence, that by any standard,

it in our view it would be difficult to argue credibly that clinicians and government ought not to have identified the risk sooner. And that's why I go on to say that they seemed to miss the point that small numbers don't mean low risk.

SIR BRIAN LANGSTAFF: I thought that's what you were saying. As it reads, as you look at it, of course, when I first read it I thought, right, you're saying that there's no reason why they should have identified it, but actually you're saying the opposite?

MR ALDWORTH: Yes, and I'm sorry if that was not clearly expressed, sir.

SIR BRIAN LANGSTAFF: It will be -- it may be a matter of concern to those who read it just to understand the negative is missing. It's an easy mistake and I'm glad I think I -- I thought, when I finished your submissions, that plainly that must have been what you meant, which is why I raised it but I just wanted to make absolutely sure. So thank you for that.

The second point arises from what you were saying in respect of death certification, when you're saying it wasn't deliberately hiding the fact that people may have died of AIDS or hepatitis infection. Well, plainly it was deliberate. I think what you're indicating, as far as I've understood your submissions -- I want to make

sure this is right -- that it wasn't deliberately to cover up the behaviour of the clinicians or others in causing that situation to arise; it was to cover up the fact of the infection because of the social consequences that there might have been for the family concerned.

MR ALDWORTH: Absolutely, sir, and, in fact, you've obviously expressed it more clearly than I have. The point that we were alive to, or at least the Trust was alive to, is that there was a perception, was this done for the very purpose that you have alluded to? And we just wanted to make our position clear that we take the view that it was done simply out of the desire to assist grieving families, nothing more, nothing less.

SIR BRIAN LANGSTAFF: I mean you identify, in a sense, something which shouldn't have been done but it was done for good reason?

MR ALDWORTH: Exactly.

SIR BRIAN LANGSTAFF: Yes. I thought I'd understood that, but thank you for clarifying. Thank you very much.

MR ALDWORTH: Sir, I'm now going to hand over to Mr Robinson who is going to deal with the Blood Transfusion Service.

Closing statement by MR ROBINSON

On behalf of the Northern Ireland Blood Transfusion Service

MR ROBINSON: Good morning, Sir Brian. Good morning, everyone.

Sir Brian, I am grateful to you for the opportunity to make submissions on behalf of the Northern Ireland Blood Transfusion Service. At the outset, of these submissions the NIBTS wishes to apologise unreservedly for its part in any of the events that led to the terrible hurt and loss as evidenced before this Inquiry.

In the opening submissions, sir, in 2018, the NIBTS said it was conscious of the tragedies and the life-changing impacts that have resulted from the use of contaminated blood and blood products. And whether it was in person or on a video link, the evidence was heartbreaking, sir. It was clear that there was a burning agony of loss and suffering across many, many years, and that came across very clearly in the evidence before you.

The NIBTS acknowledges the courage, the fortitude, the dignity and decorum of the infected and affected, not only during the course of this Inquiry, but also in the many, many years waiting for the Inquiry.

The NIBTS welcomed the Inquiry in its opening submissions. It said that it recognised the entitlement of the infected and affected to know the truth as soon as possible and to have the facts established as soon as possible.

In assisting the Inquiry, the NIBTS has invested

significant resources and time to assist you, sir. It's been the unambiguous intention of the NIBTS to help you in any way possible.

This is your Inquiry, sir, your investigation, exploring decades of evidence and perhaps millions of pages. You have a team of investigators, you have a team of paralegals and of counsel to explore all of that and, as Mr Aldworth spoke about a jigsaw, you have the pieces and it's your function to put them into the right order.

The NIBTS has seen its function as doing everything it can to assist that process. So our submissions touch upon the engagement with the Inquiry but also set out, as part of the exercise of looking at recommendations, setting out the context within which the NIBTS currently operates. In doing so, we've explored some internal mechanisms and some external mechanisms, and also the way in which it constantly reviews its policies and procedures to improve what is, in effect, the safe delivery of a blood supply to Northern Ireland.

The reason they've engaged in such a manner is to demonstrate transparency and accountability, not simply to you, sir, but to the infected and affected and to the public at large.

Part of the NIBTS response has been provision of

Rule 9 responses, and Karin Jackson, the chief executive, provided a Rule 9 response dated 27 November 2018, and the reference is WITN2681001. That particular Rule 9 addressed the document retention policies and how they've evolved over time, and that Rule 9 response included some 24 exhibits and we believe some 800 pages of information.

The NIBTS met with your investigation team through its information and governance officer, Paula Johnston. Significant volumes of documents were produced as part of that exercise and to ensure absolutely everything that relevant to your exercise was provided, further extensive searches were conducted across the estate, off-site storage, hard drives, offices, to produce further tranches of information through from 2019 to 2022.

The NIBTS remains alert, sir, to any further requests, Rule 9s, questions, throughout the course of the remaining time of your Inquiry to assist you.

I mentioned earlier the aim of the submissions is to demonstrate the engagement but also the current environment within which the NIBTS operates. That is to present the clear picture of an organisation that is perpetually seeking to improve the delivery of its services.

Paragraph 10 of our submission, we recall that at the opening it was said that the agency was created in April 1994. In paragraphs 11 through to 15 of our submission, we set out the legislative journey that this organisation has taken from its creation through to the 1995 establishment of -- sorry, the Functions of the Northern Ireland Blood Transfusion Service (Special Agency) (No 1) Directions (Northern Ireland) 1995. They came into force and they are at WITN2681026 and it's important, we say, sir, to explore those functions and to demonstrate how they have been carried through.

The function of the NIBTS is:

"To ensure that all hospitals and other clinical units in Northern Ireland are provided with adequate supplies of blood and blood products and that they comply with all current, national standards of safety and efficacy."

In doing so, it will:

"assess and anticipate the needs of the Health and Personal Social Services in Northern Ireland for blood and blood products.

"recruit and maintain adequate numbers of healthy, voluntary non-remunerated donors.

"ensure the health and safety of blood donors during their contact with the Blood Transfusion Service, also

provide counselling to donors found to have abnormalities during routine screening.

"[It is] to perform appropriate processing and testing of blood and blood products.

"ensure that an effective quality assurance programme is applied ...

"[And] provide an education and advisory service on the utilisation of blood and blood products by clinicians."

In Karin Jackson's second Rule 9 in September 2021, that's at WITN2681027, this level of scrutiny that the NIBTS is subject to is set out in detail. It is accountable to the Department of Health, who conducts biannual reviews covering *inter alia* current and future activities, policy development, safety and quality issues. The chief executive's role is to provide leadership, vision and direction of travel for the NIBTS. It is a registered blood establishment with the Medicines and Healthcare Products Regulatory Agency, the MHRA. It must comply also with all relevant legislation including the Blood Safety and Quality Regulations 2005 as amended.

We set out, sir, at paragraph 20 of our submissions the senior management team and, specifically, there are two posts of note: the quality and regulatory compliance

manager and the supply chain manager.

There are a number of internal mechanisms. The Governance and Risk Management Committee, the Quality Improvement Review Group, the Medical Devices and Equipment Management Group, the Research Government Group and the Change Control Group. All of those groups, a description of what they do is set out within the submissions and I don't intend to open them but, essentially, they are there, sir, to ensure that every link in the chain of the safe delivery of blood is scrutinised and improved where it can be.

I take one example, and that's the Change Control Group. That group looks at recommendations and best practice changes. It then works to ensure that those proposed changes are implemented effectively and efficiently.

Part of the Inquiry, sir, dealt with relationships between organisations and pharmaceutical companies. The NIBTS wishes to make clear it does not receive financial or non-financial incentives from pharmaceutical companies to use certain blood products. Further, sir, it has a conflict of interest policy and requires employees to complete a declaration.

On the issue of the sufficiency of blood supply in Northern Ireland, the NIBTS current functions policies

and practices are effective in ensuring a sufficient supply of blood within Northern Ireland.

We set out, sir, in paragraph 31, eleven steps regarding safety and ensuring safety within the organisation. They have an extensive risk management process.

As I touched on earlier, the change management process. All new systems and processes have to go through a comprehensive validation process before being put into use. The NIBTS is regulated and inspected by the MHRA. It has a quality manual as part of its quality management system. It is externally audited by the United Kingdom Accreditation Service, and holds UKAS accreditation against ISO15189. It also regularly participates in national external quality assessment schemes, that's NEQAS. It has an extensive internal audit programme and many standard operating procedures and good practice standards.

We further set out, sir, at paragraph 32, further mechanisms that the NIBTS puts in place to ensure the maintenance of safety. So it's not simply establishing it; it's maintaining that. So it liaises with a number of external bodies. And I'm grateful to Mr Cory-Wright who on Tuesday set out the various bodies, for example, JPAC. So the NIBTS received and implements the

recommendations. It requires donors to complete health check questionnaires, all blood is screened for infections, and the NIBTS is also required to inform the Public Health Agency when any donations test positive for hepatitis B, C and E. It also has an incident management process.

In relation to identifying risk, the NIBTS insists that its biomedical science staff continue to develop professionally, and they engage in a regular cycle of appraisal and training to maintain registration with the GMC and also the Health and Care Professions Council.

In relation to external organisations, I've mentioned JPAC. NIBTS also engages in the UK Blood Transfusion Service Forum, the UK forum, and also the UK Quality & Regulatory Forum. These bodies provide advice and guidance as part of an inspection process, and NIBTS can access the Serious Adverse Blood Reactions and Events (SABRE) and Serious Hazards of Transfusion.

In relation to the evidence that you've heard from Northern Ireland in relation to the Blood Transfusion Service, you will recall the evidence of Dr Morris McClelland who provided that evidence on 1 February 2022. We raised in our submissions just some characteristics that were perhaps unique to Northern Ireland during the currency of the development

of the NIBTS. I don't intend to open them all but just simply to touch upon them, sir.

We had the civil unrest during that period of time there was a more conservative society within Northern Ireland. And there's evidence that there was a low incidence of IV drug use. And also the prison population, part of it also derived from the civil unrest. So there's a number of various factors in play that we say were unique to Northern Ireland.

To conclude, sir, we've set out our concluding points from paragraph 42 of our submissions. The NIBTS has strived to discharge its duty to fully cooperate and provide as much information to the Inquiry. NIBTS has also sought to convey, through these submissions, a clear apology for any part it played in the unimaginable pain and suffering experienced by the infected and affected. The level of engagement is to dispel any suggestion of a lack of transparency. And we've set out the regulatory context to demonstrate to everyone and to assure everyone that the NIBTS is striving to provide a service of the utmost safety and quality. The NIBTS of today exists in a highly regulated and scrutinised environment, all to ensure the encouragement of donors and the delivery of a safe blood supply to Northern Ireland.

And on that point, the NIBTS wishes to acknowledge those donors who have helped to both enhance and save the lives of people they will never meet.

Sir, the NIBTS is a forward-looking organisation, and it earnestly awaits your recommendations so that it can look to further improve the service that it delivers.

Sir, unless there's anything I can assist you with further?

SIR BRIAN LANGSTAFF: Just one thing. This really goes back to the issues of safety that you've been touching on, and paragraph 31 of your submissions, which is headed "Ensuring Safety", and you describe there the extensive risk management process, what is described as the change management process, which is ensuring that a change is managed and risk assessed prior to implementation, and:

"(c) new systems and processes have to go through and pass a comprehensive validation process prior to being put into use."

So this is ensuring, by taking time and effort and concentrating on whether they do work, that the new systems would apply.

MR ROBINSON: Yes.

SIR BRIAN LANGSTAFF: Can I just put one purely hypothetical example to you and see how it might work in an agile

manner. Suppose that in the Republic of Ireland, there emerges some evidence that there is a new virus which could affect, let us suppose, women giving birth, and suppose that it was thought that it might be and probably was -- not sure -- transmissible by blood. The change would be testing or introducing a test, would it, for such a virus to ensure that it didn't get into the blood supply in the North?

MR ROBINSON: I suppose one of the key elements of the evidence that we've seen before the Inquiry in relation to the modern-day practices is the nature and extent of the communications between the four jurisdictions. We also have, I suppose, the benefit of the Internet and instant communications. If something arose in Dublin and there was a concern about this, I would have no doubt that that would be communicated to the other bodies.

SIR BRIAN LANGSTAFF: It's what then happens after that. It's whether this then means that there would be a change in introducing a test, let us suppose, for the virus, to make sure it didn't catch hold in Northern Ireland.

MR ROBINSON: I suppose there's a lot to unpack in that, Sir Brian, because we would have to look at the evidence of how transmissible the virus is, what is the nature of

the virus? Is it similar to a virus that has originated before? In my view, it would involve an intensive exercise to determine what has actually been dealt with, what are the dangers, what are the characteristics, what is it vulnerable to and how transmissible is it?

SIR BRIAN LANGSTAFF: You see my question really is how quickly there might be a reaction. If there were a change necessary because of, let us suppose, a new viral threat -- that's what I've been putting to you -- how quickly, given the nature of the processes you've set out in paragraph 31, could this system respond?

MR ROBINSON: For an example like that, I would need to take clear instructions. However, given the focus on risk management, given the precautionary approach that's taken, I imagine an immediate response would be undertaken to look at process to see where the virus may enter the blood supply system, manage how that could be stopped, and if it does require, for example -- I suppose there would be a spectrum of responses.

One would be to simply monitor and observe, but the other side of the spectrum would be to stop production immediately or to stop use immediately, or to trace, do a look-back exercise through the different blood samples, through the individuals that may have carried this virus to find out how they may indeed have entered

the blood system.

It would also, I imagine, involve determining the symptoms of the virus, amending any questionnaires that go to donors. So the whole chain would need to be looked at to determine the best entry point at which to stop the further transmission of that virus.

SIR BRIAN LANGSTAFF: It might be helpful in due course simply to know if any, and if so what, thought has been given to how quickly new systems and processes may go through and pass a comprehensive validation process before being put into use, because those form of words suggests a lengthy consideration when, in some situations, it might be said that a quick consideration is at least necessary, even though further consideration must follow.

MR ROBINSON: I entirely agree, Sir Brian. I suppose, it being hypothetical, we can certainly go off and respond to you, sir, but I would say that, given the history of the difficulties with blood transfusion, the dedication of the teams involved to ensure the safety of the products on a precautionary basis, action would be taken as soon as possible to stop an event like a possible transmissible virus entering that blood supply.

The processes and systems that we speak about in the submission and in the Rule 9 response from the chief

executive Karin Jackson is talking about the system in its entirety, the NIBTS. So, for example, if there was a particular way to analyse samples and if there was a new process involved, that would take time to ensure that it's properly assessed and validated.

When dealing with a transmissible virus, in my view there would be a very quick reaction, given the body of evidence that you've heard, not only from the NIBTS, but also from NHSBT. And also I recall the very detailed statement from Dr Miflin who provided evidence, written evidence, but was not called.

So, in summary, it very much depends on exactly the mechanics of the virus, but, given the regime that it would be entering, action would be taken immediately.

SIR BRIAN LANGSTAFF: Of course, everything depends upon the immediate circumstances and details of the case, but the reason for my putting that to you is simply that, as expressed, what is said in paragraph 31 may not suggest that -- or may be read to suggest that actions may take time, when perhaps they might better be done quickly. And that was just what I was exploring. It was a question of systems that I was really asking you about.

MR ROBINSON: Yes.

SIR BRIAN LANGSTAFF: Anyway, thank you. I think we'll

leave it there because --

MR ROBINSON: I just want to say --

SIR BRIAN LANGSTAFF: I'm probably asking you to do something which ought to be covered, if it's going to be covered at all, by Karin Jackson or whoever wants to --

MR ROBINSON: Before I sit down, sir, I'm assuming that the answer will be that they will react as soon as possible to any potential threat to the blood supply. And if indeed there's a further Rule 9, we can respond to that.

SIR BRIAN LANGSTAFF: Thank you very much.

MR ROBINSON: I'm obliged, sir. Thank you.

SIR BRIAN LANGSTAFF: Thank you, Mr Robinson.

MR ALDWORTH: Sir, I'm conscious we are approaching what I understand to be the traditional time when one takes a break.

I do have, as I've indicated when I started my submission, a short statement to read out on behalf of the Department of Health. I estimate it would take me a matter of minutes. It's entirely a matter for you whether you would like me to do that now or whether we take a break and come back and then I will read it?

SIR BRIAN LANGSTAFF: I think probably it will be sensible for you to do it now, and I see at least one or two nods.

Closing Statement by MR ALDWORTH KC

On behalf of the Department of Health in Northern Ireland

MR ALDWORTH: Thank you very much.

This is a statement on behalf of the Department of Health in Northern Ireland.

You will be aware that there is currently no functioning Executive in Northern Ireland, and the Department of Health in Northern Ireland has no minister in post, and it is due to these circumstances that the Department considered it inappropriate to make a written submission to this Inquiry about the conclusions it thinks the chair should reach about factual findings and recommendations.

However, I would like to take this opportunity to make some brief closing remarks on behalf of the Department.

In his opening statement on behalf of the organisations in Northern Ireland in September 2018, Alphy Magennis acknowledged the tragedies and the life-changing impacts that have resulted from the use of contaminated blood and blood products. The Department is sorry that this suffering was caused.

Mr Magennis noted the courage, fortitude, and dignity shown by those infected and/or affected, and indeed, we have seen this continue throughout the past

four years.

The Department is grateful to all those who have contributed to the Inquiry's work, particularly those from the infected blood community, many of whom will have found it traumatic to recall their experiences. Mr Magennis provided an assurance that the Inquiry could expect the full co-operation and engagement from Northern Ireland Core Participants, and the Department has indeed remained committed to supporting the Inquiry throughout the last four years.

Parity of financial support was a commitment in the political agreement, new decade new approach in January 2020, and since March 2020 there has been a dedicated team in place within the Department to respond to the Inquiry and take forward important work on financial support. The Department has provided as much assistance as possible to this Inquiry, including the provision of over 100 paper records, 180 electronic records, and 13 written statements.

On behalf of the Department of Northern Ireland -- I beg your pardon -- the Department of Health in Northern Ireland, I would reiterate the position of former minister Robin Swann, who described the use of contaminated blood and blood products in the 1970s and 1980s as a tragedy for everyone involved.

Mr Swann was aware of the financial hardships and suffering endured, and when he gave oral evidence to this Inquiry, agreed there was a moral responsibility not only on the Department of Health in Northern Ireland or Northern Ireland executive, but on Government as a whole to acknowledge this, and to do what we can for those who have been infected and/or affected in recognition of the devastating impact contaminated blood has had on their lives.

Throughout his tenure, the former minister remained committed to doing everything possible to support those affected by contaminated blood, including introducing a significant number of improvements in financial support.

The Department stands ready to respond to recommendations arising from the chair's final report when it is published, and this commitment will not end with the final findings and recommendations of the Inquiry, as this will help to inform and shape the delivery of healthcare in Northern Ireland in the future.

Sir Brian, if you just bear with me a moment, I would just like to ...

Essentially, I would like to say to the infected and affected community that we appreciate how difficult and

how traumatic participation in the Inquiry has been. However, we have been so impressed by the dignity and the resolve and the courage of you all. We have been frequently deeply moved by the evidence we have heard and we want to thank you for your contribution.

We also want to thank the Inquiry team, Sir Brian, who have been exemplary in the assistance and in the spirit of co-operation. It really has been a model of good professional relations and, coming from another jurisdiction, we are extremely grateful for the way in which we have been received and all the help we have also received. I can honestly say nothing has been too much. So thank you very much indeed for that.

SIR BRIAN LANGSTAFF: Well, in my turn, can I thank you and, through you, Mr Robinson, for your submissions this morning.

MR ALDWORTH: Thank you, sir.

SIR BRIAN LANGSTAFF: I shall of course consider them along with others. And can I thank the Northern Ireland -- if I can call -- or deal with the Trust, the Blood Transfusion Service and the Department of Health, by using that portmanteau term -- can I thank them for their degree of co-operation in making their point, their position clear to the Inquiry.

So thank you very much.

MR ALDWORTH: Thank you, Sir Brian.

MS RICHARDS: Sir, just before I indicate who we'll be hearing from next week, just an update in terms of some of the outstanding presentations.

There's been a written presentation on the use of Factor IX concentrates, which has now been disclosed to Core Participants and should be available on the website next week. Then perhaps topically, given today, there is a further presentation on decision making at a governmental level in Northern Ireland, which I hope will be available to Core Participants by the end of today -- if not then, it will be or should be Monday morning -- and there's a further presentation in relation to Government decision making in Wales, which will be available early next week.

That, I think, then concludes the written presentation notes that we had promised that were outstanding.

Then, as to next week, we will be hearing first of all from Mr Bowie on behalf of the Scottish Blood Transfusion Service and the Scottish Regional Health Boards, that's Tuesday morning. Then Tuesday afternoon we will be hearing submissions on behalf of the Core Participants represented by Leigh Day solicitors.

SIR BRIAN LANGSTAFF: Yes. Thank you. So it's the Scottish

Blood Transfusion Service, et cetera, on Tuesday morning at 10.00. 10.00, Tuesday.

MS RICHARDS: Thank you, sir.

(11.22 am)

(The hearing adjourned until 10.00 am on Tuesday)

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