Friday, 4 February 2022

(10.00 am)

SIR BRIAN LANGSTAFF: Good morning, Dr Boulton.

THE WITNESS: Good morning.

SIR BRIAN LANGSTAFF: You can hear me then, good. Can you see me?

THE WITNESS: Yes, I can see you, yes.

SIR BRIAN LANGSTAFF: There's a slight lag, I think on the connection. You're at home, are you?

THE WITNESS: I am indeed.

SIR BRIAN LANGSTAFF: And you're with your wife?

THE WITNESS: At the moment she's out but she's around.

SIR BRIAN LANGSTAFF: But in the room at the moment it's just yourself, then?

THE WITNESS: Yes.

SIR BRIAN LANGSTAFF: Now you're talking to Aldwych. There's a select group of people here to listen to what you have to say, but your significant audience is that beyond this room. They'll be watching remotely, YouTube or live stream, and there will be something like 100 or thereabouts or more people who want to hear what you have to say. So that's your audience. The questions are going to be asked by Ms Scott. She is also asking them remotely, and so we'll just have to hope that the connection is maintained. We've managed pretty well so

far. There has been the odd hiccup. If it happens, please forgive us.

In a moment or two I shall ask Mary to ask you to take the oath.

Mary.

Then Ms Scott will ask questions.

THE WITNESS: It is actually an affirmation which I have agreed to give, thank you.

SIR BRIAN LANGSTAFF: The oath is a global term.

DR FRANK ERNEST BOULTON (affirmed)

Questioned by MS SCOTT

SIR BRIAN LANGSTAFF: Ms Scott.

MS SCOTT: Dr Boulton, I'm going to start by asking you some questions about your career.

So you were a trainee pathologist at St Thomas' Hospital from 1967 to 1970, and then took up a post in 1971 as a senior registrar in haematology at the London Hospital; is that right?

A. Correct.

Q. You then became a senior lecturer at the London Hospital Medical College, a post you held from 1973 to 1975?

A. That's correct.

Q. You then became senior lecturer and honorary consultant haematologist at the University of Liverpool and Royal Liverpool Hospitals between 1975 and 1980; is that

correct?

A. That's correct. The difference in the senior lectureship is that in Liverpool I had NHS consultancy whereas at the London I was not quite of the consultant standard status, but I was an honorary consultant in Liverpool.

Q. And I'll come back in a moment and ask you a little bit more detail about those posts. Then you took -- moved to Scotland and took up a post as a consultant haematologist at the Edinburgh and South East Scotland Region Blood Transfusion Service, based at the Royal Infirmary of Edinburgh, a post you held from 1980 to 1990, albeit you became deputy director of the transfusion centre in 1982; is that correct?

A. Correct.

Q. Then in 1990 you moved to the Wessex Regional Blood Transfusion Service in Southampton, as medical director, a post you held until 1995. And then when the National Blood Authority took over all of the regional transfusion centres, you remained working, as it were, in Southampton, but your post changed to consultant haematologist at the National Blood Authority; is that right?

A. That's correct. Yes.

Q. And you retired, I believe, in 2006?

A. Yes, yes.

Q. You've also been a member of a number of advisory committees and working groups, and just to pick out a few of those, you were a member of the Standing Advisory Committee on Donor Selection, and that was a UK Blood Transfusion Service and a NIBSC committee. You were a member, and then became secretary, and then became chair of that committee; is that right?

A. That's correct, and the full title that evolved during my time there was the Standing Advisory Committee on the Care and Selection of Donors, the caring bit was important.

Q. You were also on the Standing Advisory Committee for the UK BTS NIBSC on Clinical Transfusion Medicine. You were a member of the Coagulation Factor Study Group?

A. Yes.

Q. You were a member of the SNBTS, Scottish National Blood Transfusion Service, Ethics Committee (Clinical Research and Investigations), and you were a member of the SACTTI Working Group on vCJD and the SACTTI Advisory Group on Blood Parasites, and chair of the British Committee for the Standards in Haematology Blood Transfusion Task Force, and a founder member of the British Blood Transfusion Society, and their president from 2005 to 2007. Is that -- are all of those details correct?

A. That's broadly correct. I'm not quite -- didn't quite catch the earlier bit about the Ethics Committee, I think you said.
Q. SNBTS Ethics Committee (Clinical Research and Investigations).
A. I'd forgotten that. Yes.
Q. July 1986 I've got --
A. That's correct, yes, yes.
Q. You also provided both written statements and oral evidence to the Penrose Inquiry?
A. I did. Yes.
Q. So if I can turn now to your role as senior lecturer -- sorry, senior registrar and senior lecturer at the London Hospital, so that was between 1971 and 1975. Can you tell us a little bit your role in those posts over that time?
A. Well, as senior registrar, I was still trainee, so consequently I was learning my trade and also preparing for the qualifying examinations for the Royal College of Pathologists, and also I was -- both at the St Thomas' stage and later, I was preparing an MD thesis which got accepted in 1974, I think.

So I was training, studying, learning my trade, treating patients, learning the laboratory technology of -- in haematology technology, which included

cross matching of blood, compatibility testing, and assaying clotting factors such as Factor VIII.
Q. There was a Haemophilia Centre there under the directorship of Professor Jenkins; is that correct?
A. Yes, he was not professor then, he became a little later, but yes, he was the head of department of haematology at the London Hospital, and indeed was the -- was my boss, both as senior registrar, and then, when the university granted academic status to the haematologists, he became the professor -- yeah, he became -- sorry, George became the -- in charge of me as senior lecturer.
Q. And were you --
A. Sorry, that was a little bit garbled, but you're correct.
Q. Were you treating -- providing clinical care to people with haemophilia in that period?
A. There was some incredibly good and very cooperative haemophilic men who were patients in that unit, so I was both seeing them as outpatients and as inpatients.
Q. So you had experience, did you at that stage of administering cryoprecipitate and factor concentrates?
A. Indeed. In fact, my very first experience of administering cryoprecipitate goes back to my houseman days in Portsmouth in 1966/67, when there was a patient

presenting with horrendous bleeding from his bladder, which was due to a cancer and he was a haemophilic and, at that time, cryoprecipitate had just been discovered, and the haematologist at Portsmouth, Dr John O'Brien, was able to procure large quantities of plasma for cryoprecipitate production from the Royal Navy base in Portsmouth.

So I had my early experience in cryoprecipitate then but I knew about it when I learnt more, when I became a trainee at St Thomas', and actually helped prepare cryoprecipitate at that time.
Q. Now, your witness statement tells us about your work in this period, that you began to expand the service to local haemophiliacs. I wonder if you could just tell us a little bit about what you meant by that.
A. Well, we hadn't quite got as far as home therapy although that was beginning to develop among the haemophilia consultant community, but we were just able to procure more cryoprecipitate from the Brentford Transfusion Centre, and also just to make available more treatment. So there were people who presented to us, some of whom I can remember very clearly, who were treated effectively as inpatients for their bleeding disorders, and that included some really quite difficult cases who required surgery. So we were able to support

them mostly as inpatients from the London Hospital.
Q. You've also told -- you've also recounted an incident in your witness statement of a patient who, after receiving one batch of commercial product, was infected with both hepatitis B and non-A, non-B --
A. That is correct.
Q. Can you just tell us, again, a little it about the circumstances in which that incident arose and the impact it had on you?
A. He was a 50-year-old man with mild haemophilia, about 5 per cent of Factor VIII activity, who had not really had very much problem with haemophilia, although he knew it all his life that he'd had it, he'd had three other brothers who were also affected. And he presented on Christmas Eve with a raging toothache and an abscess, and this was bleeding, and there was no doubt that he needed to have urgent treatment which involved the extraction of a tooth. I'm not sure if he was actually admitted but he was -- certainly spent some time in the hospital.

We gave him -- we felt that cryoprecipitate may not be sufficient to control the bleeding and, in fact, I think there was very little cryoprecipitate in the hospital at that time, so we delved into our small stocks of commercial Factor VIII, which I cannot

remember the exact variety, but it was there available. We got him up to 100 per cent full activity, the tooth was extracted without a problem. The abscess was drained successfully, the antibiotic course was successful and he went home and had a good Christmas.

About two months later he presented with a rash and mild jaundice and, in fact, we didn't give him any treatment. He was mildly affected, mildly symptomatic, and went home and recovered. He then had a recurrence about two months after that, and I contacted Dr Craske at Manchester and he was able to inform me that he probably had both forms of what was then called serum hepatitis. One was probably hepatitis B, and I think we were able just to check that, but the other form was neither A nor B and was my first clear-cut experience of non-A, non-B hepatitis.

He recovered and, for the rest of the time I was at the London, I -- he was no problem. I do not know what happened to him. It's possible that Dr Colvin, who was my successor, may have some knowledge of that.

Q. Your witness statement suggests that that incident had an impact on your later practice; is that right?

A. Yes.

Q. Can you tell us about that impact?

A. Well, particularly when I went to Liverpool -- I mean,

in fact it was probably not very effective, but going to Liverpool and being aware, not least through the World in Action Tainted Blood programme that came out in 1976, I think, that I was very anxious not to purchase American blood products, but if there were blood products -- well, there were products available on the market that were -- the claim was that they didn't come from American donors, although they did come from European donors, basically, in Austria, who did -- who were paid for their donation but at least it wasn't American.

So, in that sense, I tried to avoid the risk of using American plasma with its, by then, well-known association with the transmission of disease and tried to avoid it by giving Austrian.

In fact, we were let down because, within a couple of years, a patient who'd received that Austrian product actually developed hepatitis in Liverpool. So, consequently, that was a vain tactic but at least I tried.

Q. So moving on, then, to your time in Liverpool, so just reminding ourselves that that was 1975 to 1980, I'm going to ask you, first of all, a few questions about the arrangements and set-up of the centre itself. Were you the Centre Director or was Professor Bellingham the

Centre Director? There's different documents that name one, either -- or sometimes both of you as Centre Director?

A. That's understandable. Professor Bellingham was the head of department and, therefore, took nominal responsibility for the care of the haemophilics, but he delegated that entirely to me, so that, for example, the purchasing policies that he -- clinical management of the haemophilics who presented was my responsibility. Of course, there were times when I was away, so either he or, for the first couple of years of my time there, the other senior lecturer, Dr Michael Leyland would take over my clinical duties while I was out of hours.

But, apart from that, I basically ran the haemophilia service and filled in the returns for the directors' organisation.

Q. What region did the Haemophilia Centre cover?

A. Merseyside and North Wales, so it went from the boundary between Merseyside and Manchester. So it went from Stockport on -- in the north through to the Welsh peninsular, including Bangor hospitals. So we actually had a significant population from North Wales, as well as those in Merseyside. So it included St Helens in Lancashire, as well as the -- as well as North Wales, and, as I say, the rest of Merseyside.

Q. Is it right to understand that Liverpool -- that the Haemophilia Centre in Liverpool was not a reference centre; your reference centre was the Manchester Centre?

A. That is correct, and we had occasional dealings with that, although most of the time we were able to function separately.

Q. That's my next question. What did, if I can put it this way, your reference centre do for you?

A. Well, it was another forum for discussion and sharing of problems, and understanding. And they were professional, helpful colleagues, so spreading the burden of responsibility was welcome to me. And there were one or two episodes involving a slight confusion among some of the north Welsh hospitals, I think Wrexham in particular, who clearly thought that they were -- if they had a problem with a local haemophilic, which was rare, they tended to turn to Manchester. I think possibly because the laboratory staff there had more experience of the Manchester set-up than the Liverpool set-up.

But -- so there were occasional cross-references but they weren't very often.

Q. In --

A. And I was able to go to the Haemophilia Directors Organisation meetings but not to the meetings of the

reference centres.
Q. In terms of those discussions with your colleagues in Manchester, were those formal meetings or was it more a question of picking up the phone when you've got a problem and asking somebody for a view?
A. It was a mixture but there were formal meetings. I think, actually, to be honest, there were only two or three meetings during my time there. The rest was by general conversation, and, of course, we would meet at other functions, like annual meetings of the British Society for Haematology. So there was a certain degree of informality as well as formality.
Q. Is it right to understand that most, if not all, children with haemophilia in the Liverpool and Merseyside area were treated at the Alder Hey Hospital?
A. They were treated. The -- you use the word "all". There was an understanding that as boys became teenagers they were probably in some ways better dealt with in the adult unit rather than the children's unit, although it was a bit of a mixed blessing. Some of those young men were quite challenging, understandably, and it was felt that -- and I went along with it -- that they would be -- as they were growing older, it would better for them to develop links with the adult centre rather than, say, with the children's centre.

So the age differentiation was a little bit vague. Somewhere between 14 and 18, a boy would transit from Alder Hey to the Liverpool Royal Infirmary. But we held joint clinics with John Martin, who was the consultant paediatrician in care of the haemophilics at Alder Hey, and so there was, I think, a good understanding of the transition those boys were transiting from, being young boys to young adults.
Q. The joint clinics were in respect of all of the -- all ages or --
A. No, the joint -- those were joint clinics for the children. So John would bring along his nurse specialist that he would work with it -- although I think her time was not fully time with the haemophilia -- he'd also bring along a dentist, and we had access to social workers, physiotherapists, occupational therapists, so it was a sort of combined clinic. And, in that sense, it was really quite advanced, it was really good thinking on John's part to actually bring in all the professionals who were dealing with these children who were growing up and it was a joy to work with them.
In the -- as adults, I ran a service which was also in conjunction with the physiotherapists, occupational therapists and social workers and, of

course, we had nurses on the wards who were particularly skilled with dealing with patients with haemophilia. And so, again, it was a sort of combined service, multi-professional in a way, which was important for these people but particularly important for the children as they were growing up.
Q. In terms of the staffing of the centre, were you dedicated -- was your role entirely taken up by the centre?
A. By no means. I would say that the haemophilics -- my haemophilic commitment was about 10 to 15 per cent of my time. The rest of the time I'd be dealing with the clinical laboratory, so I was actually the consultant for the laboratory services, which included the blood bank, the anaemia services, the leukaemia laboratory diagnoses, all those aspects as well as the haemophilics. So the haemophilics were a very important part of my job and that's why I was pleased to move to Liverpool, but they were -- but I was by no means the -- they were by no means my only commitment.
The -- it would be fair to say that -- sorry, I've slightly lost my thread but it would be fair to say that my commitment was -- because of my interest in coagulation as a whole, my commitment was spread a little bit beyond the haemophilics and, indeed,

included the Liverpool School of Tropical Medicine which was next door, which was also interested in disorders of haemostasis because of the snake venoms with which they specialised.
So my time -- I was very interested in haemostasis, haemophilia was a big part of that but there were other aspects, which I would explore too, which was helpful in the sense that it was -- it gave me a broader insight into the general nature of haemostasis problems.
Q. So is it right to understand that there would have been no dedicated nurse for the centre or junior member of staff?
A. That is actually what I was slightly stumbling over now. There was no specific building or room with a door that said on it "Haemophilia Centre". The services were provided and I was -- I think I could describe myself as director of the haemophilia services to Liverpool but the site was split. There were -- there were the specialist laboratories, part of the laboratory block in pathology; there were the wards; and there the outpatients, where I would see the haemophilics.
So the function was split over several sites, and that assisted when we moved to the new Royal Liverpool Hospital in 1978/79, which incidentally was a very

disruptive experience. So consequently my time was -- and that of Professor Bellingham -- was spent very much on coordinating the move of the laboratory and clinical services from the old and rather decrepit site to the new, better site, but there were still problems on the new site as well. So we had a lot to contend with but the haemophilics were an important priority for me.

Q. We see a reference in some of the documents to people with haemophilia being treated on the tropics ward. Which hospital was that in; was that in the old or the new or both?

A. The old -- the old Liverpool Royal Infirmary, and it was called "tropics" because in the first part of the 20th century the school -- the Tropical Medicine School next door would attract people who'd been overseas and caught horrible diseases like malaria and others which had a profound effect on the blood.

So when they were admitted, they were admitted to this really rather wonderful ward which was of a unique design. It was circular, and the 20 beds were spread around the edge and they were pointing towards the pillar in the middle. That was partly to dissipate the risk of transmitting infections from bed to bed, like the old Nightingale model but this was a different model, and they were the preserve of the physicians who

specialised in tropical diseases.

As time went on, the instance of tropical diseases needing inpatient care declined, while the development of other services in the haematology expanded, not least the blood bank and then, later, the haemophilia disorders, but particularly the leukaemia disorders. And so tropics ward was effectively the ward -- the clinical haematology ward, which included leukaemias in particular, and some haemophilics.

Q. Did you have a relationship with Dr Rob at the Walton Community Hospital?

A. I knew her quite well, at one stage, but there was never any real dealings with -- as far as I remember, with the haemophilic community.

Q. I'm going to look now at the annual returns with you, I'm going to look at two of them, 1977 and 1979. The Inquiry has had a presentation on Liverpool and has looked at more than that, but if we start with 1977, that's HCDO0001178.

If we start, please, on page 14, we can see at the top that says "Annual Return for 1977" for Liverpool Royal Infirmary, and you're noted as the director along with Professor Bellingham.

And we can see there that the number of patients treated that year were 56, none with Factor VIII

antibodies, Christmas disease patients, eight, none with Factor IX antibodies.

Then if we look at down at the table, we can see that there was no treatment with plasma.

Can we have the whole table up? Thank you.

Cryoprecipitate was approximately 800,000 units. Then NHS factor concentrate, just over 13,000 units. No Abbott Factor. Some Armour Factor, 58,000. Quite a lot of Koate, 207,000. Some Hyland Hemofil, and some Immuno Kryobulin. And then we can see there NHS Factor IX Concentrate at 244,000 units.

Just trying to understand that, then, we can see relatively little NHS factor concentrate being used in 1977. Why was that?

A. Well, firstly, the handwriting is mine. So I can take clear ownership.

The relative reduced amount of NHS Factor VIII was simply because it wasn't available in the quantities which we would have otherwise required, so we were reliant mostly on the cryoprecipitate, and you can work out from there I've assumed that each pack of cryoprecipitate had about 70 international units -- that's the maths -- had about 80 international units. That's the maths. Later on I think I assumed there were more like 70 units.

So as far as the cryoprecipitate dosage is concerned, that is very much approximate depending upon how much Factor VIII was in each pack, and that could vary a lot, between about 20 and 100 units.

So that's an approximation. But the others are clear-cut numerals relating to the amount of international units that those were given. International unit being the amount of Factor VIII in 1ml of plasma, basically. So that's the sort of activities that they were given. And yes, there was a lot of Immuno. That was the-- as far as I remember, that's the Austrian product, and that's what I was using mostly that year. But I was already beginning, as you see, to spread to the others. Basically to spread the load and make sure that we had enough Factor VIII in stock to allow for emergencies.

The smallest amount there, Hemofil, is the product that was manufactured by the company that was most criticised in the World in Action programme. So that's the small quantity compared with the amount of Kryobulin. But I do admit that there was a real mixture of origins of the Factor VIII that was given.

SIR BRIAN LANGSTAFF: I think you may be in error in suggesting that the biggest commercial concentrate usage was Kryobulin, because I think, if you look again at the

figures, the Koate is 207,330 units, isn't it?
Have I got that right?
A. You are correct. You are correct.
SIR BRIAN LANGSTAFF: So it looks as though Koate was essentially just under half of the commercial concentrate being used.
A. That is correct, Sir Brian. And indeed the number of bottles would confirm that it was -- that was the dominant factor that I was using in that year.
MS SCOTT: And the policy you've explained of -- the rationale, if I can put it that way, behind the policy of having this spread of different types of commercial product was to ensure you always had a supply; is that right?
A. That's correct.
Q. Because there was a concern that if you just had one commercial concentrate, that it may run out and you may not be able to get a replacement?
A. That was our thinking.
Q. If we then turn to page 15, we can see -- no, sorry, that was the annual return for Christmas disease, but that shows as nil.
Sorry, that's carriers. I didn't mean to go to this page. I actually wanted to go to page 13, sorry. Can we go to page 13, which shows the von Willebrand's.

Here we go. So we've got "Summary of Patients Treated ... 1977 [for] von Willebrand's Disease", and you've got three patients there. We can see that they were treated primarily by cryoprecipitate, but a small two bottles of Immuno Factor VIII concentrate used in 1977.
Can we turn to page 9, because we get some information about the home treatment programme in 1977.
Again, if we look at the top of that page, "Total amount of materials supplied during 1977 to Haemophilia A Patients on Home Treatment", and we can see there that we -- you have 330 bottles approximately -- I think that says 23,100 or 28,100 units you've estimated --
SIR BRIAN LANGSTAFF: I think it's 23,000, if you apply the factor of 80.
MS SCOTT: Yes, thank you.
Just pausing there, so you had a home treatment programme in 1977 in which people used -- patients used cryoprecipitate?
A. That is correct.
Could I just go back to your previous one about the von Willebrand's patients?
Q. Yes.
A. That treatment was dominated by one individual. Two

others received small amounts of treatment for bleeding episodes but one individual, based in North Wales, who had severe von Willebrand's disease, was bleeding from his vocal chords, and he required a lot of treatment, and eventually we managed to control it with large amounts of cryoprecipitate. The small amount of clotting factor concentrate he was given seemed to make no difference. So that was why so much was given in that unique circumstance in that year.
Coming back to what's in front of me now, yes, you correctly point out that we were giving some cryoprecipitate to patients on home therapy.
Q. Then we can see a small amount of NHS factor concentrate given as home therapy. Again, the reason for that was because of the limited amount of NHS factor concentrate; is that correct?
A. Correct.
Q. Then we see a range of different commercial concentrates being given as part of the home therapy treatment. Were there -- then, sorry, if we turn -- if we look at the bottom of this, below this table, we can see:
"Comments: These figures include ALL patients from Merseyside including children who are normally treated by Dr J Martin either at Alder Hey Children's Hospital or the Royal Liverpool Children's Hospital.

There is also one patient included from [North] Wales, under the routine management of Dr T ..."
Kom is that?
A. Korn, K-O-R-N.
Q. So that reflects what you've just told us about the arrangements with those centres.
So the numbers that we see, the number we saw, of patients treated in 1977 by a Liverpool Royal Infirmary, of 56, includes, does it, the children at Alder Hey and the North Wales patients?
A. Yes. And that one patient was the man with von Willebrand's syndrome who was mostly treated in hospital, but he may have received a little bit of cryoprecipitate at home, but I can't confirm that, at this stage. My memory is not too clear on that point. But I actually do remember the patient very well, because he was a very significant problem.
Q. I don't think this form helps us, this document helps us with home treatment for von Willebrand's but we do get some information about home treatment with ... I beg your pardon. Yes, sorry, we do get some treatment for patients on home treatment for haemophilia B or Christmas disease.
If we look at page 11, we can see there:
"Total amount of materials supplied during 1977 to

Haemophilia B ... Patients on Home Treatment."

We can see it's all NHS factor concentrates, no commercial products used or other products used.

A. That's correct.

Q. You tell us in your witness statement that during your time at Liverpool the number of patients on home therapy increased from 15 to 27. Was there a policy of trying to get more patients on home treatment during this period?

A. Yes, I was committed to expanding the already established home therapy programme.

Q. Can we then look at the last page I want to take you to on this document, at page 1, please, which gives us a breakdown of the treatment by patient, but for each patient.

The patients' names, which have been redacted, and dates of birth are on the left-hand side, and then we can see various bits of information about their condition.

Then we have, on the right, the type of material received during 1977. And we can see that, for many of the patients, they received a number of different types of commercial concentrate during 1977.

Is it right to understand from looking at this document and the following pages that there was no

policy in 1977 of trying to keep patients on one type of commercial concentrate?

A. Yes, that's correct.

Q. Can we then turn to the 1979 return, which we find at HCDO0001344.

We can see at the top, "Annual Return for 1979", for patients with haemophilia or Christmas disease. RLH. The move to the new site. And the director on this -- this time is noted to be Professor Bellingham.

Total number of patients treated during the year is 49. Now, the previous year it was 56. Can you help us with why there's been a reduction over the two-year period of seven patients?

A. This return was made by my successor sometime in 1980. But I had taken care to prepare most of the data before I left, so that the -- my successor was not left with need to go through all the paperwork involved in filling out this data. So by the time this was returned, Alistair Bellingham was, in effect, acting as the director, at least nominally, but I think that my successor would have taken on much of this work. So that's why my name is not there. I wasn't there at the time of completing this return. But most of those figures were worked out by myself.

As for the reason for the reduction in treated

patients, that's just chance, I believe. So some years it would be in the high 40s and other years it would be in the low 50s. So I don't think there's any great significance in the change of numbers of patients treated.

Q. And we can see there number with Factor VIII antibodies, two. Total number of Christmas disease patients treated, five. And none with Factor IX antibodies.

Then if we look down the page, we can see that there's a figure for the "Cryoprecipitate: Whole region" of about 18 million units. You didn't fill out this form. Can you help us at all with what that means?

A. Sorry, could you just repeat that again? The?

Q. The first entry on the table is "Cryoprecipitate: Whole region", and then we've got "Cryoprecipitate (RLH only)". Can you help us at all -- I understand you didn't fill this out, but can you help us at all to understand what "Whole region" might mean?

A. Also that top line is deleted by whoever prepared it. So I can't give a clear explanation of that.

Q. And then we've got --

A. I think the fact it's deleted implies that it was actually an error.

Q. Cryoprecipitate (RLH only), 630,000 units; NHS Factor VIII concentrate, 220,000; Armour Factor VIII

Concentrate, 550,000; Hyland, a small amount, 750; and Immuno, 150,000.

Then at the bottom there is "(Oxford)", 177 bottles, approximately 115,000 units for Christmas -- for haemophilia B Christmas disease.

And then "Other Materials" it says "DDAVP".

Just pausing there on the DDAVP, that is the first time we see DDAVP entered onto the annual returns. Can we take it from that that DDAVP would not have been used before 1979?

A. Um, no, we were using DDAVP. It became available -- I think it was licensed for treating haemophilics in about 1976 or '77. And I remember presenting the ability to treat mildly affected haemophilics and people with von Willebrand's disease with this desmopressin, or DDAVP, which could be given by injection and would induce an increase in the level of Factor VIII, and indeed of von Willebrand's factor, in the blood of these mildly affected patients or patients with von Willebrand's. So I'm sure I was doing that from 1977.

I think the haemophilia returns did not request data about DDAVP until this particular year. So I may well not have documented for my successor how much DDAVP was used, and so he would be unable to actually complete

that detail. So that form is a slight victim of a handover which might have been better, but I was doing my best to ensure that all was accounted for before I actually left.

Q. I'm going to ask Sully, please, to put this -- keep this page on the screen and to go back to the 1977 document and have it next to it, so we can see how the prescribing practice has changed between 1977 and 1979.

So Sully, could we please have next to this page 14 of HCDO0001178.

So I hope you can read this, Dr Boulton, but we can see -- we just looked earlier at the cryoprecipitate from 1977, approximately 10,000 bottles or 800,000 units. And we can see that that's reduced somewhat by 1979 down to just over 7,000 bottles or 630,000 units.

We can see that the NHS factor concentrate has gone up from 13,000 units to 220,000 units. Can you tell us the reason for that?

A. I believe that BPL had expanded their capacity to prepare Factor VIII concentrate from English donors of donations of plasma. So as a result of a building programme, they're able to supply the whole country with rather more Factor VIII than they had in earlier years. So I think that's the explanation.

Q. Then we can see that there's a rather different pattern of -- well, perhaps not very different, but, rather than having four commercial concentrates in 1977, there are three commercial concentrates, although one is -- Hemofil is a small amount, and it's primarily Factorate at that stage, with some Kryobulin?

A. Yeah.

Q. Again, was there a different policy by 1979 in terms of spreading the concentrate across different manufacturers or was that just a matter of chance?

A. I think we were becoming more aware of the need to be a little less liberal in the resourcing.

Each commercial firm was charging roughly the same amount. I think it was 10p per unit of Factor VIII. So it wasn't so much a price difference, although there were occasional tussles that would try to make one more attractive than the other. But the other thing that was of significance, and I cannot remember the details, but the haemophilics themselves, or their mothers who were treating the children at home, really liked the stuff that dissolved most quickly. And some of these preparations, particularly those in 1977, did not dissolve all that well. And so the same manufacturer would produce improved batches that dissolved more easily.

So some of this may have been slightly driven by the preference of the patients or their parents in terms of the convenience of dissolving the powdered material, that was kept in their fridge at home, in water that I advised be not kept in the fridge, of course cold water didn't dissolve things as well as water at room temperature. So there was a lot of those little details. But some of that difference might have been due to patient preference, and it looks as if that's the case, that the one product they did prefer was the Armour Factorate.

Q. Then just looking at the amounts, by my calculations, the 1977 number of units for commercial factor concentrate across those four that we see there comes to 457,320 units and, by 1979, that has increased across the three commercial products, we see there, to 920,750.

So I don't expect you to be able to do the mental mathematics on the spot, Dr Boulton, but we can see, looking at it, that there's -- sorry, I think I've got that figure wrong, I beg your pardon. I think that's the whole -- sorry, that's the whole of --

A. It's 700 --

Q. Yes, thank you.

A. Yes, it's 700,750 that made up those three.

Q. It is, and the figures I gave you, I beg your pardon,

were not just for commercial concentrate, they were for concentrate altogether. So the 457,320 was for all the concentrate, including the NHS factor, and the 92 -- now I can't read -- 920,750 was for all the concentrate, including the NHS factor concentrate.

So the question I have for you is: is it right to understand that between 1977 and 1979 there was quite a considerable increase in the amount of factor concentrate that was being prescribed by the Centre?

A. That is correct, and it would be related to the expanding home treatment programme.

Q. I'm going to ask you now some questions about the policies and the rationale for those policies, and how you made treatment decisions.

First of all, I'm going to start on the home treatment program. What criteria did you use to decide which patients should go on home treatment and which patients should not get home treatment?

A. Well, I personally trained the patients or their parents usually their mothers. So that would involve physical face-to-face meetings, discussing, first of all, the pros and cons of home therapy, and discussing the practicalities, like did they have a refrigerator, and what were the conditions like. I don't think I actually visited their homes, but I -- and that was an option

that could be done, if necessary. But it involved a lot of close conversations with the people affected and, in a sense, just to get a feel of how suitable they were, how well they could cope.

Needling veins is always a challenge, and you can imagine that for a mother faced with a four year old, five year old little boy, learning to put the needle in the vein is a very stressful experience. They were very well motivated and they, on the whole, learnt it very well, but there needed to be care in the process of training, advising, and I had to be reasonably satisfied that they were able to cope.

I do remember one occasion with one young man, I think in his early teens, who said he couldn't dissolve the Factor VIII in the vial and I found out that that was actually because he was warming the water and basically cooking the Factor VIII as he put it in.

So that's the sort of thing that would be dealt with in the course of training these people. So that was quite a lot of time spent just doing that.

But, on the whole, it was worth it, in terms of the relief of access -- of pain and difficulties. Although more Factor VIII was used, in the course of the home therapy programme, what was used is probably used more effectively in cutting short the time that the

people were actually bleeding, if you're bleeding into a knee joint very painful. If it took an hour or two to come to the hospital, prepare the cryoprecipitate and -- or Factor VIII and administer, there was still a few hours of quite intense pain.

At home, the patient would say, "I've got something in my knee I know it's going to bleed", and they would be able to treat it much more effectively, and so, consequently, although more was used, it was also used more efficaciously.

So the training programme was important in order to do that. So, consequently, I did develop a fairly close relationship on those terms with the patients and their parents.

Q. So were all the people on home treatment severe haemophiliacs?

A. Sorry, I missed a little bit of that.

Q. Were all the people on home treatment people with severe haemophilia?

A. Yes, yes.

Q. What about people with moderate haemophilia, would they be put on home treatment?

A. I don't think I offered home therapy for those with moderate -- we're having a distinction here, aren't we? There's the severe, less than 1 per cent; the moderates,

who are up to 5 per cent; and the milds, more than 5 per cent. As far as I remember, but I can't be totally accurate on this, none of the mildly affected haemophilics actually needed home therapy, in one sense, but it is possible that a few of the moderately affected might have done but I cannot remember. It was principally directed at those with severe haemophilia.

Q. Can we just look at a document, then, that you wrote to Dr Martin about home treatment.

So that's WITN0173002. It's a letter that you wrote to Dr Martin and, when it comes up, we'll see that it's dated 29 October 1976. Can we go to page 4, please, of that document. We can see at the second paragraph down:

"Because of recent queries from the Central and Southern District Administration concerning the expense of buying commercial clotting factor concentrate, I feel that wherever possible we must initiate home therapy programmes on the basis of Cryoprecipitate. Mrs [X] has a deep freeze, but is not sure of its temperature range. However, if this turns out to be satisfactory (and of course the BTS will have to be satisfied with this) I think we should encourage her to continue on the basis of Cryoprecipitate at home, although we can get powdered concentrate for travel.

"I have not made a further appointment, but have asked Mrs [X] to bring" --

SIR BRIAN LANGSTAFF: Just pause there. We've lost the bit on the screen because of the highlighting.

MS SCOTT: I beg your pardon, sorry.

SIR BRIAN LANGSTAFF: Sully, can we move the --

Thank you.

MS SCOTT: Thank you, sir.

"I have not made a further appointment, but have asked Mrs [X] to bring [presumably her son] to Tropics on the next bleeding occasion so I can be satisfied that a) she can needle properly, and b) she is confident about re-constitution of Cryoprecipitate."

So we can see from this the process of you consulting with Dr Martin in relation to a child patient; is that right?

A. That is correct. Can I just offer my profound apologies for the somewhat *maladroit* wording of the first paragraph? Those are words which I would not use these days about people having "slight histrionics". So I regret that particular use, it was not appropriate.

This was a lady who was clearly concerned for her son who was then, as I say, a remarkably lively little chap so, clearly, I warmed to him as a person, as a little boy, and she was exhibiting the very

straightforward and understandable anxieties about the future of her son.

So, on behalf of us as professionals, I would say I regret that wording. Of course, it's quite extraordinary how one's past catches up with one and something you think is confidential, will never be revealed to the public, that's a lesson that I think is very profound for the whole of this Inquiry. The amount of confidential material that was inappropriately confidential and which hampered communications was quite profound. But I do apologise for that.

As for the rest of the letter, I was -- I only saw this a week or so ago, and I have to say that, apart from that first sentence, as far as this letter was concerned, I was quite gratified to be reminded of this particular episode, which I had otherwise almost completely forgotten and it is rewarding to have even a little bit of feedback from a patient, even though, as I see from the rest of the document, it was the beginnings of a really rather tragic experience for this man.

But, nevertheless, it did confirm that we were training people to give cryoprecipitate at home, although I developed reservations about that later on because of the nature of the material and of the

alternatives that could be given. But, in those days, when there was very little NHS Factor VIII around, if one had to give Factor VIII it was either commercial or cryo, and cryo was obviously, at that time, an option I preferred for certain types of people and that included this mother and child.

Q. You set out there that the pressure, if I can put it that way, on you as a prescriber, in terms of paying for commercial clotting factor and that --

A. Yeah, we were given a budget, and it was a fairly tight budget, and I was very keen to keep to it. And the budget was about £40,000 a year to buy commercial Factor VIII, and I think in that particular year I spent £50,000 and the treasurer was actually pleased that I hadn't spent any more. He was expecting a hugely bigger sum but we were trying to keep within reasonable bounds.

But, nevertheless, there were certain financial constraints and that's why, for certain patients, I felt that cryoprecipitate was a good option.

Q. So you were reserving the more expensive commercial concentrate for this patient for when cryoprecipitate really couldn't be used, for travel, and so on?

A. I think that's right. I mean, children would respond -- you didn't need to give much cryoprecipitate in terms of volume to a child, so that child was only exposed to the

number of donors who contributed to that cryoprecipitate pack, which might even just be one, or maybe two or three people. But, as they grew up and their blood volumes got bigger and they needed much bigger doses, one was sometimes forced to use materials that they could inject more easily, because the concentrate was made up in much smaller volumes of water, so that an adult may only need to inject 10 or 20ml of liquid that contained commercial concentrate, compared with the equivalent volume for Factor VIII content of cryoprecipitate.

So children were more tolerant, in a way, of receiving cryoprecipitate but, as they get older, needing more, we had to resort to the more concentrated forms of commercial concentrate.

Q. Can you recall how many of your patients you had on home treatment with cryoprecipitate?

A. I can't recall with any accuracy -- seeing this reinforced what was on the earlier displays that you showed -- that cryoprecipitate was being used. But I cannot remember how many patients. It was probably not a large number. By which I mean, you know, half a dozen or so, I think. But I have no clear memory of how many people I would be treating with cryoprecipitate at home.

Q. For those patients that you considered to be appropriate to -- and would be able to manage cryoprecipitate, did it work reasonably well as a method of home treatment?

A. Well, I think it's the patients and their parents themselves who are more qualified to answer that question, mainly because of my lack of memory. But the fact that it was documented in the returns of 1977 that we were doing it, as well as this particular child receiving it, confirms that some people were able to use it and, presumably, with some satisfaction, although I think it wouldn't be surprising if sometimes the -- we had to resort, even for those children, for concentrates. And I think that is what happened to this particular boy.

Q. Now, you've just told us that one of the factors that was important when deciding whether a patient should get cryoprecipitate or factor concentrates was the age of the patient. Were there any other factors that you took into account when making that decision?

A. Well, apart from the social circumstances that the child or their family or the patient were actually living in, which was quite an important factor in advising how to care, I think probably the cryoprecipitate was more reserved for the smaller people, which would be basically children.

Q. What about when you were making that decision for a treatment -- for a patient who was coming into hospital for treatment, say somebody that's not on home treatment? What factors would you take into account when deciding whether or not to give them cryoprecipitate or factor concentrate?

A. I think cryoprecipitate was preferred for most of those who attended the hospital. Either for a day treatment or for -- admitted for several days. Those circumstances, although I've described it was time consuming and people would be in some pain, we -- if we heard in advance that a patient was coming, we would have time to start forming and preparing the cryoprecipitate in advance.

So, consequently, we would be able to prepare the cryoprecipitate ready for them to use -- to be given, and also we, ourselves, were reconstituting the cryoprecipitate under controlled circumstances; we, ourselves, would be putting the needle, although sometimes the patient still preferred to needle themselves, once they'd got expert at doing it.

But it was done under more controlled circumstances in a health setting, which lowered the threshold, if you like, for using cryoprecipitate.

The other thing about cryoprecipitate that is

important is that it was accompanied by a significant frequency of adverse reactions, mostly fever and headache. And, somehow, the children seemed to be more resilient, I think, for this, whereas the older children and adults were more prone to having these adverse events.

And it was much easier to deal with those adverse events when they were actually in the direct care of the nurses and doctors administering the Factor VIII. So, in many ways, cryoprecipitate was reserved for hospital care because we could keep a closer eye on the circumstances of the actual infusion, whereas at home we would be less able to keep a close eye, that would have required a standard of training, a standard of trust, a confidence among the parents that they were able to infuse the cryoprecipitate, and a confidence among the parents that they were able to infuse the more concentrated Factor VIII in dissolving it and preparing it for infusion.

So it's quite a long and complicated process. It's not just an easy thing to say "home therapy"; it involves an awful lot. And, actually, Peter Jones's book on *Living with Haemophilia* was immensely helpful in that particular regard.

Q. When you are faced with a patient who you want to treat

with concentrate, what criteria did you use or how did you decide whether or not that patient should get commercial concentrate or NHS factor concentrate?

A. Well -- and I think this mostly applies to the latter year, so -- because that's when we had a more substantial amount of NHS Factor VIII. One important thing is: why were they admitted? If it was for surgery and we were, you know, giving -- there were patients who required surgical episodes, either urgent or planned. The occasional orthopaedic surgeon would be required to do something for patients for a haemophilic joint. Under those circumstances, we required large amounts of Factor VIII and the most readily available sources would be the commercial.

For other episodes, for example dental extractions that could be done at home, these -- some dental extractions that could be done in an outpatient department of the hospital or the dentistry, we would possibly give either NHS Factor VIII or cryoprecipitate, accompanied by antibiotics and also antifibrinolytic agents to stop the clot dissolving. So, in those circumstances, we might be able to avoid the use of commercial Factor VIII but, quite honestly, I cannot recall any details.

These are something of a supposition from what

I can recollect about what our general policies for treatment were at that time and I don't think we can place too much reliability on what I've just said about whether we would choose to use NHS factor concentrate or commercial Factor VIII. But clearly there was more commercial Factor VIII around and so, consequently, they were used for patients as a sort of second resource, with the NHS Factor VIII being the first resource of choice but I cannot make an accurate comment on those policies going back 40-odd years.

Q. Did you introduce a prophylactic programme of treatment at Liverpool?

A. No, I didn't. I know that there were advocates of home therapy, but I felt that -- sorry, of prophylaxis and home therapy prophylaxis, but I felt that the home therapy programme was adequate in aborting the early stages of a bleed that the patients knew was going to be painful. And that was not a form of prophylaxis, but it was a form of treatment, a preventative treatment stopping an established bleed getting bigger. But I did not introduce a prophylactic programme in patients who were not experiencing a bleed who nevertheless inject themselves with enough Factor VIII to tide them over the next few days so that if they did have some sort of accident, the blood -- their blood would clot normally

within them. I did not do that as a prophylactic programme.

Q. So just drawing this together before we break, can we look at a paragraph in your witness statement, WITN3456002, page 28 of that witness statement, to understand what the treatment policies were during your time in Liverpool for people with mild haemophilia.

At the bottom of that page, you're asked:

"To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates?"

And then you say at paragraph 72:

"In 1977, of ten patients: one had only DDAVP; 8 had cryo; one had 'Koate'."

And if we go over the page, please:

"In 1978, of five patients, all had just cryoprecipitate.

"74. In 1979, of seven patients: three had just cryo; 2 had cryo [plus] DDAVP; one had cryo plus 'factorate'; one had just 'factorate'. I cannot recall the clinical circumstances."

So from that, do we understand that, certainly from 1977, the primary -- the preferred course of treatment for somebody with mild haemophilia was cryoprecipitate, and cryoprecipitate and DDAVP?

A. To be honest, I don't think that the patients were offered much of a choice of concentrate. In other words, I don't think they had an opportunity to say, "Could I have the NHS one, please?" Maybe that is regrettable, but for much of the time there wasn't much NHS around until the last year. So it was a little bit of sort of Hobson's choice. But nevertheless, on reflection, it would have been good practice to have reserved the NHS Factor VIII for some of the most needy cases, for whom -- who perhaps didn't require treatment quite so often.

That's a little bit of a contradiction, I realise, but there were some patients who were severely affected in terms of their Factor VIII content in their blood, the Factor VIII activity in their blood, but who didn't present very often, and if they needed therapy, they needed it properly.

There's no -- you couldn't go halves on this, and that's also true for people with mild haemophilia. If they needed a large amount of Factor VIII, because DDAVP would only give a boost and it wouldn't last -- and you couldn't give it the next day. You couldn't give repeated courses of DDAVP, it was the first dose that was the most effective, it was a sort of exhaustion effect of the stores of Factor VIII in the body.

A. I think so. This data in my witness statement is based entirely on the returns, which we've already shown. So I really cannot add any more details to this description. So I think I have to leave it at that.

But yes, for mild haemophilia, and indeed von Willebrand's disease, when DDAVP became available, that was the matter of choice. As again, particularly if they needed a dental extraction, in which case we would also give, as I say, antibiotics and antifibrinolytics. Saliva has enzymes that dissolve clots, so it was important to try to inhibit that. So that was part of our treatment programme, including DDAVP.

I think that's all I can really say.

Q. And again, drawing together what you've told us about those with severe haemophilia, is it right to say that it's not really necessarily possible to identify a first line of preferred treatment for all of those severe with haemophilia, it would depend on their age and their circumstances as to whether they should have cryoprecipitate or factor concentrates, and if they're to have factor concentrates it might depend on their own preference, or availability, as to whether they have NHS factor concentrates, commercial factor concentrates, and if commercial, which commercial?

But patients with mild haemophilia, as far as their activities were concerned, if they started bleeding, they could bleed very heavily and they needed quite a lot of Factor VIII. So perhaps for them, the first choice should have been NHS Factor VIII, but I cannot remember the details of my policy at that stage in 1979 in the Liverpool Haemophilia Centre.

So I can only give general comments and not perhaps what I actually did.

MS SCOTT: Sir, I note the time. Would now be an appropriate time to take a break?

SIR BRIAN LANGSTAFF: Yes, it would. We'll take a break until 11.50.

We're just starting a break, Dr Boulton. Let me tell you what I say to all witnesses at this stage. It's this: you're giving evidence, you must not discuss anything you've said in evidence with anyone, your wife, anyone else; you must not discuss anything which you think you may yet be asked to give evidence about but you can talk about anything else you like. I'll see you back on screen at 11.50.

A. Thank you very much, I take all those points.

(11.21 am)

(A short break)

(11.49 am)

SIR BRIAN LANGSTAFF: Yes, Ms Scott?
MS SCOTT: Dr Boulton, I'm going to move on now to ask you some questions about your knowledge of risk of hepatitis.

Is it right to understand that you have known since you started practice that there was a risk of hepatitis B being transmitted by blood and blood products?

A. From the start of my practice, I'm not sure when to define that, but certainly as students we were taught about serum homologous hepatitis, the fact there are two sorts of hepatitis, which became known as A and B, and the B was the homologous serum hepatitis that could be transmitted by, for example, injections using shared needles, as in vaccinations, for example.

As my training proceeded, we got more specifically aware, and while I was senior registrar at the London Hospital, I spent five months at the Brentwood Transfusion Centre, which is where I first learnt specifically about the tests for the hepatitis B surface antigen, which was still known then as Australia antigen, had been known about 10 years. But the testing was introduced for blood donors in the early 1970s, and I was actually taught by the scientists who performed those assays how to do them back in about 1972.

the hepatitis B virus. But it has a propensity in most people to over-produce that and it makes it very obvious. So it's easy to detect a person -- most people who are at the stage of carrying hepatitis B virus either because they've been acutely infected or because they're one of the minority who become a chronic carrier. And the chronic carrier state is quite important to us in transfusion, because those are people who are entirely healthy, well, asymptomatic, but do transmit the infection.

So we were aware that hepatitis B was an extraordinary virus, easy to detect, but not always foolproof. There were some people who, infected, did not exhibit this particular overproduction phenomenon, and also sometimes the carriers would go through phases with very low production of surface antigen, so it would still be quite possible for someone to test negative with those tests but still actually be infectious. And we knew that.

Q. You tell us in your statement that you understood from a very early on in your career the importance of pool size in determining the infectivity or potential infectivity of a blood product; is that right?

A. Absolutely, yes. There was some excellent early work done in the war, and actually I've also just seen

Q. Is it also right to understand that from the time that you were at the Royal London, that you understood that screening process did not screen out all cases of hepatitis B?

A. Um, I obviously learnt from the experience I recounted earlier that there was more than one form of serum hepatitis. So that, in a sense, one was not surprised to hear that others were aware of this particular situation. Dr Craske in Manchester in particular was very helpful in improving my understanding of that situation.

So yes, from the early 1970s, we were aware that not only was there other forms of infectious hepatitis, like hepatitis A, but other forms of hepatitis that could be transmitted by "serum", which included B but then other forms, which initially were called non-A, non-B.

Q. And that the screening processes for hepatitis B didn't pick up all of the hepatitis B infections, some of them still --

A. Yes, that's also true. Yes. That's also true. Hepatitis B is a strange virus in that it has of the habit in most people it infects of going through a phase of vast overproduction of this protein called the surface antigen, which is the protein on the surface of

a paper that came out in 1949 by Dr Lehane, who became the director of the Liverpool Centre, which also indicated the impacts of pooling. In those days they called large pools of the order of 300 donations in a pool, which is very much smaller than the pools that we became more familiar with in the preparation of Factor VIII concentrates.

Q. So is it fair to say that you have always known that there is a risk of getting a transfusion-transmitted infection from concentrate and that that risk was significant?

A. Yes, we -- that was well recognised by not only myself but all my colleagues. But -- and you may be coming on to this -- the consensus of opinion in the 1970s among haemophilia doctors, and indeed among many other physicians, was that the non-A, non-B form of hepatitis was often mild, even asymptomatic, and people might get an infection from it, but only be slightly ill, if ill at all, and in time would completely recover.

It was that complete recovery that in the end came to -- back to bite us, because we obviously learnt in time that most people with non-A, non-B hepatitis -- that became labelled as hepatitis C still -- were still affected for the rest of their lives, and their livers gradually deteriorated.

Q. Just for the transcript, you mentioned some work that came out in the war relating to pool size. I think you might have been referring to the work of Dr Vaughan in 1946, and for the transcript, that is RLIT0000052. I'm afraid don't have the transcript reference for the Lehane article that you --

A. No, that was very recent. I can send that.

Q. As I understand your evidence, you were aware, were you, of the publication of Professor Preston's study in The Lancet in 1978 in which he had carried out biopsies on asymptomatic people with haemophilia, and discovered a wide range of quite serious liver disease.

You're nodding. The transcript --

A. Yes, I will -- I mean, that was a remarkable piece of work. That was received in some quarters, including myself, with some incredulity at first. Partly because I think there was a sort of wishful thinking, partly because there were some criticisms about -- well, many of his patients, and there were eight biopsied, were middle-aged men, and there are lots of causes for cirrhosis in middle-aged men, particularly alcohol. So we were -- there was a certain amount of scepticism which, on reflection, was completely unjustified. Of course that is an incredibly bold piece of work.

There is also -- I know these things shouldn't

happen to the clear-cut academic mind, but nevertheless there was some reason to note the irony of the need to insert large needles through the skin into people's livers in order to get a bit of tissue. And if you do that to anybody, they will bleed. And if you've got a haemophilic there, then of course they will bleed even more. But Eric took the precaution of transfusing them with Factor VIII -- and I don't know where it came from, but I wouldn't be surprised if some of it was commercial -- to raise the activity of Factor VIII in those patients' plasma to normality, one hundred per cent. And that's a lot of Factor VIII, you had to give three to 4,000 units, and it only lasts for about 12 hours, it starts deteriorating immediately.

So he was giving the very materials that were potentially causing the problem to people with -- by doing the liver biopsy.

And so there was a sort of atmosphere of incredulity about the whole thing. But Eric is a very fine scientist, as is the tradition from Sheffield anyway, and we should have taken more notice of that. We still rather hoped that even if there were signs of cirrhosis, if the people were asymptomatic and leading normal lives, they were -- the actual clinical consequences would not be quite so severe as the

biopsies indicated.

It's a classical case of looking at the patient, seeing how they are, and then noting what the laboratory investigations say without necessarily linking the two. So a bit of self-denial among the haemophilia doctors community. And I include myself in that. And we were wrong. There's little doubt of that.

Q. When you say you should have taken more notice of that paper, are you referring there to amending your prescribing practice to turn away from factor concentrates back towards cryoprecipitate?

A. There was a lot of talk, not so much then, but I think in the early '80s and particularly with the onset of -- of HIV/AIDS, that these infections -- these diseases that were caused by infections in the Factors that were being transfused to these people should have made us think more than twice about expanding the use of those concentrates. But the power of persuasion of those who witnessed -- and that's not just the families but the doctors -- who witnessed the instantaneous relief of the suffering that could be -- that could follow, that did follow the treatment of the haemophilic bleeding episode with these concentrates, it was -- this was miraculous. I mean, haemophilics before the 1960s had to lead an extraordinarily limited life. They were crippled and

their life expectancy was short. And I think others to the Inquiry have given witness to that. And certainly those haemophilics who I saw as a student at St Thomas' were brave young men already incredibly disabled.

So the prospect of being able to reduce or even prevent that degree of crippling by a relatively simple procedure of intravenous injection, that people could learn, sometimes even the patient themselves could learn, offered a bright future for these young men. And the persuasive power of that image -- it wasn't just an image, it was direct experience of the -- not just of the patients but of those treating the haemophilics -- was very, if I can put it that way, seductive. So we felt, as a community, that it would be wrong to radically alter the approach.

There were stages when people thought about reducing it a bit and reducing the commercial doses a bit and improving the cryoprecipitate a bit, but actually, these were quite difficult to enact on a large scale.

Q. Would you agree, as a matter of principle, that patients being treated with factor concentrates should have been told that a risk of that treatment was contracting non-A, non-B hepatitis when you were practising in Liverpool?

A. Yes, that is a fundamental principle. And, to my recollection, we did as doctors, try to -- well, we did -- we did not deny and we actually did assert at opportunities that there was a risk of infection in the materials. But in the late 1970s, even after Eric's paper, which is why I say we should have learnt more, there was still a feeling that that risk was acceptable because the infection symptoms were short lived and, as far as we could see, the long-term effects were minimal, so consequently the short-term disadvantage of a short period of relatively mild jaundice -- although some actually became quite ill -- that short-term effect was outweighed by the long-term benefits of not being disabled as their predecessors had been.

So I think we did tell patients and their families but we almost certainly underplayed it. I can certainly remember speaking to the haemophilics in Liverpool in the newly formed branch of the Haemophilia Society about the prospects of treatment and the patients were excited about the possibility of leading a life like diabetics, who were injecting themselves every day with insulin, and I sort of acknowledged the validity of that aspiration, but -- and I think others may need to be asked about this -- but my recollection is that I did say that little bit of a "but": there is a risk

associated with every injection and that could include infection.

But I, almost certainly -- in fact, I'm sure I did -- underplay that particular risk, and so the good news suppressed the bad news in practically everybody's mind.

Q. Just unpacking some of what you've said there, is it right to understand that the primary way of patients being informed of risk from treatment came through contact with the Haemophilia Society, rather than being told on a one-to-one basis when they were getting their treatment from you as their clinician?

A. I think it was both. It so happened that the Haemophilia Society branch in Liverpool, the setting of that was encouraged by myself, but not every haemophilic attended meetings of the societies so, consequently, it would have been quite easy for them to have missed information. So it was incumbent upon us to actually inform every patient that there was a risk. But how well that was done, I have doubts. I think it was -- probably the message was transmitted by me rather than inadequately in retrospect, looking at what we now know.

Q. You have said that you almost certainly underplayed it and you've used the word "inadequate"; why was that? Why was that approach taken?

A. Well, as I said earlier, it's because the visible benefits and the relief of suffering that these concentrates were able to produce seemed so much greater than the apparently minor adverse reaction of suffering from a short-term burst of hepatitis. So we got the balance wrong. So basically, as I said, the good news suppressed the understanding of the bad news.

Q. Were your patients subject to liver function tests at appointments?

A. No, I don't think they were, not as a routine. If they showed signs of jaundice, then they would have been conducted. But not as a routine.

Q. If you suspected that a patient had been infected with non-A, non-B, would it have been your practice to tell them that?

A. Or indeed with hepatitis B, yes.

Q. Well, yes, so you would have -- if you'd got abnormal liver function test results back and suspected non-A, non-B, you would have told the patient that under your practice?

A. Well, I think it worked like we had regular follow-up clinics, so roughly every three/six months, or so, for an individual haemophilic. So they would come, we would ask "How are you getting on? How are you managing your home therapy?" et cetera, and they would answer. If in

that conversation there was apparently "I felt a bit ill, I felt a bit funny the other day or last week", at that point we might do -- include tests of liver function for those patients and, if they were abnormal, we would (a) test further specifically for hepatitis B, because that was -- that test was available, obviously no test available for hepatitis C. It wasn't even called that then.

So the combination of disordered liver function and hepatitis B was certainly *[audio disruption]* worth passing on. And I imagine that we did so. But I have no recollection of precise conversations of that nature in the clinics. But that's what the follow-up clinics were for, to check not only how they were coping with the haemophilia, but how they were -- what their general state of health was.

So there were ways in which we could be informed but I don't think we regularly -- I don't think we conducted liver function tests on patients at every clinic they came to.

Q. Would you accept, as a matter of principle, that if you had made a diagnosis of non-A, non-B, to the extent that it could be made, a diagnosis could be made, given the limitations, would you accept, as a matter of principle, that the patient should have been told?

A. Yes.
Q. Do you have any recollection of giving advice to patients about lifestyle and infecting others, if you had made a diagnosis of non-A, non-B?
A. Which would include reference to their sex lives, for example?
Q. Precisely.
A. I think probably not on a regularly basis. I mean, the attitudes to those personal lifestyle matters were very much more constrained in those days, although obviously people working in the -- the staff working in sexually transmitted disease clinics would have a very different take. But I think -- and particularly with mothers and young children -- we would not really be referring very much to those lifestyle aspects.

And certainly in Liverpool, the attitude towards those lifestyle factors, and including injecting drug use -- and, by the way, it's much better to use the term "injecting drug use" than "intravenous", because some drug users don't intravenously, they actually do it by cutaneous injection. But we rarely, if ever, touched in any detail on that aspect of the lifestyles of the haemophilics and their families, back in the 1970s.
Q. In your statement you have suggested that some information was given about the risk of needle-stick

injury, for example, for a patient that had hepatic illness or hepatic virus, but you say that you had no evidence to suggest that the parents, when you were giving this information, understood the risks that -- understood what you were getting at -- I paraphrase, but can you tell us a little bit more about that?
A. I think so. I think I can. I'm not sure if the risk of infection was specifically identified. So, in other words, when training a mother how to inject her son, we would have said, you know: take care about these needles, of course they are sharp, that's why you have to be careful about your technique of injecting your child. But I am not sure if the specific risk of hepatitis transmission from the contents that they were injecting, how much that was emphasised.

But, clearly, the risk was that the concentrate was reconstituted in water at home, taken up into the syringe through the needle, so that needle was obviously then -- it was -- it contained the therapeutic materials. It was then injected into the child and if, in the meantime, a mishap occurred, and the mum scratched herself with that needle while giving the injection, that was an undesirable event.

Whether I stressed that the undesirability was as much to do with the contents of the vial being at risk

and how much it was due just to the undesirability of an unfortunate accident like that, in general -- you don't want to hurt yourself unnecessarily -- I cannot really accurately recount. So it may well be that the mums didn't really understand -- excuse me using that phrase -- that the parents giving the injection didn't really understand the risk was in the materials they were giving.

They were much more concerned about the benefits from the materials they were giving and the risks was, sort of, put in the background, and probably my training schemes didn't emphasise that aspect to them as much as probably it should have done. So that's the way it went. As time went on, we learnt much more about how to deal with these things. But that was a difficult phase, at that particular time in the '70s, when home therapy was expanding, because the benefits were so obvious, and the disadvantages were much more obscure.
Q. Were referrals made to hepatologists for those that had a diagnosis of hepatitis B and a diagnosis of non-A, non-B?
A. Um, when the -- patients who developed jaundice, whether it was identified as hepatitis B related or not, would have been seen by a physician, referred to in the hospitals, both in the children's hospital and in the

adult hospital.

But actually it was really quite rare. There were a few, as you will see from the tables, about up to six different people, although sometimes there was some double counting, who in my time did develop clinical jaundice. They would not only have had their liver function tests determined but they would have been referred to a physician, and also their GPs informed. But I honestly cannot remember specific episodes of such referrals.
Q. What role -- you touched on this to an extent, the role that patients had in choosing their treatment at the time you were in Liverpool, and I think you said they didn't get a choice between NHS concentrate and commercial concentrate but, as I understood what you were saying, if they had a preference for a particular type of commercial, that may have -- they may have had a say in whether they wanted a particular type of commercial if they found one easier to use than another? Is that a fair assessment of -- a fair summary of what you have said about their --
A. It may be a slight overinterpretation because all these things come from a memory, which is of events of more than 40 years ago. But I do remember conversation, not least at the meetings of the Haemophilia Society group

which I met, of discussions about the problems and the choices that they had of giving Factor VIII concentrates. I think all of them would have preferred the NHS, had that been available. But, even in 1979, even though there was considerable increase in the productivity from the BPL laboratories, it was still in short supplier.

So I think, in many cases, they just had to accept what was made available to them. So there wasn't that much choice about it, although there could well have been preferences.

Q. Would you agree, as a matter of general principle, that treatment decisions for patients involved weighing up the risks and benefits of one product against another?

A. Among commercials, I don't think there was much differentiation. But I think people, on principle, would have probably preferred the NHS, had that been available in the quantities that were required.

So I think the dividing line in choices would have been between NHS concentrates and any of the commercials, the latter being given roughly the same degree of acceptance compared with the rather greater desirability of the NHS concentrates, for reasons which they understood on terms of pool sizes and where the materials came from. In other words, often

North America for the commercial stuff, but only British people -- people donating in Britain for the NHS concentrate.

Q. And they knew the risk, the difference in the risks between the NHS commercial and -- the NHS and the commercial because you had told them that or because it was generally well known, amongst the haemophilia --

A. I think it was generally well known among the haemophilia community, but -- because probably out of a sense of, as much as anything else, a national loyalty to what the NHS was able to do. So if the NHS was able to produce something that worked compared with a commercial company that was being paid, then ideologically, the -- everybody, including the patients, would have preferred the NHS.

But it was a sort of in -- ill-defined as that. When it actually came to the hard facts, data, that here was something that could save your life, stop your bleeding, and -- save your life, stop you from bleeding to death, there was a sort of more pragmatic approach about -- what they wanted was something that worked, rather than where it came from.

Now, I have to emphasise that these are recollections and impressions and what I, in a sense, would like to think I would have done under those

circumstances. It may well be that my performance, had anybody been around to witness it and document it accurately at that time, was not up to the ideals which I have perhaps currently said. So I do have to point out that the ideology which we've all been able to develop since may not have been fulfilled quite so much in practice -- in my practice -- for the haemophilic communities in the late 1970s.

Q. I've just got one more topic to ask you about before we move on to your time in Edinburgh, and that's record keeping.

What was the system for recording products received and batches used? Were records kept as part of the patient's medical records or were they kept separately?

A. I think there were two systems of recordings.

The main one would be in a patient's notes. Every time a patient received a blood transfusion or transfusion of blood products, the requirement for the doctors writing in a patient's notes, sometimes with the help of the nurses, was to document not just the fact that they'd been transfused but with the specific donation number of the transfusate.

And it is sometimes accompanied by laboratory forms that were sent back to the ward, including those

precise identification markers. So those should have been inserted in the patient's notes every time.

Obviously with a haemophilic, receiving lots of treatment, they would have been -- they would have accumulated and got a very thick set of notes, but that was the accepted.

So that's what should have happened, and I'm pretty sure it did happen in Liverpool.

The other set of records would, of course, be in the laboratories, where there was patient data associated with the laboratory findings, because quite often -- not always, but quite often -- particularly when covering surgical procedures, the samples were taken for assay, those assay details were recorded and kept on record in the laboratory files. So those would be less complete but there would still be records.

And I would imagine after I left Liverpool, those two sets of records still formed the principal of data access for subsequent searches.

Q. What about home treatment records? Were patients or patients' families expected to keep those and return them to the centre?

A. They were expected to return the -- well, yeah. Sorry, let me just go back on that.

I honestly can't remember exactly what the home

therapy patients in Liverpool were -- what instructions they received about disposing of the waste materials, the products and needles, et cetera.

I think this would be the days before sinbins, so they were still instructed to take care about the disposal of the needles and that goes back to my previous recollection that I think that the people who were doing home therapy were certainly advised to take care about the disposal of the waste products.

The batch numbers of all the materials they were given should have been recorded in the patient's notes, whether that was the case or not, I cannot honestly answer, but they should have been recorded in the patient's notes. And that would have been the main record, because the ward would have had a refrigerator where these materials were kept. So, although they came from the blood bank and the blood bank would also have kept details of the batch numbers, the ward would have known -- would have been able to identify those that they were giving to the patient.

So, ideally, there should have been a record of the batch numbers on every bottle of Factor VIII concentrate that was given. But I honestly cannot recollect the details of how that system worked.

Q. Can we look at a document, it's HCDO0001093. It's

a document we've already looked at. It's the 1977 returns.

Sully, can we go to page 3 of that document, please. This is a letter from you to Ms Spooner at the Oxford Haemophilia Centre, dated 23 September 1977, and you say this at paragraph 1:

"I recall, rather shamefacedly, that when I saw you in Oxford on the day of Dr Biggs's retirement I promised to send you our Annual Return at our earliest opportunity. All I can say is that the final compilation has not been quite so easy as some of our medical records have the annoying habit of going missing just when they are wanted."

Then the next paragraph you say:

"However this is the best I can offer you at this stage. As you will remember from a telephone call some months ago I feel I am not able to take part in Dr Kirk's jaundice survey and this is a bit regrettable as two of our patients have had some form of hepatitis during 1976/1977."

Then you say:

"I would like to amplify a bit on those two cases."

Then you refer to one case, and it's just the first part of that in relation to records that I want to

draw your attention to. You say:

"[The] man was treated with a batch of Kryobulin to cover a vasectomy, but unfortunately the doctors who with do the material failed to observe the departmental rule of the registration of batch numbers, etc. This has been a salutary lesson to me and I have tightened up our recording procedures but I must comment that, with the best will in the world, little can be done about doctors who fail to observe the rules."

So, just pausing there, then. There seem to have been two problems that you've identified in this letter, first of all problems with the recording procedures, which you've just told us about, and having to tighten up the rules and, at the beginning of that letter, the records have an annoying habit of going missing. This letter might give an impression of a somewhat chaotic recording and record-making system at Liverpool at the time you were there. Is that a fair conclusion to draw from this letter?

A. I think it's fair in one sense that it was highly undesirable, but this is not a unique experience, particularly for patients who were regular attendants at the clinics and on the wards. There would frequently -- they would go missing in transit. So the wards had their record collections, the outpatient clinic would

require those records to be available to me when I saw the patients, and after I saw the patients and made my extra notes, I would put them on one side for them to be returned to the ward when possible.

With the best will in the world, sometimes it would be some days, or even occasionally weeks, when the records were not locateable with any great ease.

I think that was a day-to-day experience in many hospitals up and down the country in many specialties, so it wasn't unique. It's fair to comment on the chaos that surrounded that particular system, but I am sure this was not a unique experience, one of those that we sort of shrugged our shoulders and got on with.

It was difficult, it made life difficult to make accurate records at the appropriate time and, therefore, would prejudice the quality of those records. But these are busy hospitals, with regular recurring patients and ever-growing notes and finding pages missing in the notes was all much more difficult.

That's the problem with paper records. Similarly with donor records, when computerised systems became available, theoretically they should have been much more accessible through local devices, but those were the days of intensive paperwork, and depended upon the commitments of the -- those who were working and writing

the notes and keeping them as to how they would be used, and made available to others.

So it was a sort of standard expectation but -- and it was chaotic, but I think not more chaotic than was often found throughout the health services.

Q. I'm going to move on now to ask you some questions about your time in Edinburgh. Just to remind ourselves of the chronology, we're now in 1980 and you spent 10 years in Edinburgh, first of all as a consultant, and then 1982 as the deputy director of the Edinburgh and South East Scotland Centre.

Now, we've heard oral evidence from both Dr Gillon and Dr Brian McClelland, who have covered some of the issues and events during the time that you were there, so I'm going to just pick up some specific issues with you, rather than run through all of the matters that are set out in your witness statement.

First of all, I'm going to ask you some questions about the centre itself and the role that it had. You describe to the Penrose Inquiry the South East Scottish Transfusion Centre being a transfusion centre that also had an active clinical base. What did you mean by that?

A. One of the reasons why I was attracted to the Edinburgh post was that, unlike the standard system in England, where you have a Regional Transfusion Centre that is

separate from the hospital activities, sometimes in the same grounds as the hospital but actually organised as a separate unit, and sometimes quite remote from the working hospitals.

So the Transfusion Centre would be solely concerned with the collection and testing of blood donations with -- there would be reference laboratories that would do the specialist investigations mostly on rare blood group types for suitability of a transfusion to patients. So the patient contact was much less from the English centres, and I think -- well, in fact, I know the same really occurred at Glasgow when the centre was at Law Hospital, which was like 20 miles away from the main Glasgow hospitals. Whereas in Edinburgh, and the other centres in the east of Scotland, the centre was not only within the geographic hospital, but also directly issued blood for patients who were identified and crossmatched in the labs of the Transfusion Centre and not in the labs of the haematology laboratories, which is the case in most other hospitals.

But furthermore, in the Edinburgh Centre, there was a laboratory for haemostasis and blood counts. Blood counts were standard in Transfusion Centres, of course we needed to have some sort of investigation into

the donors who were anaemic, so we were able to do blood counts but, in Edinburgh, not only were we able to do blood counts, we could do platelet counts on donors and we could do also clotting factor assays on donor plasma.

Also, this laboratory was available -- serviced the hospitals, and particularly the Royal Infirmary, for patients who had acquired bleeding disorders or thrombotic disorders as a result of an acquired condition, often surgery or some other illness, including liver failure. And so we were able to investigate those patients. So there was a rather greater availability to the hospital clinicians of investigations, laboratory investigations, for patients, conducted in the transfusion centre which in other places would have been conducted in the haematology laboratories.

I was given that responsibility for the clinical advice from that extra laboratory and particularly for the clotting factors associated with patients, because it wasn't just haemophilics who had abnormalities and clotting factors. So, although Christopher's laboratory would also have been able to and did the assays of Factor VIII and clotting investigations, particularly on the haemophilics, there was a sort of competition between the two, and I wouldn't blame Christopher at all

if he felt that we were intruding on his territory.

But, for me, that was one of the reasons I came up. I was advised by Dr Cash when I came that this facility was available and I found it very attractive. It enabled me, for example, to participate actively in audits around the hospital of blood usage, and particularly useful, and I think this has also been commented by others, for the cardiac surgery. When I arrived, the cardiac surgeons basically wanted 10 pints of fresh blood for every open heart surgery operation they conducted.

By the time I left, partly due to my work but also partly due to increasing awareness among the surgeons and particularly the anaesthetists, the use of blood was much more rational, much more use of red cell concentrates and much less emphasis on the freshness of the blood, which actually caused quite a hurdle in the provision of services, because it does take time, when a transfusion centre has received the blood from a donor, to get it tested for and suitable for transmission, usually two days at least between receipt and availability for issue. And those -- the virtue of the freshness of the blood would disappear within those two days, according to the surgeons.

And there was some justification of that

particular thinking. But as a result of my close contact with the clinicians, physicians and particularly the surgeons, we were able to develop an audit system. And that was all to the good of the standard of practice within the hospital.

But that explains a little bit sometimes of the interactions between Christopher and myself that went on.

Christopher was also very busy looking after other patients. Again, for him, only part of his service was to do with haemophilia, although it was a very important -- and he was very committed to that, but we were both busy doctors doing other things, but ultimately, very committed to high-quality standard patient care. And I, having left Liverpool, knew that I was deserting, if you like, the haemophilics there, about which I felt quite bad, not least because I never had to face up to the difficult conversations with those haemophilics in the -- and their families -- in the 1980s. And I felt bad about that.

But I was, therefore, an experienced haemophilia doctor in the hospital, but I did take care to intrude minimally on Christopher's practice. It was his job, and my -- I had a different job. And I think I said that to the Penrose. So that we respected each other's

interests and commitments, and indeed what we were expected to do, but there were times when we had to have open, friendly, frank conversations about how we actually approached a particular deal. And that came particularly for when it came to assaying haemophilics who were receiving the new heat-treated products to see how effective they were, not just clinically but also by the lab tests.

And so there was a real need for Christopher and I to work together, as well as the need to work together on ensuring he got adequate supplies for his own expanding home therapy program.

Q. Dr Boulton, we'll come on to look at some of those issues you have just told us about in a little bit more detail, perhaps by reference to some documents.

Just picking up, then, on the work done by the centre, did the centre do ALT or AST testing of people with bleeding disorders?

A. No, I don't think we did. Just as in Liverpool, the Edinburgh Centre would have referred those samples to the local laboratories in clinical chemistry, I think, for those particular determinations. So I don't think we had a lab in the Centre that would do those tests.

Q. And what about white cell or immunological testing?

A. Well, we were an immunohaematological unit, blood transfusion is sometimes described as immunohaematology, so I'm not quite sure what you mean about the -- what you were referring to?

Q. It's a question I've been asked to ask you, so perhaps we -- so perhaps we can -- I can get some more detail --

A. Well, we were doing tissue types for patients in relation to the organ transplantation. We were looking at lymphocyte subtypes. That was part of the immunological aspects of the work in the Centre. So we were pretty thoroughly involved in immunohaematological investigations.

Q. We heard evidence yesterday from -- as -- we'll come back to some of those issues, but, just before we do, we heard evidence yesterday from Dr Gabra, who said that in Glasgow they were heating plasma over many years, and he thought that the same was happening in Edinburgh.

Do you have any -- can you assist us with whether that was taking place in Edinburgh or, to your knowledge, in Glasgow?

A. I didn't know about the heating of plasmas in Glasgow. We didn't do any heating of plasmas in Edinburgh. What was going on in Glasgow, which was intriguing, was that they were freeze drying units of cryoprecipitate, in other words they were exposing donations of plasma

collected -- that were decanted into bottles, and treating it in a freeze dryer in a way analogous to that which was developed at the Protein Fractionation Centre for freeze drying the fractionated concentrates. So Glasgow was keen and had been doing for a long time a freeze drying of plasmas, and they extended it, I believe, in the 1970s, to the freeze drying of cryoprecipitate.

I think -- and the idea there would be that we could have bottles of cryoprecipitate that, instead of expiring within hours, unless it was deep frozen, these were cryoprecipitate preparations that could be stored for months or years, and then reconstituted in a few minutes by adding water in the same way that the Factor VIII concentrates were being reconstituted.

So those were being prepared from the Glasgow Centre. They may have been heated, I just don't know.

My understanding is that the -- sadly, the freeze drying apparatus in Glasgow, which was of Second World War time vintage, by the 1970s had become -- it had failed the standards of Good Manufacturing Practice required by the Medicines Inspectorate. So, consequently, the process of making and distributing freeze-dried cryoprecipitate for the use of haemophilics

within Scotland, or even in Glasgow, I think it never really got off the ground in the way that the Glasgow Centre Directors hoped. But that was certainly a valid aspiration, and it was worth trying to do.

But what happened in Edinburgh, of course, is the Protein Fractionation Centre moved out to Liberton Hospital sometime in the mid-1970s and took with them the equipment, including the freeze dryer. So the Edinburgh Centre was never in the position itself of freeze drying plasma or cryoprecipitate in quite the same way that Glasgow was hoping to do.

Q. I'm going to pick up now on some of the points you mentioned earlier in terms of consultation and discussion with your clinical colleagues about the use of blood and so on, and the audit of the use of blood.

We've heard from other witnesses the use of blood ordering schedules. Is that a practice that was used in Edinburgh?

A. Yes, we did. We developed the MbSOs, and I -- that was developed in quite -- in quite some strengths.

Q. And you have made reference to having various relationships with clinical colleagues. Was the audit and the training and discussions that you were having limited to those colleagues in the Edinburgh Royal Infirmary or was that work you did throughout the whole

area covered by the Edinburgh and South East Scotland Centre?

A. Well, I understand what you're saying, because the -- but just to clarify, which I think you've already got, the blood bank provided by the Edinburgh Blood Transfusion Centre, sited in the main Royal Infirmary, also supplied blood to small peripheral hospitals that have long since closed, the Elsie Inglis, the Bruntsfield Hospital, and others that are scattered around Edinburgh that had an interesting history providing specific services -- Bruntsfield for women in particular, for example. So only about 70 per cent of the blood which we distributed to the Edinburgh hospitals was distributed to the Royal Infirmary.

There was the other major hospital in Edinburgh called the Western General Hospital, which was also staffed by haematologists -- an excellent haematologist, Dr Norman Allan -- who had their own blood bank, so we would supply the blood to them but they did the cross matching. They did not treat, as far as I'm aware, any haemophilics at all. That was specifically for us in the Royal.

But the -- that hospital was a significant user of blood and they would have been drawing up their own blood ordering schedules.

Similarly for the more remote hospitals in Melrose and in Livingston in West Lothian.

So consequently -- and also, I think, in the Kirkcaldy hospitals, because I think I forgot to say, but the others would have said, that the Edinburgh Centre also distributed hospital blood to hospitals in the south of Fife, across the Forth.

So consequently, although we in Edinburgh were crossmatching blood for -- mostly for the -- although the blood we distributed was -- went to several other hospitals, most of it went to the Royal Infirmary but the Royal Infirmary also had satellite hospitals, and our efforts on blood ordering schedules would have been concentrated mostly on the practitioners in the Edinburgh Royal Infirmary.

That, of course, was facilitated considerably when the realignment of hospitals to the new Royal Infirmary occurred, somewhat after my time.

But yes, it -- we were doing the services, we were doing it for surgeons and for some of the physicians as well, but it was -- it came to be more expanded as the services within Edinburgh also got modified with the new hospital buildings.

Q. I'm going to come on to ask you some questions about your role in terms of procuring PFC concentrate for

Dr Ludlam in the Edinburgh Haemophilia Centre, and discussions with him about the use and prescribing of that. But now I'm going to ask you some questions about -- and you've already touched on this in your answers earlier -- your role and your input with those people with haemophilia being treated at the Haemophilia Centre in Edinburgh.

We heard evidence from Dr Brian McClelland who told us that it was his impression or his view that those patients were, to use his phrase, jealously guarded by Dr Ludlam, and that you hadn't got -- didn't have a chance to have any direct dealings with them. Is that correct as a matter of fact, that you didn't have face-to-face dealings with the patients being treated in the Edinburgh Haemophilia Centre?

A. Brian was immensely supportive of me. He was a great colleague. And so, consequently, he would have been prepared to, sort of, defend me in those sort of -- any of those sort of situations. I'm not sure I would use the words "jealously guarded". I mean, Christopher did allow me to speak to his patients at one meeting of a Haemophilia Society gathering there. I was well known to the laboratory scientists in his department, and that included in the haemophilia laboratories. They knew me. We also knew some of the -- were working with some of

the senior registrars who actually rotated through the blood transfusion centre, so it's not as if there was a brick wall between us.

The departments were next-door neighbours. So it was inevitable that there'd be some informal, quite a lot of informal contact. So yes. There was -- Christopher was very keen to make it clear that he was the one who was now running the Haemophilia Centre. I had no difficulty with that. He had every right to expect that, and also to expect that *[audio disruption]*, and say, "Ooh, I think you've got that bit wrong". So, Christopher and I met within two weeks. We were both new, and I knew that he was wanting to expand his home therapy programme. Was fully supportive of that and always was.

As time went on, within two or three years, the expanding programme caused stresses on the supply, and so I was called in to advise Christopher. I think the words in my letters were "warn", which is a bit unfortunate. I think it would have been better to use the words "inform and advise" but, basically, I needed to clear with Christopher the degree of -- how the Transfusion Service and particularly how PFC could best respond to his requirements.

So it did require a regular set of meetings and we

had them and some of them are documented and the correspondence around them are documented in the Inquiry's files.

So we developed a working relationship, which I think worked well for him, and particularly even more importantly, for the haemophilics. Some tragically developed inhibitors, others tragically developed hepatitis, others developed AIDS, and that was awful, and I think you've gone through that episode in November 1984 when, to our horror, in the Transfusion Services, and also Christopher's own horror, a batch of PFC Factor VIII concentrate was contaminated with the HIV virus and transmitted it to, I think, at least 16 or even 17 patients, and one or two possibly in Glasgow.

So that was -- and it may -- whether it's one donor or two or three we never quite got round to, but it was probably a very small number of donors over those years, you know, giving hundreds of thousands of donations, who infected that batch. An absolute tragedy. And we never quite got to the bottom of how that transpired, but it was awful. For us, for Christopher, and in particular for the patients.

So that degree of cross-communication was vital.

I was under a bit of disadvantage, which Brian did his best to alleviate, in that there were meetings

between Christopher and the transfusion directors from which -- which I didn't attend. And I understood that.

Brian briefed me as much as he could about those meetings, otherwise I couldn't have done my job, but it was a little bit of a barrier from that side, but it wasn't as if the Transfusion Centre's meetings were jealously guarded. But even less so did I think that "jealously guarding" is really the best way of describing Christopher's attitudes.

So he and I needed to work together, we both recognised that, and, yes, it caused, you know, a little bit of blood pressure raising occasionally in the way that these conversations do, but it was a dialogue. It was not a debate.

And so, consequently, we, on the whole, got on amicably, and I would still say that if I were to meet Christopher again today, and I don't quite know when I last met him, we would be on the best of friends terms. So that's the sort of memory that I've got and that's how I think we behaved at the time.

But it was not always easy, I do have to say.

Q. So just picking up, then, on the role that you played between -- with the Haemophilia Centre Directors, and -- with -- sorry, the Haemophilia Centre. We'll look at some of the correspondence but would it be fair to say

that you were doing two things, really. On the one hand, you were providing Dr Ludlam with the PFC product, the Factor VIII product from PFC that he wanted and sometimes having to borrow and beg it from other areas because he had exceeded what you'd already given him; and, at the same time, telling him -- or you use the word "warning" or whatever the correct word is -- telling him, warning him, reminding him, to prescribe within the Edinburgh -- the South East Scottish Regional Transfusion Centre's allocation of PFC product.

A. I think that's correct, yes. And I think the correspondence speaks for itself.

Q. So, in a sense, you are almost carrying out a coordinating role between, on the one hand, PFC and, on the other, the Edinburgh Haemophilia Centre, and there's you representing the South East Scotland Regional Transfusion Centre and/or the SNBTS in the middle, coordinating between those two?

A. Yes, and the most valuable part of that coordination was the trialling of the various heat-treated products from PFC to see how effective they were, both clinically and with regards to the testing, and apart from the one episode which we may not need to refer to, when there was a misunderstanding, that was carried out with cordiality, cooperation, not least from the patients,

who needed lots of needlings to get the samples, and that was, in my opinion, highly successful and very satisfactory work, to actually be able to demonstrate that these materials were actually working.

We were not able really to test how safe they were hepatitis-wise or HIV-wise, apart from the *in vitro* tests on those materials to see how well they were inactivating viruses. So part of those trials did not really include a detailed study of their liver function; it was more directed toward the haemostatic functions and that was carried out in some detail with schedules that Christopher helped me draw up. So this was collaborative work of a very satisfying nature.

Q. We see you being appointed or taking on the role of coordinator of some of those research or clinical investigations.

A. And not just with Christopher but with outsiders such as Dr Mayne in Belfast and, indeed, Dr Bloom in Cardiff.

MS SCOTT: Sir, I'm about to look -- on the same topic but look at a couple of documents, and I note the time. I don't know whether it's appropriate to continue now for -- which will take us probably until 1.05 or possibly 1.10, or to take a break now.

SIR BRIAN LANGSTAFF: All right, let's take a break now, and come back at 2.00.

So 2.00.

A. Thank you.

(12.59 pm)

(The Luncheon Adjournment)

(2.00 pm)

SIR BRIAN LANGSTAFF: Yes, Ms Scott?

MS SCOTT: Before I return to my questions in relation to Dr Boulton's time at Edinburgh, he has asked me to bring up a table that he has put into his witness statement. He wants to say something about that.

It's WITN3456002 and it's page 26.

So here, Dr Boulton, we've got a table that you've put into your witness statement. The beginning of the table is on page 26. The table's titled "Liverpool Royal Infirmary Haemophilia Centre, numbers of patients treated and therapeutic materials used 1976-1979".

And you've put a note there:

"... some paediatric patients were treated at Alder Hey Children's Hospital."

And the table starts here and it goes over to page 27.

Could we have page 27, please.

And it continues there.

What would you like to say about that?

Can we try to get both pages up at the same time?

That's helpful, thank you.

A. Well, thank you.

Yes, this table is compiled entirely from the records which *[audio disruption]* that I was sent in advance, but I'm sure they are authentic and they are -- they're a distillate of the separate returns to -- which we discussed earlier.

I think this shows a bit more clearly, perhaps, and I took some time preparing this, and although I'm fairly -- I am very confident about the numbers -- one or two may be slightly exceptional, but they show, I think, a very clear indication of [audio disruption] developing uses.

First of all, the number of patients treated is different from year to year a bit, so that's the degree of variation. I think that by 1979 a couple of the adult haemophilics had died, I think one of a brain haemorrhage and one in a road traffic accident, so that's one of the reasons that numbers vary. And of course new ones present.

The amount of cryoprecipitate that was used was quite substantial, and it increased from 1976, and that 700,000 represents, to my calculation, about 10,000 packs of cryoprecipitate, which would be a significant output from the Liverpool Transfusion

Centre.

Then when it comes to the next row, the NHS Factor VIII use for haemophilics, you can see pretty clearly the very substantial increase in 1979, which is the result of BPL's success in increasing their general outputs.

And I rather assume that there are similar patterns from other centres.

If you go to the next page, you can see that in 1976 -- well, it starts off with the number 387,665 of the amounts of units used of the various commercial factors -- you can see that although in 1976 it's a bit higgledy-piggledy, it was Immuno Kryoglobulin, which was the Austrian product, which was dominating in 1976. But that was associated with the outbreak of hepatitis I believe in the patient who had a vasectomy under cover of Kryobulin, and he got the -- he was found to have hepatitis, and so we dropped it. So the next year is considerably less and I think the residual in 1979, that's 750, possibly represents the remaining bottles in the bank before they expired.

You can see that the most important, most significant replacer was the Armour product which dominated in 1978 and 1979, while at the same time of course the NHS product increased, and in that row

towards the end, "Total [Factor] VIII given", you can see how it almost doubled in total from 1976 to 1979.

I think that gives a fairly clear summary of the changing patterns of use in the Haemophilia Centre at -- by the haemophilics in Liverpool and at Alder Hey during that period, and I think that might be quite useful, I hope, to the Inquiry.

Q. Thank you.

SIR BRIAN LANGSTAFF: Just one question on these documents. It's really an arithmetical question, I think.

Can we just go back, Ms Scott, to the 1979 returns which we looked at earlier.

MS SCOTT: Yes. The 1979 return is at HCDO0001344.

SIR BRIAN LANGSTAFF: Yes. You see there the cryoprecipitate which is 7,000, roughly. Now 630,000 units, that I think works out at 90 per bottle. If you go back, please, to what we've just been looking at.

MS SCOTT: That's WITN3456002. I've already forgotten the page number, I beg your pardon.

SIR BRIAN LANGSTAFF: Yes, 3456002.

MS SCOTT: Dr Boulton, can you recall the page number?

A. I can't recall the page number I'm afraid.

But Sir Brian, you're absolutely right. The maths do differ a bit.

SIR BRIAN LANGSTAFF: The reason I mention that --

A. -- (overspeaking) --

SIR BRIAN LANGSTAFF: Sorry, the reason I'm mentioning that is on your table you say that you're assuming that it's 70 per bottle.

A. Yes.

SIR BRIAN LANGSTAFF: And obviously that doesn't work out, does it? There's a slight inaccuracy there.

A. You're absolutely right.

SIR BRIAN LANGSTAFF: I wouldn't have --

A. It --

SIR BRIAN LANGSTAFF: -- drawn your attention to it if it hadn't perhaps been that as a result it looks as though there's been more cryoprecipitate than any other single product in that year, whereas actually, on your figures, it looks as though there's actually been more of the -- what is it? Let me just find where I am.

A. The Armour?

SIR BRIAN LANGSTAFF: Yes, I think that's the Armour. That's it. Thank you.

A. Sir Brian, you're absolutely right. I have made one or two assumptions here, but it does illustrate the rather irregular characteristic of cryoprecipitate. Whereas all the concentrates were meticulously and accurately determined, their potency, cryoprecipitate is highly

variable. And my later experience, I think in Edinburgh, indicated that the average per donation was about 70. But it could be anywhere between 20 and 120, depending upon the volume collected, the way it was processed, the temperature it was stored at, and indeed blood groups have an impact as well, because people of blood group O have distinctly lower Factor VIII levels than people of blood group A, 90 per cent compared with 110 per cent, for example. So there is variability in the potency. And I have shown 70 per cent arbitrarily across all, so that although in the returns it's a bit variable, sometimes 90 and I think others were 80, this table has the virtue, if you like, of consistency, although it is bedevilled by the variable characteristics of cryoprecipitate.

So, yes, there will be an impact on the interpretation of the absolute values as recorded here, by that particular variable.

So, once again, it shows one of those problems with cryoprecipitate that made it a little bit more difficult to use. The patients -- or at least I never knew exactly how much Factor VIII the patients were getting, so we had to do a certain amount of guesswork.

And that's, again, one of the reasons why cryoprecipitate was often pooled, even in maybe only

three, because three would be just a little bit nearer the average -- you know, a third of the total value of three would be a little bit nearer the average of, I chose 70, compared with others. And later cryoprecipitates, when more plasma was taken from each donation, would have been a bit more powerful, because more plasma was taken from each donation for making into cryoprecipitate.

So I'm sorry, this is a fairly long-winded answer, but the cryoprecipitate is useful for a comparison, but not too much reliance should be placed on it for the actual units that were given. Of course, they were not directly assessed, whereas for all the others, the concentrates, commercial and NHS, they were [audio disruption]. Thank you.

SIR BRIAN LANGSTAFF: We have, I think, elsewhere seen, in respect of some of the commercial products, that what it said on the bottle was not necessarily what you got if it was assayed in the lab. Am I right about that too?

A. You could be but the lab's assays were just as vulnerable to variation, not error, but the -- what you're assuming is that the lab's performances are within, say, 95 per cent of what it says. There are different ways of assaying, there's one stage and two stage. There are different conditions under which those

assays are conducted. I had the advantage over some of the witnesses of actually performing assays of Factor VIII and IX in plasmas during my training, I learned how to do it. And it's an intriguing technique.

And furthermore, there are other techniques that involve what's called chromogenic, colour generation from precursors. These all tend to give slightly different absolute value, so it's one of those important features of laboratory medicine to realise that there is a variability on the values of the factors. And people themselves vary. So it would be fair to say that you couldn't totally rely on the number on the label of the bottle.

But I really doubt that the commercial manufacturers exaggerated the amount in there. Quite apart from anything else, they were subject to inspections. The Americans, the FDA was quite a fierce body, the federal drugs authority. So I think that they would have been very wary about massaging the numbers on the bottle.

But -- no, they might have done, but I rather doubt it. But there are other reasons. They would come back, if they were challenged, with all those points I have just made.

So biology is not physics. Physics you can do an exact measurement and, of course, it's very mathematical. Biology is real life, with all its variety and diversity. So that's where I leave it, Sir Brian.

SIR BRIAN LANGSTAFF: So the bottom line is these tables give you a spurious sense of absolute accuracy. The truth is they're a pretty good indication. Is that a fair summary?

A. Yes.

SIR BRIAN LANGSTAFF: Thank you.

A. Pinch of salt is very reasonable in that but I do think they give a reasonable representation of the varying patterns of usage, and the almost doubling amounts of Factor VIII given between '76 and '79. I think that is a reasonable assumption. It may not have been exactly 860,000 to 1,550,000, but it would be somewhere between, you know, 800 and 1,500, or 700 and 1,600, or whatever. So I think you can take it that that's a reasonable assumption, reasonable indicator, but not an absolute. Thank you.

SIR BRIAN LANGSTAFF: Thank you very much.

MS SCOTT: Dr Boulton, I'm going to pick up now where we left off before lunch. I'm going to turn first to a document, a letter that you wrote to Dr Ludlam, and

it's PRSE0003044. When it comes up on the screen we'll see it's a letter you wrote to Dr Ludlam, dated 10 May 1982. You start in the first paragraph by saying:

"Please find enclosed our Table of Haemophilia Home Therapy Patients and the amount of Factor VIII that they were ..."

A. "... that they were issued [with] for home therapy ..."

Q. Thank you, I couldn't read that:

"... in the first quarter of this year."

Then you go down into the second paragraph and you say:

"My concern is the amount of Factor VIII that has been issued."

Then you set out some detail about this, in terms of what's been issued and what's been -- what's been issued by Dr Ludlam, and you say at the end:

"This means that for each of the 20 patients, the average annual consumption would be 41.360 [*sic*] units -- or 34,467 units if you include all 24."

24 patients, I presume.

A. Yes.

Q. "These figures are obviously pretty close to the UK national average."

Then you say:

"However, the amount of Factor VIII that we were officially issued in the first quarter of this year was only 261,530 units, although we did get some ... from Inverness [for a particular patient].

"Hence, you will see that your home therapy programme alone has accounted for about 80% of our allocation from PFC.

"As you know, this allocation is actually based on the amount of plasma we supply to PFC."

Then you set out what that runs to, and what that will produce in terms of PFC stocks.

So just pausing there before we go over the page, is it right to understand this letter to be saying to Dr Ludlam: look, there's a problem, we've been allocated this X amount, you've used 80 per cent of X amount. You seem to be specifically saying, "Your prescribing figures are actually pretty close to the UK national average", so you don't seem to be making a point there about how much Factor VIII Dr Ludlam is prescribing to his patients, but there's a problem because of what we've been allocated from PFC; is that a fair summary of this part of the letter?

A. I think it is. The numbers at the top are subject to the same caveat as we've just been talking about but, again, I think they're reliable enough to indicate the

trend. And there was indeed what the English call the *pro rata* system, that the regions got back the amount of Factor VIII that would have been extracted from the kilograms of plasma that they were -- the PFC was sent from the centres and, in this case, we were clearly dependent upon an extra burst from Inverness.

So, in terms of its comparison with the national average, I'm at a disadvantage here in not having a copy either of the list of patients or indeed what the current practice was in the rest of the UK. But your surmise of the message I was giving is accurate.

Q. So can we then turn over, please, to page 2. You say this.

A. Next page.

Q. Ah, page 3, it's my fault.

"I think that the SNBTS as a whole can just about hold your requirements as long as the following points are borne in mind:

"1) Maximum use is made of the Cryoprecipitate Programme ..."

Pausing there, what was the cryoprecipitate programme?

A. Thank you for putting me on the spot there. That's basically the -- I don't know whether it was agreed -- negotiated beforehand, but the understanding of the

amount of cryoprecipitate that would be made available for the haemophilics -- haemophiliacs in Edinburgh. So I can't remember the precise details of that programme, but it clearly was -- I assume it was a programme that was guiding the amount of Factor VIII that would be available in the form of cryoprecipitate for their patients.

Q. Then:

"No more patients are put on home therapy;

"No patients are put on the cold operating lists ..."

If you just explain to us what the cold operating lists are?

A. Elective surgery. So that if, for example a patient had a disordered joint, an elbow joint, or knee joint, or hip joint that would justify surgery, it would be -- the suggestion was that they might have to wait a bit. Now, that's a very significant thing to say, because I think in general we're all aware, particularly these days, of the impact of waiting lists. So, in many ways, this was a bit of cheek from me to ask Christopher to do all this but, nevertheless, there was a problem and we had to look at ways of alleviating it.

Q. Then you go on:

"We try to borrow from other Regions who may have

lower haemophilic loads, particularly if we are treating 'their' patients;

"Some of the heaviest users are counselled to use less."

You then go on at the paragraph below, if we can just miss out that next paragraph, and say:

"I feel therefore that you should be warned that we are now very definitely at the limits of our production for home therapy and therefore you may consider the necessity for buying some commercial product."

Then you set out future plans for increasing plasma procurement.

So what you're doing here is you're effectively setting out to Dr Ludlam a plan, a way in which you can just about cope with the home therapy programme and the amount of Factor VIII that he is prescribing by taking, as you've just described to us, these steps, some of which are pretty serious, and making it very clear to him that the alternative is purchasing commercial, because there's no more PFC; is that right?

A. I think that's correct. It was a real dilemma, and so putting Christopher on the spot was -- I felt I had to do, but tried to do it in the most constructive way. And, possibly, although this would be, again, a bit of

a cheek on my part, my experience as a director in Liverpool may have given me a little bit of authenticity in making these suggestions, but I am not in any way belittling the significance of those suggestions. They are quite profound and so, consequently, not to be taken lightly.

So I had a lot of sympathy for what Christopher was faced with, and I would have loved to have been able to give him more PFC Factor VIII but there were -- there was a limit to what they could produce and so there was -- we were in that very unfortunate dilemma of limiting the service to patients, which was a thing we hate doing, we hated it even more in those days than perhaps now is sometimes the case. But, nevertheless, it was important that we tried to work through those particular problems if we could.

Q. Can you recall what the response from Professor Ludlam was to those -- your suggested plan?

A. I can't remember, to be honest. I wouldn't be at all surprised if, on opening the letter, he uttered a sigh of exasperation. But we did have further meetings, you know, down the line and we were able to continue a level of supply. I think he may have acquired some commercial Factor VIII and tried to put them aside for specific patients, rather different from the higgledy-piggledy

fashion which I was practising in Liverpool in 1976 for example, because he was very conscious of the need to rationalise the use of these products.

And I nearly used the unsayable word in healthcare, which is "ration". That's, in a sense, what we were having to do, but it's not a concept that either the public or the healthcare professionals like to consider. So that was -- it was a difficult time. I can't remember his exact response but I'm sure he was going to do his best, what he thought was best for his patients.

Q. Can we then look at a later letter from February '83, PRSE0003653. This is a letter we looked at with Dr McClelland and when it comes up you will see it's not a letter from or to you, but it's a letter cc'd to you. It is, in fact, a letter, as we can see, from Dr McClelland to Dr Cash dated 2 February 1983.

In the second paragraph he is updating Professor Cash, or Dr Cash as he then was, about the discussions that you had had with Dr Professor Ludlam about the PFC -- the supply problem. And then it's in the third paragraph that I want to draw your attention to and ask you a question:

"My conclusion is that while I'm more than happy to meet with you and Chris (and Frank) to attempt to

resolve the problems, this really isn't the whole answer to the difficulties. I would suggest that there is a need for a peer review by the Haemophilia Directors producing some clear guidance as to a reasonable level of consumption for the SE haemophiliac population."

So is it right to understand, this letter, that matters had moved on somewhat from the letter we just looked at, where you weren't expressing a concern about the levels at which Dr Ludlam was using Factor VIII for his patients, because you had noted that it was along the national average, but by the time it comes to February 1983, having set out the plan that -- the workable plan, you're saying something rather different. You're saying, "Actually, there may be a problem now with whether or not there is a reasonable level of consumption for the South East haemophiliac population"?

A. Yes, I do actually remember this letter, and seeing it again a few weeks ago reminded me.

This was a difficult period, in more ways than one. And the idea of a peer review by the haemophilia directors is one which I'm sure Christopher would in principle welcome, so long as it was shared among all the haemophilia directors and was not targeted at particular ones.

I honestly don't know if there was a peer review

among the Scottish haemophilia directors. Of course I don't think I would have been involved in it.

I think Brian felt that I was the appropriate person to deal with Chris, because the beginning of this letter indicates that if I couldn't sort it out, John Cash was thinking that perhaps Brian could sort it out. But Brian was basically saying he didn't think he could sort it out because this needed a more -- a wider approach, and if anybody in the Edinburgh BTS had some understanding of the actual practical problems, it would be me rather than Chris, because of my previous experience.

So I think your analysis is correct that we were really approaching the brink of supply now, ahead of a period of trying to work out how to inactivate the viruses in the products, in the Scottish products, and so consequently there was a real concern that we might run out and there may have to be major recourse to commercial materials. Which in Scotland was anathema. Particularly for John Cash, because he was committed, as was Brian, and indeed myself, to the so-called self-sufficiency, whereby we didn't have to buy anything from other sources but obtain it within our own system.

So I think a peer review is a very nice idea from the outside. Practical difficulties from within, but --

but I'm pretty sure that Christopher would have welcomed the concept of sharing experiences among the Haemophilia Directors and trying to get some consistency across the level of demand.

But again, this is biology, it's not mathematics, and variables occur all the time. Nevertheless, this is on a background of increasing demand to supply factor to a population group who were very much in need of the best that could be made available.

So I have sympathy on all sides. But whether that peer review was conducted and how effective it was, I cannot really remember.

Q. Did you have discussions with haemophilia clinicians in the South East of Scotland and hear their views about PFC products, Factor VIII products, Factor IX products?

A. Not with the haemophilia directors as a community. It would have been mostly with Christopher. I did know the Directors in -- of the adult haemophilics in Glasgow, and indeed the paediatricians as well, but I don't think we had detailed discussions about the significance of the supply -- you know, significance in terms of not just numbers but the concept of plasma coming from products being made and supplied from the PFC.

So my main contact with the Scottish haemophilic community in that sense would have been with

Christopher. But I mean he was a very informed person, so his opinion was pretty sort of -- I think he was a bit of a leader among the haemophilia doctor community actually in the UK, quite apart from Scotland. So his feelings were very important to understand.

Q. But did you gain an impression either from him or from, as you say, any of the other clinicians that you were in contact with about what their view was of the SNBTS intermediate product that was available between '83 and '84?

A. Well, their opinion and our opinion would have been very much influenced and shaken by the discovery of a contaminated batch or a batch or two in November 1984, because until then there had been a hope -- I don't think it was complacent hope, but a hope -- that blood donated in Scotland from a carefully selected group of donors would not be contaminated with the AIDS virus. The fact that that was -- unfortunately proved to be misguided by this contamination was indeed a shattering blow, as I said earlier, and may well have had an impact. But until then, I think there was a real hope that Scotland would be more or less HIV -- Scottish-derived blood products, not just Factor VIII but the donations, would be pretty well free of the HIV virus.

This is an interesting period, because that donation was probably collected in 1983, which was the year, the crunch year, in many ways, for the country, and particularly in Scotland, because Brian in particular, Brian McClelland, and his -- our colleague Anne Smith, were working very hard on preparing the leaflets for donors to understand the significance of the impending HIV/AIDS epidemic, as it became, and would therefore refrain from donating. And this was because we felt -- and I shared this with Brian and with Anne -- that the most likely explanation for the rise of HIV that was beginning to appear among the haemophilics in America and then beginning over here, could only really be explained by infectious organism.

I do know that Christopher also accepted that as a probability, but [audio disruption] was, along with others in the English centres -- and I -- as you know, I had correspondence with others, including Professor Bloom and Peter Jones, in which, in the middle, in May 1983, they were still of the opinion that the chances of HIV actually being an infectious disorder and indeed, if it was, of it arriving in Britain, was sufficiently dubious for them not to abandon the use of American product.

In other words, they were hoping against hope that

the contamination was not due to an infected organism but was due, as I think I said in one of the other meetings, due to a concatenation of inflammatory experiences and lifetime experiences that put a strain on the immune profile of the people who were most likely to get AIDS as a result of their lifestyle.

It is too glib to say, but someone did say to me once, that what we are transfusing -- "We're not transfusing lifestyle, we're transfusing particles". That's too glib a response, but it gives a flavour of the difference of hopes and attitudes at that crucial time in May.

But we in Edinburgh were working our socks off in trying to produce a way of excluding donors who might be at risk from donating, even if it was at the cost of less blood being donated.

So we were working hard at that angle, and -- so to come across a requirement that implied some sort of attitude to the PFC products, that's where we came from.

The experience in November would undoubtedly have changed the attitudes of the haemophilia community in Scotland about the safety and reliably (sic) of the product. The other thing of course going on at the same time was the virus inactivation programme, which took two or three years to mature.

So we were working very hard in the donation community to deal with that particular threat, but that window period of 1981 to -- well, actually, late 70s through to the mid-80s, was the crucial one, and it's during that period in particular that patients may well have been at most risk of acquiring HIV through blood products, which did cast a significant question over the reliability of the Scottish products. Which was a shame, shattering, but nevertheless understandable and inevitable.

Q. So that response you've just given me brings me on to my next topic of questions, which is AIDS.

As I understand your witness statement, you were aware of the July 1982 MMWR report reporting on the infection of three people with haemophilia with AIDS. And you say in your statement that that was, to you, the first clear-cut evidence that haemophiliacs were affected by AIDS.

Is that when you, July 1982, put your understanding that there was -- the most likely explanation for AIDS was a transmissible agent carried by blood?

A. I have to say, on reflection, that I'm not too confident about the July date. I am confident that later, at the end of 1982, we were pretty -- we felt it very likely

that it was a transmissible agent. I -- on reflecting my Penrose Inquiry statement, I see that I was pretty firm about that July date. I'd been thinking more about that and, quite apart from anything else, it took a little time for the MMWR reports to reach us. You know, a few weeks. And it may well have been a little later in that year.

I think it's fairly likely that we were aware enough of this particular risk, before the Edinburgh Festival of 1982, which of course was a very significant event in Edinburgh -- in Edinburgh life, but I don't think I could totally I say with certainty how much that impacted us for 1982.

We wouldn't know what to do, really, at that stage. By 1983 it was much more evident and so we worked very hard at that particular time. But I am confident by December 1982 we were of the opinion, in the Edinburgh and South East Transfusion Centre medical community that the most likely explanation of the increasing number of haemophilics -- in early 1983 there were some in Britain as well -- would have been due to an infectious particle with an epidemiology resembling that of hepatitis B, although probably a very different kind of particle. Different kind of virus, different kind of organism. May not even have been a virus but it

would have been a specific organism.

Q. In your -- forgive me while I just try to find a file. In your witness statement you refer to a -- wait a minute, that's not the right -- let me just find the right reference.

A. I think I know what you're referring to.

Q. The meeting -- ah, sorry, found it. Okay, I've got too many files here. Here we go.

Right. In your witness statement you refer to a meeting that took place in September 1982 of UK Haemophilia Centre Directors in Manchester that you attended. I don't think we need to go to it but, for the transcript, the reference is CBLA0001619. Your witness statement tells us that, in the discussion about AIDS, and in the minute there is a discussion about the MMWR report about the three haemophiliacs who were diagnosed with AIDS, and you comment on the fact that the minutes say, "It appeared that there was a remote possibility that commercial blood products had been involved", and then Dr Craske asked the directors to let him know if they have any cases of the AIDS syndrome.

In your witness statement, you make it clear that, at that meeting, you were surprised, troubled, noticed, that this was being underplayed by, as you saw it then, the English Haemophilia Centre Directors, in a way that

took you by -- I think took you by surprise. Does that help you date your knowledge of AIDS being caused by a transmissible agent?

A. Yes, that did. And, in fact, I probably understated in that report. I think you've been reading between the lines successfully. I think I understated in that report my attitude to the way the English directors were reacting to this particular oncoming challenge. That's why I said I wasn't quite sure, I couldn't be quite confident of the June date, I'm not quite sure how soon after that June date I actually saw that report but, certainly by the end of that year, there was enough around in my head, and probably discussed with Brian as well, because Brian would have been very, very aware of the implications there.

So I think there was a sort of split between the transfusion doctor community and the haemophilia-treating doctor community about the significance of this oncoming set of findings, and we were seeing dark clouds over the horizon, where perhaps they were trying to look for some sort of relief beyond that particular challenge. So there was an important difference of emphasis among the carers.

But that's why, in particular in Scotland, the transfusion community was working very hard to find

an appropriate set of wording for the leaflets, and Brian and Anne were really working hard to get the communications right, talking to the Scottish -- it wasn't, I think, the Terrence Higgins Trust, it was the Scottish Homosexual Rights Group that they were talking to and to the GP Roy Robertson, and those sort of people, in order to get to the community to discourage them from donating.

And that's why it was so shattering to find in November 1984 that, probably during that period, one or two donors were infected with HIV and the result was 16 haemophilics getting it, and suffering as a result.

Q. Can we turn to a document, a memo that you wrote to Dr McClelland in May 1983, PRSE0003709, and when it comes up on the screen we'll see that it's dated 30 May 1983.

A. Yes.

Q. It says:

"Dear Brian

"Just to let you know I telephoned Peter Jones on Tuesday 24 May, on the subject of AIDS. I was basically following what he was claimed to have said on the Nationwide Programme the previous week about non-rejection of gay donors.

"He told me that what he actually said was that

there should be no discrimination against anyone who wished to donate blood and in particular there should be no questions into their sex lives. However, literature should be provided, to include definition of high risk categories etc."

Then if we jump down to the penultimate paragraph:

"He also claimed that there is a lot of doubt about the diagnosis of all the AIDS cases in the UK" --

SIR BRIAN LANGSTAFF: We haven't got the right bit up on the screen.

MS SCOTT: Thank you.

"He also claimed that there is a lot of doubt about the diagnosis of all the AIDS cases in the UK, and in particular the haemophiliacs. I felt he was ... being somewhat less than cautious in his attitude, but this is not unexpected given his interests etc."

So is this an example of what you were describing, a reticence on the part -- or reluctance on the part of haemophilia clinicians to accept what you saw as clear, even as late as May 1983?

A. Yes, that is the case. I think -- Peter Jones, I knew very well. I'd met him, I think, during my time at Liverpool and he was a leading author on the care of -- *Living with Haemophilia* was his book, which came out in several editions, and he was a very informed and

concerned clinician, concerned for the welfare of his patients.

So I sort of heard secondhand about what he was alleged to have said on that Nationwide programme and I wanted to check with him what he actually said, and he gave his answer, which, I have to say, I don't find totally satisfactory, partly because I felt he was trying to tell us how to do our job in donor selection, when we were working so hard on it already, partly because there was no guarantee that any donor turning up at a session would read a document like that and, in fact, later on we tried to initiate a system whereby donors would sign that they'd read up. All very difficult, contentious stuff.

So we were definitely doing rather more than he, I think, was assuming. So, as I say, he was sort of, in a sense, trying to tell us how to do our job.

I mean, he had a good point because donor sessions were difficult and confidential conversations with a haemophilic about their sex lives would have been very difficult but, nevertheless, a leaflet, we felt, was not sufficient, and we needed to do rather more than just the techniques which he was saying it was important to try to get this -- a more thorough aspect, and coyness about sex lives is not necessarily the best way ahead.

The second part, which you've still got up, about diagnosis, this is precisely what I was saying. There was what we thought, even then, a sense of wishful thinking among the haemophilia-treating community that this awful condition was not due to an infection but might go away because it was not very common yet at all in the UK.

So that's basically the thinking that we had. So we were not convinced by Peter's argument that this might not be an infectious disease after all.

Q. The degree of wishful thinking that you've described, is it right to understand, from what you said earlier, that this was exhibited not only by the haemophilia clinicians in England but also in Scotland? I think you included Dr Ludlam in that camp, if I can put it that way.

A. Yes. Yes, I think that would be fair. I'm sure that, intellectually, Christopher accepted the probability of infection but, emotionally, the implications of that were so vast, in terms of potential withdrawal of treatment for patients, that, in a sense, it was almost unthinkable. So he, poor chap, was faced with that particular dilemma. For us, it was a little bit easier, in that, although there were other patients than haemophilics who would suffer as a result of

contamination of blood -- and we certainly know that from later experience -- but -- nevertheless, this is the value of a sort of dialogue situation which both sides can discuss their viewpoints in and come to the understanding of the other viewpoint.

I think in May we were not there yet and so, consequently, it wasn't until even more data became available from the MMW reports, and also occasions like Dr Galbraith's descriptions of a patient in Cardiff, which I think became more and more convincing, that this was not a condition that could be passed on by a concatenation of environmental circumstances or lifestyle, but actually, did represent the outcome of an infectious organism contaminating the blood donation and persisting in the end product even though it had been diluted more than 1,000 fold.

Q. I'm going to ask you about a different document now.

Can we have up, please, PRSE0003845.

It's a document, when it comes up, that's dated 27 June 1986. It's a letter from you to Dr Perry, and you say:

"May I pass onto you a couple of verbal comments about blood products from Christopher Ludlam."

It's the second paragraph I want to take you to:

"A young haemophiliac who previously had minimal

therapy with factor VIII received an infusion of the current heat-treated product a month ago. He now shows signs of liver enzyme rises indicating non-A non-B hepatitis. Christopher is a bit ruthful with his own staff about this because he feels that his patient should have received VIII Y or an equivalent product. However, the patient is apparently quite well clinically."

Did you discuss this case with Dr Ludlam? This incident?

A. I think the letter indicates that that indeed was the case. This is the value of -- I think this was at a formal meeting, which was, nevertheless, not really minuted but these were verbal descriptions, reports to me, by Christopher of his experience. So the first one is a good experience, Factor IX that was heat treated, seemed not to transmit infections, but the last paragraph refers to the product which would be known as VIII Y, which was a product that had received enough treatment to inactivate home hopefully the HIV virus, HTLV-III virus, but there was some doubt about whether it was able to inactivate the non-A, non-B hepatitis viruses, and this was informative, in that this patient's experience indicated that that process that Dr Perry was -- the unit in the PFC was exercising on

this particular batch of Factor VIII -- VIII Y, was indeed not sufficiently treated to inactivate the non-A, non-B viruses, although it probably was able to inactivate the HTLV-III viruses.

So -- but also note the little point about the patient being apparently quite well clinically. This would be characteristic of the usual sort of course of non-A, non-B patients.

So this was a very informative exercise, and this illustrates the value of the meetings that Christopher and I were holding. And this is three years after the previous correspondence that we had and nearly two years after the dreadful experience of November 1984. So this is a useful bit of information to pass on to Bob.

Q. The use of the term "ruthful" in the letter, does that suggest that Dr Ludlam had thought there'd been some mismanagement of the situation by his staff?

A. I have to say I don't quite know what "ruthful" means. It's obviously the opposite of "ruthless", but basically he was a bit cross with his own staff about this, because he felt that they should have selected this 8Y, rather than, I think, the previous product was NY. I think it was NY that they gave him and, somehow, the selection of products system had gone wrong, and he didn't blame me for that, but it was his own staff,

somehow, that were implicated, which is probably a bit unfair because I think it was a shared responsibility between the Transfusion Centre staff and the haematology/haemophilia staff in the laboratory there.

But, nevertheless, Christopher regretted this particular episode, and possibly felt that the staff were responsible.

Now, Christopher would have to answer that for himself. This may be a misinterpretation on my part, but that's the impression I think I got from that particular meeting. Apportioning blame is always a bit easy when you think about a situation like this, and it would be a more complicated episode than perhaps immediately meets the eye.

Q. I'm going to ask you some questions now about some correspondence on 7 July 1986. Yes, that's correct. The first document -- I'm going to go to both of them and then ask you the questions.

The first document is PRSE0003814, which is a letter from Dr Perry to you, dated 7 July 1986, "Factor VIII Trials". It refers to a note of 4 July which we don't have and makes a couple of comments, and says:

"The PFC phase IV product (very high purity, non-infective as assessed by model virus studies etc) is

planned for production in January '87", and hope that there will be supply by September '87, and saying that after they've:

"... used up the stocks of Phase III product. This product is more than equivalent to 8Y [the BPL product 8Y], it's much better!"

Then:

"While there will be no PFC product virucidally comparable to 8Y until September '86, after that time it would be my intention to supply the Phase III product to 'virgins' since we hope to demonstrate by that time that it is virucidally equivalent thus removing the need to go South. However, in the immediate future (July-September '86), we could probably get supplies of 8Y for special cases. It would of course be preferable if these were obtained and supplied through PFC."

The other letter I wanted to take you to is PRSE0004097, which is a letter of the same date -- I think you suggest in your witness statement that these would have crossed -- and it's a letter from you to Dr Perry. And it starts off saying:

"Sorry to be pestering you again."

It says:

"Last week, Dr Ludlam wrote to Brian asking if it would be possible to obtain some of the BPL products for

use if a previously untreated haemophilic presented for replacement therapy".

Then you say in the third -- miss out the next paragraph, and then you say:

"Before I write back to Christopher, would it be possible for you to obtain perhaps 10,000 -- ie 50 vials which would at least enable us to cover the initial injection for such a case ..."

We can see from subsequent correspondence that indeed you did manage to get some 8Y from England, and it was provided on the basis that it was still in clinical trial, and so information had to be provided to BPL. Is that right?

You're nodding.

A. Yes, that's so. I think that's so. The previous letter, the top paragraph, the high purity product was -- that was -- later became known as Z8. And actually, I think there was some delay in the production. I think they ran into some technical problems when upscaling the production for this Z8 product when it came to the freeze drying process, which, as I alluded to earlier, is a delicate procedure and, when upscaled, it probably needed a further tweaking to ensure that the freeze drying was completely freeze dried, because it had to be completely freeze

dried in order to dissolve on reconstitution easily.

So it took a little longer to come out than they had initially hoped. But in the meantime it was known that BPL had this product, 8Y, whereas the product I think that was usually distributed from PFC was NY.

Now, I get confused by these various acronyms, but I think the NY was the one that inactivated HTLV-III, but may not have inactivated the hepatitis viruses, whereas the 8Y and Z8 inactivated both.

Z8, there was great hope for, because that was very pure, and that purity would also be a factor enabling its constitution in small volumes, very powerful and good to administer. So that was the ambition.

So in the meantime there was a gap, and Christopher needed reassurance that he could get hold of NHS produced [audio disruption] that would be -- that would be effectively virus-inactivated. So we managed to procure 50 for him. Actually, I sort of beat him down. I think I beat him down from 500 to 50, which would have been quite difficult for him, but the 500 would have been quite difficult for us to have taken from BPL.

But nevertheless, we did come to an amicable arrangement whereby some was available for Christopher's

new patients; in the case of need, was available from us in the Blood Transfusion Service.

So in summary, that's correct.

Q. And did you understand that Dr Ludlam's request for this safe 8Y product was triggered by the episode we looked at in the correspondence from June, the minimally treated patient who had been infected with non-A, non-B?

A. I think so. That sounds likely.

Q. Would there have been any impediment to you making a request of BPL for a supply of 8Y earlier than you did?

A. Well, we know that BPL were also facing up to the same problem of quantity and supply. And we were loath to put them under extra pressure. In fact, the -- I think one would have understood that BPL may have thought: well, the Scottish haemophilics are getting quite a good service already, why would we have to give them some of our stocks to -- which might prejudice our own ability?

Now I'm sort of over-stating the case because the relationship between the Scottish PFC and the English BPL was one I think I'd described as cordial rivalry, in which they shared ideas about production, and there was sort of a lot of cross-talk between them and indeed mutual benefit. But the way these things go, at various stages, one centre would be ahead of another

centre in terms of the quality of the products it was making.

It's not possible to just transfer one technology from one place to another in toto, because there would be different scales, different degrees of equipment design and that sort of thing, but nevertheless, there was a cordial relationship. And, okay, there was a bit of a barrier. We would be reluctant, because, quite apart from anything else, it would indicate that the Scottish system was failing, possibly. But we did recognise that there was a value in this product from BPL, and it would be better to offer that to the Edinburgh haemophilics than, for example, commercial concentrate. So BPL were very willing to help us out on that to the extent that they actually did.

Q. And then last document from me in your time in Scotland is PRSE0003825. And when that comes up on screen we will see that is a letter from Dr Ludlam to you dated 11 June 1987, and it's in relation to the treatment of his patients with the Z8 product that you were just talking about. And he says:

"I'm led to believe that the issue of Z8 patients has begun. I was aware that the standard product was running short ..."

Just pausing there, the standard product, is that

the NY product? Is that your understanding?
A. Yes, I think so, yeah.
Q. "... was running short and that we had agreed to discuss the further evaluation of the new material but I was under the impression that there were several weeks' supply left. I do not recall that I agreed that patients should be treated with this material. So far as I am aware it does not have a Product Licence from the CSM nor a Clinical Trials Exemption Certificate. I am unclear on what legal basis it is being issued and who is responsible for any adverse side effects."

And then he says at the bottom of the letter, the last paragraph -- or penultimate paragraph he says:

"As you know one patient who received Z8 developed central chest tightness ... and I am naturally very worried that this material has been issued without any agreed monitoring arrangements.

Then in the last paragraph he says:

"I am now faced with a fait accompli over Z8. This has comprised my position and reduced the clinical options open to me; ie either to accept the situation and hope for the best or to go over to the purchase of commercial factor VIII."

Now, just bearing in mind the letter we saw from Dr Perry earlier, who said that the plan was to start

issuing the Z8 once the NY had been used up, was that the situation: that in fact there was no more NY, which was why the Z8 was being issued?
A. I believe that was the case. I've gone through this particular correspondence in great detail, because it's significant and an indication of how seriously, and rightly, Christopher took his responsibilities.

So that is my understanding.

The other thing is, that I didn't -- wasn't aware of at the time, is that there were detailed negotiations going on between the Scottish haemophilia doctors, I think in a sense led by Christopher, and the Scottish Home & Health Department about the licensing of these modified products from the Protein Fractionation Centre. And I was actually not aware of the depth of those discussions. I think they were going on for months. And the Scottish office were not really -- they weren't satisfying Christopher, and at one stage there was a meeting, the minutes of which Christopher actually disagreed, and I think that's among -- on record, certainly in the Penrose Inquiry, and I guess it'll be on your records as well. So consequently, I was, again, sort of piggy in the middle, expected to activate these particular investigations into Z8, because it was the product of the future and the more quickly it could be

validated, the better. And this was in a period when Christopher was away out of the country, and therefore not able to keep a close eye on things.

I actually remember some aspects of this episode quite well because I know that I actually went into the ward with the registrars who were conducting the infusion and I actually spoke to the patient, but I didn't in any way actually participate in any procedure directly, I didn't put the needle in or anything like that, but I was in conversation with them.

One thing about the reaction he had, which I witnessed, he himself said, "Oh, I've had this before, with other products". So he wasn't by any means a previously untreated patient. He'd received previous products. And he wasn't particularly concerned about the reaction he had. Although Christopher was already aware that if there were adverse reactions in any of these patients, and if the product they were receiving hadn't been properly validated or licensed, then we were all on thin ice.

So he was absolutely valid in that concern.

I -- as I say, I was somewhat a bit piggy in the middle. I thought that the product we were giving had been approved. Christopher thinks it had not been approved, and so consequently he was on thin ice and, as

I said, his situation was compromised and he was faced with a fait accompli.

Very regrettable, very upsetting for him. As far as I was concerned, this was obviously an important matter, but I was relieved (a) that the patients didn't suffer any extra degree of adverse effect than he'd already experienced, and in fact within a few hours was entirely well. That's not to minimise the significance of an adverse effect of this nature but nevertheless that was a little bit reassuring.

And I also feel that, in the long run, this was a very unfortunate episode, but it didn't impair the further work that we were doing, and that indeed I was doing with the other Haemophilia Directors I've already alluded to, Dr Mayne in Belfast and Professor Bloom in Cardiff, about further trials of these materials.

So actually, we were able to ensure the clinical validity of Z8 over the course of the next few months, and this very regrettable episode fortunately didn't impair that but it certainly was a lesson learnt, that I learnt in particular, about the need to be absolutely sure that the products you were giving were properly approved.

I cannot blame Dr Perry and the PFC staff for issuing it, and I cannot blame Dr Ludlam for his

complaint. If there is any person to blame at all, it's myself for not being sufficiently aware of the background to what was going on to be able to say, "Hang on a bit, we shouldn't do it just yet". But in the event this episode happened, and it did not impair the professional relationship that I continued to enjoy with Christopher for the rest of my time in Edinburgh.

Q. This letter gives an impression that the Haemophilia Centre is a passive party in the process of getting products into patients, that actually it's you that is making -- you, as in the blood transfusion centre -- that's making the decision about what products they get, and so therefore what products they give their patients. Is that in reality how it worked?

A. Well, I think that sort of happened in this particular instant because Christopher wasn't round, the registrars didn't know what was happening, the blood bank staff in my department knew we had this product waiting by, and so consequently the procedure was activated, possibly against the better judgment of those registrars, but they hadn't actually received enough -- they weren't confident enough about that. And possibly, although unintentionally, they may have been reassured by my presence that it was an okay thing to do.

Regrettably, they didn't ask Dr Alistair Parker,

who was standing in for Christopher at the time, and possibly, had they done that, there may have been a different outcome.

I don't think what you've said, Ms Scott, just recently, just now, about the force of choice is true on a total basis. I think on this particular episode there was perhaps an undue pressure put on those registrars to actually give this product in a way that ultimately their own boss did not approve.

Q. I'm going to move now to your time at the Wessex Regional Transfusion Centre in Southampton in England.

When you arrived there, as Centre Director, is it right to understand that the previous holder of that post, Dr Don Smith, who had been in post since 1969, had retired in 1978 (*sic*) or 1988, so a couple of years before you arrived, and there had been no director in that two/three-year period?

A. That is correct. 1988, when he retired.

I think he was persuaded by the region to stay on for another year. So consequently, you know, he was still around. And indeed, those returns which I've seen were signed by him and -- including the return for 1988 to 1989.

But yes, Don was very experienced. The history of the Wessex Transfusion Centre is that it was created in

1970, 1969 or so, and was to be run by the Wessex Regional Health Authority, which was a sort of carve-out of the south-west bit of south Thames and the southeast bit of Bristol, to produce the region of Wessex, and a parallel thing happened for the Transfusion Service. So there was a decision to build a new transfusion centre in -- to open in about 1970.

And that was also in the background of Southampton University becoming an undergraduate school of medicine, so medical students started arriving to be trained in medicine around that time, and it was thought, I would say on good grounds, that to have a regional transfusion centre sited in the teaching hospital grounds of -- of the new teaching hospital, which was also being rebuilt, with lots of money, was a good thing.

So it all fitted together that there should be a nice new shiny transfusion centre that was distinctly post-war to be built in Wessex at that time. And I think the Centre opened in about 1971.

Regrettably, it had not escaped the whole style of the past, in that the main feature in the building was a bottle -- glass bottle washing plant expected to wash bottles analogous to a milk dairy in order to prepare. Because until -- during the war and afterwards, for the

first couple of decades, blood was supplied in bottles. In fact the first blood transfusion I undertook to -- as medical student to patients was conducted with -- from blood in glass bottles.

These were transitioning during the 1960s and 70s to plastic. So most of the regions in the UK by 1970 were almost entirely using plastic for collecting blood, which was a great advance. Wessex wasn't there, and it didn't really get to a -- full plastic equipment until well into the 1970s. But that was the thinking of the Wessex Centre at that particular time.

And Dr Smith did retire, but there was a vacancy for the directorship. I saw the first advert in 1988 and decided not to apply because I wasn't getting good signals from Wessex, from the rest of the transfusion [audio disruption] centre about what Wessex was like. And, also, I was nowhere near ready in 1988 to actually consider a move. So when they readvertised in 1990, I was surprised because I thought the post had been filled. And when I went to visit the Centre in about April 1990, in order to consider whether to apply, he wasn't there. The only consultant there was Dr Andrew Herborn who did not want -- expressly did not want to be appointed as director because he felt that being a director would take him away from the hands-on bench

job that he was actually doing as a consultant, mostly involved with blood donation procedures.

And Andrew was a very conscientious and good consultant, utterly reliable in his work and I can sort of understand why he did not want to take on the extra responsibilities of being a director.

So the place had been devoid of a medical director. The region had appointed a senior administrator/manager, whose name is Jim Smith -- there were lots of Smiths around at this time. Jim Smith was appointed from the region to be the administrator of the centre and, without making too great a play on this, it was everybody's opinion within a few months that this was a disaster and that he was not really leading the Centre in the direction it should have been. And that came from the senior staff there, not particularly Andrew, but from the senior scientific and nursing staff there, who felt that Mr Smith didn't really understand the business, felt -- underestimated the degree of work involved in running a transfusion centre.

So when I came, I was appointed to be his co-director, so I didn't take the post of director directly, I was required to work with Mr Smith. So when I went to visit them, I had a conversation with him and, never having met him before, I didn't really get to

grips with his own particular abilities. He was able to say all of the right words, so I didn't see beyond that.

So I applied, was appointed, somewhat to my surprise -- of course, there are other good candidates as well -- took on the post, and within two or three months realised that I was working with a man who was impossible to work with. He sort of countermanded everything that I instructed the staff to do.

And, eventually, other people, not in other -- the clinicians, the haematologists, not so much in Southampton, but in Portsmouth, and in Bournemouth, and in Winchester, went to Dr Winyard in the region and said, "You've got to give Frank the freedom to do what he wants to do because he's got all the right ideas and is not being allowed to do that".

Now, I didn't say that to anybody. They were able to discern that from the activities in the centre. So Jim Smith was reabsorbed into the Regional Health Authority, and Graham Winyard funded me to go on a King's Fund course in medical management in order to be prepared to take up the post of what he rather grandiosely described as chief executive officer of the Wessex Regional Blood Transfusion Service.

Naturally, I was a bit flattered by that, I enjoyed working with the Regional Health Authority,

there were lots of interesting people to meet in public health and it was an attractive way of working. It wasn't to last. That particular link was disrupted in two stages so that by 1995, the Regional Transfusion Centre -- there was no Regional Health Authority and the workings of the Regional Transfusion Centre were transferred to the National Blood Authority.

So that, in a nutshell, is the history of my appointment, the working which I took on, the relationships I had to develop, and how it went from there. But after Mr Smith's departure, the region were extraordinarily helpful [audio disruption].

They were 12 miles up the road in Winchester, and we were in Southampton and I honestly think that for most of the 1970s and '80s, after the initial flush of opening the centre, Dr Smith was more or less neglected by the region in many meaningful way to help him cope. When I arrived at the centre I found that there were five different bank accounts. That was quickly rationalised by me, in the course of the year, into one, when we took on a new treasurer for the Centre.

The region supported us very well, Dr Winyard supported me, as did Ken Jarrold, a very senior figure in the NHS management structure nationally. So, consequently, we were well supported for the last two or

three years of my time, which enabled to us develop a good comprehensive computerised system and, even better, a really spanking up-to-date blood processing operation, which I think was, in 1994/1995, would be among the best in England by that time, because we'd learnt the lessons from so many of the other centres.

So that was my beginning at Wessex and quite understanding why Dr Herborn didn't want to be director, he was doing a fine job as consultant and the two of us did get on very well.

We did take on a third consultant for a few years and that was less of a success because I think there were some aspects of the job that were taken over by the National Blood Authority so, consequently, what happened then is that Dr Herborn moved to Birmingham, I think, in about the year 2000, or so, or the late 1990s, and so it was left with me and Bob, really, to continue to be the medical staff at the Southampton centre. But, by that time, neither of us were directors because the National Blood Authority had taken on the principle role of the Wessex service from a more central base, actually a base in Bristol. Of course, we were part of the Supra South West Region.

I've gone on at length about that but that's a quick summary of the development of the Wessex

Transfusion Centre during -- before, during and after my -- well, before and during my time.

Q. Just a couple of points -- of details I want to pick up with you, so the area that you described, some of the area that the centre covered but, importantly, it included the Lord Mayor Treloar school; is that right?

A. Yes.

Q. You set out in your witness statement -- I don't think we need to go to it -- the urgent priorities that you needed to address when you arrived at the station, which included the fact that donor records were completely paper based, and you've described that that was the system of computerisation that came in; and the research scientists had not received any guidance for developing research programmes; session organisations needed reappraisal; and the blood products facility needed updating, and you explained that that did, in fact, take place; and the stores which had been operating traditionally as a repository of equipment needed updating.

So those were your urgent priorities when you first arrived; is that right?

A. You don't need to go to my statement. Those are -- that's an accurate summary. It was a more challenging job, in many ways, that I went to but I did get a little

bit of forewarning about that. I have to say that, in spite of the lack of leadership, the staff were very conscientious. Although it was a paper-based record, it was meticulously maintained. For that, Dr Herborn deserves a lot of credit. So when it actually came to computerisation, the data that was transferred was pretty reliable and so, consequently, we were -- we'd jumped from being the back -- the least developed to one of the most developed computerised centres by about 1993. So that is to the credit of the staff there.

The sessions -- one of the things that helped us, and I didn't put this anywhere, I'd just like to add it, for the record. One of the things that was obtained during my time was a new bus: donor services bus. There had been an old one which had got -- become dilapidated and it was replaced at a cost of over £100,000 in, I think, 1992/3 with a bus that travelled with the team to, usually, industrial sites and was able to collect something of the order of 100 units of donations a day from that bus, which was a considerable contribution.

It was a new bus, it was actually a left-hand drive, because it was American designed, and that was very good for the drivers. They enjoyed doing it. It certainly enhanced our ability to get good quality of blood donated and collected and sent to the centre so

I just want to at that for the record.

But the other points that you've made are entirely valid. Those are the areas that needed improvement.

Q. Just for the transcript, that's paragraph 178 of your witness statement.

MS SCOTT: Sir, I note that I've gone on rather longer than 3.15. I've got at least half an hour left of questions to ask Dr Boulton about Wessex. I don't know whether now would be an appropriate time to take a break.

SIR BRIAN LANGSTAFF: I think if you've got half an hour, yes, it would. So we'll take a short break, shall we, until 3.45, if that's okay, and come back then and finish off your questions.

Dr Boulton, there will then be a short break again while those who have been watching remotely have a chance to put questions through Ms Scott to you in what will then be the final session of the day. So I can't tell you yet how soon you will be finished, how soon we'll be finished. We'll have to wait and see.

3.45.

A. I understand, yes. Thank you.

(3.26 pm)

(A short break)

(3.44 pm)

SIR BRIAN LANGSTAFF: Yes, Ms Scott?

MS SCOTT: Dr Boulton, just to orientate you and those listening to what I'm going to ask you in relation to Wessex, I'm going to ask you some questions about your relationship with clinical colleagues and then I'm going to ask you some questions about hepatitis C testing and the arrangements were put in place for that, and the hepatitis C look-back programme, and then about record keeping.

Just on my first topic, on the relationship you had with clinical colleagues when you were at Wessex, is it right to understand that when you arrived in Wessex there was no hospital transfusion committee in place, but there was a regional association of haematologists which met every three months?

A. That is correct.

Q. And what was discussed at that three-monthly meeting? Was a topic of conversation the safer use of blood, the better use of blood, reduction in use of blood, in so much as it could be safely reduced?

A. I cannot remember precisely what went on. I don't have minutes of those particular meetings. But I do know, and remember very clearly, that I developed in the course of that time a real sense of the need to, as I say, cut off my nose to spite my face. That is because we had gone into a system of cross-charging,

about which I knew from the time that I'd applied for the job that was going to come in in the English Services, that there was an -- an internal market was going to develop in England, it did not in Scotland, but an internal market whereby the users of blood, the hospitals, the users of blood and blood products, would pay at a fixed price for each product, and that that money would be used to fund the workings of the transfusion centre.

It wasn't cash, it was a transfer of funds, if you like, from one source to another, so it was a translation of the use of the internal markets for using -- for funding the blood services.

The problem with that, as I saw it, was that if one took a purely commercial capitalist [audio disruption] my job would be to sell as much blood as I could, and that was professionally profoundly distasteful, because it was already becoming apparent that in order to improve the safety of the Service, we had to look very carefully at the indications for blood transfusion.

So I regarded part of my job as going round the hospitals, talking to the consultants, where I could, and talking to the laboratory staff as well, so that they were on board with the concept that it doesn't

matter what you -- what the prices are, what you need to do is to cut down your use for the benefit of the patients.

So in a sense, as I say, cutting off my nose to spite my face. I did not regard myself as a salesman.

Unfortunately, one or two of the hospitals did think that with the takeover, a few years later, by the National Blood Authority, that's precisely what we had become. That was one of the problems that we had to cope with. But that was my ideology, that there needed to be a rational, clinically justifiable system for the use of any blood or blood products that was entering a patient's veins.

So that --

Q. Did that --

A. So the consequence of that was, indeed, a series of largely informal meetings hoping to get the message home that it was a good thing to pay attention to the use of blood.

Ironically I began to realise after a time that it didn't matter what I said. What really counted was when they saw the bills. And -- it was the bills. But the bills were held by the haematology departments, not by the surgeons or by the ward users, so it was not all -- in a way, not all that successful [audio

disruption]. But nevertheless, the use of blood did slowly come down and, slightly to my chagrin, I felt that the marketing that -- the commercial -- the fact that they had to buy it sent a fairly powerful message to those in charge of hospital laboratory budgets.

But in the end it meant the same thing: that we were looking carefully at the proper use of blood.

Q. And did there come a time when there were hospital transfusion committees in the hospitals that the Wessex Centre served?

A. Yes, and some hospitals were better than others.

To my regret, the Southampton General Hospital was not among the leaders of this particular trend, whereas some of the smaller hospitals, particularly the Dorchester hospitals, were much more open to that sort of thinking.

Q. I'm going to turn now to hepatitis C testing.

It's right to understand, isn't it, that you weren't involved in any of the national English forums, such as the ACTTD and the ACVSB, in which decisions about the national introduction of hepatitis C testing were determined or were decided?

A. No, although I was kept somewhat informed about those developments, and although -- and indeed, I fairly quickly formed contact with the Donor Selection

Committee, which I later joined and took on a role on their committees, and also aware of the Transfusion Transmitted infections. That was on a UK basis rather than an English basis, so that I was less involved with, if you like, the nitty gritty of the work being done to introduce the testing of HCV.

I might just add that, personally, I was in favour of introducing these specific tests for HCV at the earliest possible moment, and I think I'm on record as -- before I came to Wessex as advocating quite strongly the need for the UK to introduce specific HCV testing as soon as possible, especially as the technology was actually coming online.

And in the event, somewhat to our shame the UK was among the latest countries in Europe to actually introduce the testing. And that was singularly unfortunate, because I felt that there was an ethical need to introduce it at the earliest opportunity. That's the specific testing of -- for the HCV virus.

Q. And that letter is at PRSE0001562.

Could we have that up, please, Sully, just to have a look at what you were saying.

When we get it up, we'll see that it's a letter that you wrote to Professor Cash on 21 February 1990. And you say in the main paragraph of the letter:

"Could I just add that in spite of obvious difficulties with the current Ortho Elisa assay (susceptibility to 'stickiness', unreliable of predictive value with heat treated samples, etc) I have developed a very strong feeling that the screening of donors for HCV antibodies should be introduced at the earliest possible opportunity. This is not because of the 'science', but because there appears to be little doubt that people have contracted HCV as a result of transfusions which they would not have received had these transfusions been screened for HCV antibody. Furthermore there are apparently five known cases of HCC due to PTH. The reason, therefore, from my proposing this view is actually one based on future litigation. I am pretty convinced that the NBTS and SNBTS will find legal action taken against them in about 10 years' time from persons who have sustained post transfusion hepatitis as a result of receiving HCV antibody containing blood which was presumably infectious for HCV at that time."

So that's your view expressed, as you say, quite forcefully in February 1990, before coming to England, to Professor Cash.

And it's right to understand that, is it, that although you recognised some -- that the testing wasn't

perfect, you nevertheless -- the science of the testing wasn't perfect -- you nevertheless thought it should still be implemented?

A. That is pretty correct.

Just one little point of clarification for a potential ambiguity. The acronym "HCC" that's about two-thirds of the way down in that paragraph, is hepatocellular carcinoma. It's not a misprint. That's a deliberate HCC, because people with cirrhosis have a high risk of developing cancer of the liver, so it's -- hepatocellular carcinoma is what that stands for.

Yes, this was actually as a result of my attendance at meetings, and there were -- I think there was a meeting in New York and around about the same time there was a meeting in London, and I attended the London one, and there was a lot of talk about this. And I -- my -- the actual reports of that meeting don't really reflect the sentiment that I'm expressing in this letter. But I was sort of picking up vibes, or maybe my antennae were attenuated because -- well, sensitive to this, possibly because of my experience with HIV back in 1983 when -- and indeed the introduction of the tests in 1985, how important it was to get this done as quickly as possible.

So that was the background. This is a personal feeling I developed. And in a way, I'm pleased that I -- that this [audio disruption] letter is on the record, because it did reflect a real anxiety at that time, although some would say that my anxiety was based on only tenuous grounds at that particular time, because of the difficulties of developing that test, the stickiness and all those sort of technical problems that were getting in the way of developing a usable test for screening.

Screening tests are very different from diagnostic tests, and that's one thing that should be recognised. You can diagnose individual people on the basis of a test that may be not particularly easy to perform but as long as it's carefully conducted on that basis by skilled technicians, then that's reliable.

Screening -- screening hundreds of samples a day is a very much -- is a very different kettle of fish, and you need to have well proven technologies for that in order to reduce the false positive and false negative readings. So I'm not belittling the problems in developing an assay but nevertheless, the assays were well on the way to being developed, and I felt it was very important that those developments should be expedited as quickly as possible.

Q. Then once you had taken up your post in Wessex and there was -- the Inquiry has seen the correspondence and discussions going back and forth between Dr Gunson and the Directors about when the screening date -- when screening should be implemented on a national basis, and the date keeps getting put back, and Dr Lloyd effectively goes early, and there's a correspondence from you to Dr Lloyd in which you are saying to Dr Lloyd, and we can look at it if we need to, but you're saying that you think that the -- everybody should go together, and that to break ranks in the way that he is is not conducive to the image of a coordinated service. And the reference for that for the transcript is NHBT0000074_021.

So is it right to say that in around May '91, when these discussions were taking place, you -- your view at that point was that it was more important for screening to be rolled out nationally than it was for screening to be introduced early on a piecemeal basis?

A. That's correct, although I would like to add a caveat or two.

This is definitely a -- reality hitting me when I got to Southampton, because the letter that's still up -- I don't think it needs to be up anymore, but the letter that's still up about me advocating an early

adoption of tests was strongly felt at the time, and I think possibly justified. But the ground -- hitting the ground at Wessex in 1991, one faced reality in that although the laboratory was very well run, by some conscientious scientists, Wessex was not one of those centres that had been participating in any of the preliminary programmes, and the -- neither the region nor the hospitals were particularly willing to put up the extra bit of money when it came to introducing the new tests, which was like an extra pound per test.

And there was quite a lot of correspondence between me and the region, and some of the hospitals, about the funding of these particular tests. And at the end of the day Wessex was only funded by the RHA rather grudgingly, who felt that the hospitals were not paying their -- pulling their weight in this.

Again, this is the sort of typical narrow insight that accompanies the thinking of the market. I think it is profoundly regrettable that this situation was arising, which resulted in a delay of the implementation of the tests in England.

The other slight mitigation for me is that I was not party to any of the detailed discussions about the timing of the introduction. I've seen them since, from Harold Gunson, from John Cash and others, and

I know that Huw was given a rough ride for his decision to introduce in June.

I now feel quite strongly that Huw was right although at the time, because I didn't know the full picture, I felt that he was -- by breaking ranks, was disrupting the Service and introducing a sort of postcode lottery for donors and patients living in certain areas.

What I hadn't really fully appreciated was quite a lot of English centres were already testing. They were describing it as trials rather than some screening, but nevertheless, a lot was already going on.

So I was a bit naive at that stage. So I feel that my initial instinct back in early 1990 was still right. The delays were unnecessary in the end. We could have introduced the technology, because -- well, I think one of the reasons was that the technology that was going to be introduced in the late year, September, October, was significantly better and easier than the Phase I technologies being used earlier that year, but experience turned out that there was really very little to choose. I may be wrong on this, but that's my impression, that there wasn't all that much difference between the standard of the two tests, but the -- but at the time it was felt that, yeah, we should all stand

together, we -- and people breaking ranks were making life difficult for the others.

Well, really now I would say that was an unfortunate attitude. We should have been -- we should, I think, have been able to introduce the test earlier. But there were all sorts of other little things that -- the virologists being pernickety about the quality of the tests and all that sort of thing, so there was a lot going on. But it was, I think, wrong to delay it until September or so in 1991. It should have been introduced earlier that year, if not actually in late 1990, which I could see might have been a bit more difficult, but nevertheless, that was an unfortunate episode. Which is why the look-back period later on was so important.

Q. Would Wessex have been able to implement testing earlier? We know from your witness statement that you had to undertake some building works. Were those complete, for example, by the time you'd arrived at Wessex?

A. Yeah, I think part of the problem was that people like Jim Smith squashed those sort of thinkings in the time they were there. The letter that -- many were aware that such tests were going to be needed but just couldn't get anywhere with the -- with what was then the hierarchy within the Centre. So the Centre was poorly

prepared to take that on, even though I had written to Andrew Herborn before I started, saying what's going on about HCV testing?

Q. And the reference for that letter, we don't need to go to it, but for the transcript, the letter you wrote to Andrew Herborn on 26 June 1990 is NHBT0000189.

You also make clear in your witness statement that you were only -- Wessex was only given three weeks' notice of the date for testing having to be rolled out nationally, and I just wanted to read out a paragraph from your witness statement. I don't think we need to have it up on the screen.

Well, in fact perhaps we should have it up on screen. It's WITN3456002.

In which you set out the impact on Wessex of that short notice period.

Could we have, please, page 148. And it's paragraph 410 of your witness statement. You're asked what happened to all the unscreened blood that had been collected prior to the HCV testing being implemented and you say this:

"In order for all blood issued after 31st August 1991 to be negative for HCV, all the blood in stock from the 1st September would have been tested -- which is why early stocking of test kits was

needed so that donations issued to hospitals during August 1991 would be HCV negative. I cannot be confident that this was the case given that Centres had at the most, 3 weeks (before 1st September) in which to introduce the systems. Hence, some untested blood may well have been issued during the first week or two after the tests were implemented. Although usually most blood was issued to hospitals within three weeks of donation, the expiry time of four or five weeks would indicate that a few HCV untested units may have been issued. I have no data on how many untested units were issued or even transfused after August 31st."

So you put the fact that there may have been untested blood being issued post-1 September down to the very short period of time that you -- the very short period of notice that Wessex were given to get testing up and running?

A. That's my understanding now of that time, which is 30 years ago, but nevertheless, it was an important development that I was faced with when I arrived.

I have to say that -- just be a bit cautious -- my -- this is another example in my memory not necessarily being totally accurate, and I don't have any papers backing this particular attitude, but nevertheless, this is a sort of -- I'm painting

deliberately a worst-case scenario here, in that if people -- if someone was able to say to me that someone was transfused in a Wessex hospital in, say, October 1991 and then developed hepatitis C, the last thing I could say is, "Well, it wasn't due to the blood."

My understanding now of the situation at the time was there was quite a lot of uncertainty about what we were doing, and I have no real means now of checking that up. But I did remember at the time feeling a little bit nervous about the possibility of HCV emerging among some of our recipients.

Q. I'm going to ask you now to move on to the look-back for hepatitis C.

If we can go, please, to NHBT0087650.

There's a letter that you have written to the hospitals served by the Centre. Now, rather curiously, this is only the first page of the letter, and the second page of the letter -- Sully, I wondered if we could have that up by the side, please -- is -- oh, there is a second page. There we go. Thank you.

We don't need them both up at the same time, it was just that on my copy it's a different document reference. But clearly not.

So if we can just look at page 1 of that, please.

So.

A. Yes.

Q. This is a letter that you wrote to -- it seems to name and shame the hospitals that you were asking to trace the potentially infected products from the HCV infected donors. And what you seem to have done here is done a sort of table, a league of shame to try to get those that had provided you with no feedback and done no investigations, to do so. Is that how to understand this letter?

A. That's correct. I might say that this, of course, is the sort of master copy of the letter, and the details of the people I was posting it to would be occupying that top left-hand corner.

I cannot be absolutely certain how many of them received it, but I do remember bringing the subject up at a Wessex regional haematologists meeting, of which there was two or three each year, usually held at Salisbury, and I remember talking about this. So they certainly were familiar -- or had no reason not to know about this name and shame league table. And I'm afraid that the reaction from most of them at the bottom there was a mere shrug of the shoulders. It was deeply unsatisfying.

Q. And you say in the letter on that last paragraph:

"Levity aside, I must confess to a profound sense of disappointment, particularly as I had visited all the hospitals and spoken to haematologists in April about the need to progress the HCV Lookback programme."

What do you think it was that some of the hospitals simply didn't engage with the look-back?

A. Well, this is September 1995. By which time Wessex had been taken over, as you'll see in the top right-hand corner, by the National Blood Service. And to some -- some of the consultants -- not the scientific staff, not the nurses, this would be a consultant-led attitude -- felt that we had been downgraded in Wessex. We were no longer a regional centre. So consequently, our credibility was a bit sort of -- we'd lost a bit of credibility. And I think that's one particular thing.

The other thing is the smaller hospitals seemed able to cope better, you know, like Poole, which had a good result, Bournemouth less so. The really big hospitals at Queen Alexandra in Portsmouth, which was not a particularly big hospital, but the St Mary's in Portsmouth and Southampton General, those were big hospitals. And, indeed, the Portsmouth haematologists were generally very supportive of me, but this particular message went down like a lead balloon, and I don't think any of them really picked up on that.

I think the response to this was still very poor.

So my powers of persuasion were tested and basically unsuccessful. I think, it's an unfortunate reflection of the sense of priorities. And the other thing is, as I referred to earlier, this was quite an expensive exercise, and they were sort of expected to take this on without being funded. This meant going into the hospital records, the patient records and, as I think I said in my witness statement, that I did, on one occasion, somewhat linked to this, but more linked to an HIV Inquiry, visit the records of the -- in Southampton General and they were in a dreadful state. I can also say that the records for the Regional Transfusion Service under the management of the RHA in the early '90s, when I was there, was also in a very disgraceful state.

So, on the whole, paper records of this nature were basically disregarded or forgotten about, put on one side, and it was too inconvenient for them to go back into the basement and dig out this data. So I felt that this -- this is why I was disappointed. Because I was prepared to do this work, why weren't they?

Q. Can we then look at NHBT0036757. This is on the second page, it's a table that's provided to you by Tim Wallington.

And if we go over to page 2, we can see the numbers for Southampton on that column at the end. So we see that number 1, the 95 number is number of donors identified who have given blood pre-1991, presumably who are HCV positive -- 95; number of relevant donations identified, 630; number of donations notified to hospitals, 306; number of recipients identified by hospitals, 173; number of recipients followed up, 176, slightly curiously more followed up than had been identified.

A. Yeah.

Q. Number of recipients counselled and tested, 34; number of recipients tested positive, 19; number of recipients tested negative, 12; and number of recipients who had died, 128.

Does that chime with your recollection of the sorts of figures that we're looking at?

A. Well, I don't -- I only recollect this retrospectively now; I'd forgotten this particular thing. I do suspect that the Southampton columns are an under -- that they would be reflecting -- reflected in the analysis that Tim's staff were doing on this, but I suspect that those numbers are an underestimate, even though row 5, the number of recipients followed up, it looked as if Southampton was doing more than any of the others.

Either the others were just as bad as Southampton or Southampton happened to have rather more people. I just don't know. Certainly Southampton, you know, those figures indicate that there was a look-back, but how effective it really was in Southampton, based on the previous slide, I've told you, I am unconvinced that those are really accurate figures. I think they may well be underestimates.

Q. So my reading of this, and it may be that I'm wrong, was that Southampton referred to the work that you were doing in the old Wessex Centre, rather than the work that was being done by the Southampton Hospital. Is that --

A. Yes. Yes.

Q. Is that how you read it?

A. Yes, this is the Southampton Centre not the Southampton hospitals. Yes, I'm pretty sure that it would be referring to the Wessex centre, not the Southampton General Hospital.

Q. Then the last document from me before we have a break for further questions from Core Participants is DHSC0004180_052. I'm going to be asking some questions about records. So this is a letter from -- if we go over to page 2, we don't need it -- it's from you to Dr Rejman, dated 15 --

A. Rejman [clarified pronunciation].

Q. Rejman, sorry. If we go back to the first page, 15 October, 1992, and you say, at the beginning of the letter:

"Thank you for your letter of 12th October 1992, requesting information regarding the above patients."

There are two patients listed there:

"I apologise for the lack of response to this matter so far ..."

Then the next paragraph down, you say:

"We instituted a search of our records concerning Mr [X] shortly after receiving your first letter on 20th July; and indeed my predecessors had kept a detailed file. However, the information is very incomplete and I cannot state with any certainty from the records that are now available to me, that any of the four unit numbers involved [then you set those out] which were transfused in April 1984, can be traced with certainty to a donor subsequently found to be HIV positive."

Then if we could just go over the page, and go halfway down that second page, to the sentence that starts -- the paragraph that starts "I think" so below the crossing out:

"I think you will appreciate this has been

an extremely difficult investigation; our time since the receipt of your first letter in July has been spent exhaustively combing through our files for further evidence which has been entirely unrewarding. I feel that some of the difficulties have arisen through a desire to maintain confidentiality of records of the donors, and indeed some of the documents which would have enabled us to provide the link have gone missing. Also, there has been no storage of any blood samples taken from donors in 1984, which now could be tested."

I think I probably should have said at the beginning, the context of this letter is a request from the Department of Health to you to see whether or not two particular patients had been infected with HIV blood or tissue transfer, in order to see whether or not they met the requirement to receive payments from a Department of Health scheme.

So two issues that arise in relation to this, the first of which is the issue about generally the state of the records at Wessex, and I'll ask you to give us your views about that. But first, perhaps, while we've got this up in front of us, the second page, the second point that arises is this point that you make about the desire to maintain confidentiality in records of donors, causing problems to those that come back to read the

records in later years.

Can you tell us what it was that you found and why you came to that view?

A. I think it would be more a case of what I suspect, rather than found. You're right, this was a very difficult exercise. The state of the records was disgraceful because I think these were ones which I referred to had been farmed out to a decommissioned mental hospital near Basingstoke, called Park Prewett, and those records were contaminated with bird droppings through a leaky roof and, indeed, some of the -- I didn't do it myself but some of the people who went there felt that they were themselves suffering -- susceptible to health hazards from the state of those records.

So a few hundred records, I think, had to be destroyed or were inaccessible on that basis. So that indicates a sort of standard of care at that particular time, under the priority that historical records were thought to have. That's one aspect.

As far as the confidentiality is concerned, again, this was the era, as I say 1983/1984, crucial years, not just in Edinburgh but in the rest of the country, in how on earth we were to inform potential donors about the risks of -- about us not wanting to have any blood that

might have been contaminated with HIV, whatever the reason might be. But the biggest reason that we were worried about was multiple men having multiple sexual encounters with other men, as the biggest risk factor.

And this was a very difficult subject and we were still getting round how to communicate with the donors about this. So it wouldn't be particularly surprising to me -- and this is well before my time, but both these patients were well before my time, and I happened to be around when Andrzej Rejman came up and asked us about this and I had two good conversations with him, but yeah, it's distinctly possible. But people didn't know how to record the suspicion of a high-risk behaviour on a donor card, or they may have put some squiggle on it that was a code, but the significance of that code was lost in a few years.

I am speculating but, basically, I think it is recognised that we didn't quite know how to deal with this sensitive data among donors around that particular time. And so I'm speculating that that may also have contributed to the paucity and poor quality of the record keeping in regard to these particular episodes at that time. But it is a speculation, although not based on idle musing.

MS SCOTT: I've come to the end of my questions. We'll need

to take a further break so Core Participants can send in any further questions that they would like me to ask Dr Boulton.

SIR BRIAN LANGSTAFF: Yes. Do you have any sense as to how long you might need?

MS SCOTT: Well, I've had some questions in from the break before, the earlier break, but I'm conscious we've covered quite a lot of ground with Dr Boulton, and so it's certainly going to be more than 20 minutes. Could I say -- I think it's probably going to be -- could I say until 4.45?

SIR BRIAN LANGSTAFF: Yes. Well, let's say not before 4.45.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Using that formulation, Dr Boulton, to allow for the fact that it might be a little later, we'll just have to take our guidance from Ms Scott, but if we're ready for 4.45, then we may well be able to start then.

A. I'll be ready at 4.45. Thank you.

SIR BRIAN LANGSTAFF: Thank you very much.

(4.23 pm)

(A short break)

(4.44 pm)

SIR BRIAN LANGSTAFF: Yes, Ms Scott.

MS SCOTT: Dr Boulton, I've got a number of questions from

Core Participants, so I think we'll be going slightly all over the place, but the first question is in relation to the evidence you gave this morning about your time in Liverpool, and you were describing how, for children, it was -- your practice was to give them cryoprecipitate and then at some point, as they got older, concentrate, and the question is at what age would you typically make the decision to move from cryoprecipitate to concentrate on the basis of age?

A. I am not sure that there was a very consistent policy there, but I suspect that it would be when they became teenagers. So somewhere between the age of 13 and 17, depending upon all sorts of things, like their -- the frequency of their bleeds, actually how big they were -- as much as anything else, it was their size. So that -- and indeed, some of the boys, by the age of 13, having been well treated, would be quite [audio disruption]. So consequently, you had to take it on a case-by-case basis. But I think it would be around about then.

But I have to say I have no clear memory of operating that policy specifically. My answer is based to some extent on suppositions and probabilities, rather than actually remembering a precise set of circumstances.

Q. In your evidence this morning, you said that the amount

of confidential material which was inappropriately confidential and hampered communications was quite profound. Now, you've given us some evidence this afternoon about what you found and what you concluded from looking at records in Wessex. Was that also the case in Liverpool and Edinburgh?

A. Is that about donor characteristics?

Q. Well, I think you, in a -- I can't remember the question that I asked you, but as part of your response, you said either these words or words to this effect: the amount of confidential material which was inappropriately confidential and hampered communication was quite profound.

A. Yes.

Q. And as I say, you've dealt with that in relation to Wessex but is there something you can assist us with, whether you found that also to be the case in Liverpool and Edinburgh?

A. Well, in -- Liverpool and Edinburgh were a very different set of circumstances. I don't ...

Liverpool, 40 years ago, confidentiality, the concept among medical practitioners, including myself, was perhaps less sophisticated than it is now. And to a certain extent my shame, I will be party to the common medical practice of making personal records of patient

details in ways that would be inappropriate these days. So in a sense, that was relying on a concept of confidentiality that no one would ever see what we'd written. Nowadays, a completely misplaced concept, but that was fairly common at that time. And as we grew more experienced and became more aware of the really important nature of patient/professional relationships, I think we changed.

In Edinburgh, I think there, it wasn't for me so much a record of patients, because it was more a question of confidentiality of communications around staff. And that was a real problem, because -- I mean, I know that some of my colleagues, I mean, were required to sign the Official Secrets Act concerning their discussions in Committees. And yet they've all been revealed. So it's actually -- that was a real hamper to communications.

So that part of my answer was probably more directed towards the degree of professional confidentiality and the way that interfered with transmission of -- the communications about policies, et cetera. There was a lot of secrecy about at that time -- which I think was unnecessary -- possibly because those who were talking felt vulnerable, but these days I rather hope that attitudes have changed,

and the concept of openness and accountability is at least acknowledged more, although sadly, judging by official public records on other circumstances, the degree of redactions when people ask for the Freedom of Information inquiries is still -- there's a lot of obfuscation at that level.

So my feeling is that confidentiality often went too far and hampered communications, both with patients, who should have been handled better, with donors, who could have had clearer information about what was required of them, and then within the professional -- professions that were involved in the whole provision of blood service. So that's my answer to that, my rather long answer to that particular question.

Q. You referred to cryoprecipitate being made, in your time as a houseman, from plasma collected from the naval base in Portsmouth in the late 1960s. Can you recall what knowledge there was or what consideration was given at that time to the risk of viral hepatitis being transmitted by military personal at the naval base? And of course bearing in mind that this was pre-hepatitis B screening.

A. But still known to be associated with transmitting hepatitis. My answer to that question is there would have been no regard taken to that particular aspect.

In fact, Dr O'Brien, who was the consultant in charge, a very eminent haematologist, part of the team that discovered Christmas disease in Oxford in 1952, was a very effective operator, and he would have had no hesitation, under the circumstances of this particular patient, in pulling strings with his contacts in the navy, getting onto the boats, and having a lot of exercise in producing literally hundreds of donations.

The effect on the staff in the lab, I learnt afterwards, was profound, particularly in the end it all turned out to be -- the patient died fairly soon. So a lot of hard work for a particular episode, but in terms of things like transmutant -- transmitted infections, no, that was the last thing on Dr O'Brien's mind. And I have to say that it wasn't very prominent in my mind either, because this was a very significantly ill person who I thought was unlikely to survive anyway.

Q. When you were in Liverpool, did you monitor the white cells of your patients, ie the CD4 and CD8 counts and ratios?

A. No.

Q. Were you involved in white cell testing on a haemophilia patients, ie CD4 and CD8 counts and ratios, while you were in Edinburgh?

A. No.

Q. In relation to the infection with AIDS in Edinburgh, what investigations were done into how the products those patients received had come to be infected by a donor in Scotland?

A. There would have been extensive -- there were extensive records of the donors who attended particular sessions. Those donors could be identified with each batch of Factor VIII concentrate that was produced by PFC. So it was indeed possible, at least in theory, to trace everybody who -- to identify, or at least have some identifying features, of everybody who gave.

It was not possible to be 100 per cent certain on following up those donors, that those identifications would reach the intended donor. They may have moved away, they may indeed have died, or something else might have happened, and we wouldn't have known about that.

So the system was very sophisticated, very intensive but by no means expected to be 100 per cent foolproof, and I think that the donor or donors who are implicated in that -- who would have contaminated that batch were never actually identified.

Q. You described NHS factor concentrates as being derived only from the blood of British people, and I've been asked to ask you whether or not that's, in fact, correct. Is it the case that tourists at the Edinburgh

Festival, for example, may have been able to donate blood?

A. You're absolutely right. I should have said people donating in Britain. So we would not have excluded tourists, that was one of the concerns we had about the Edinburgh Festival, the possibility that American visitors, in their spirit of goodwill, would turn up at a donor session offering to give blood and they would not have been turned down, unless we actually identified a specific feature.

Q. Sorry, Dr Boulton, I'm just getting in another question, so let me just -- thank you.

Do you know anything -- do you have any awareness of blood being collected at the US naval base in Holy Loch in the 1980s?

A. There were donations from military and naval institutions collected in Edinburgh at that particular time, I wasn't actually responsible for those organisations, but I think on looking back there was some sessions at those. Those would have been included as sort of public session and so, consequently, I could not exclude the possibility of that happening. But I wasn't directly involved.

Q. So presumably those sessions would have been taking donations from US naval --

A. Yes, what I don't know is how long that continued into the 1980s.

Q. Just in relation to the position at Wessex, at the time that hepatitis C testing was instituted, did you re-call blood or blood products that had already been issued prior to 1 September? So they would have been untested, sent out to the hospitals prior to the 1 September. Did you re-call those to get them tested or destroy them?

A. I'm not quite sure that I understand the question but is it that, okay, the tests were introduced on 14 October for HIV. Blood collected before that date, which was still in date, was that tested for HIV before it was distributed?

And I'm pretty sure the answer to that is they were tested so that after 14 October, no blood in the blood bank of Edinburgh Royal Infirmary had been -- had not been tested for HIV. I'm fairly sure that's the situation.

Q. So this is a question in relation to Wessex, and --

A. Oh sorry, Wessex.

Q. -- and to HCV testing. So the question is, for the blood and blood products that had been issued from Wessex prior to 1 September 1991, ie untested --

A. -- HCV, yes.

Q. -- HCV -- would those have been re-called or could

untested blood have been issued and used from hospitals post-1 September 1991?
A. I cannot actually remember if there was a re-call at that particular time, and that's why I think I couldn't exclude the possibility of untested blood being issued at that time. But I think that's what I said at the time, so I'm not sure. It's a possibility, distinctly, that some blood may have been issued that was not -- that had not been tested for HCV, but I can't be certain of that.
Q. We've heard some centres re-called all the blood and blood products that were sitting in their hospitals, and so -- that was untested, re-called it and either tested it or destroyed it; did Wessex do that?
A. I cannot recall if that's what happened at Wessex.
Q. In relation to products in Wessex that had been made and were untested prior to 1 September '91, frozen components that have a long shelf life, were they tested before they were released?
A. That's a very good question about the testing, both for the HIV and the HCV, because the frozen stuff would have been still there a year or so after they donated. So there could be stuff that was collected in September 1990 that was still in our freezers. And, to be honest, I cannot recall how those donations were

handled. So I can't give a satisfactory answer to that question.

I think it could -- it may be possible to check from colleagues who have retired, who I know are still around, what their recollection of that particular experience was, and the other person who might have an insight is Dr Andrew Herborn, if he's contactable, and we could do our best to try to contact him.
Q. This is returning now to your time in Liverpool. You said that you thought patients preferred NHS concentrates because they knew of the risk -- they knew that the risks were -- that it was a less risky product than the commercial concentrate. What's the factual basis for your belief that patients preferred NHS concentrate for that reason? Did your patients tell you that or was that an assumption on your part?
A. I think some patients would have mentioned it, possibly in passing.

Don't forget that the World in Action programme of 1970 -- whenever that was, was Granada, and lots of people in Liverpool would have heard it, so consequently there was an awareness, certainly among the haemophilic community in the Liverpool, of that particular programme, and it did cause them to ask all sorts of questions about the nature of the products. So from

that point of view the programme achieved its aims. It may not have achieved the aims of actually banning the import of American products, but nevertheless ...

So that programme was actually very informative to quite a lot of the people that I was dealing with in Liverpool.
Q. Did you tell your patients directly about the relative risks of cryoprecipitate versus concentrate?
A. Um ... I do not recall specific conversations to that effect. I think it's highly likely that I would have done, to explain to those on home programmes why cryoprecipitate was preferred. But I honestly cannot say the -- how much of detail I went into with the patients of that level.

I apologise for my lack of memory on that one. It's an important question, but I can't answer it in any more detail than I think I probably did.
Q. And it may be that this is -- the answer to this question is the same but I've been asked to ask it, so, again, did you discuss the relative merits of pool sizes and the impact on infection risk with your patients?
A. Again, that featured in the World in Action programme. So if that question was asked, I would have answered about the greater risk potentially from the larger pooled products, but again, I don't recall specific

conversations to that effect.
Q. Now you told us that you would tell patients if you thought that they had contracted non-A, non-B. Would you also tell them that the illness was due to the products that had been provided to them for their medical treatment?
A. Yes, I think I would have done. And that also -- also is for hepatitis B, as I think I said, so our patients who contracted hepatitis B, I think they or their parents would have been informed this would have come from the product which they were given.
Q. And the last question I'm going to ask you is, did you also -- for those patients that you thought had contracted non-A, non-B, did you also explain the potential long-term consequences of liver cancer, cirrhosis and so on?
A. I don't think I would have done. I was not particularly aware of those risks -- I was of hepatitis -- of the cancer, but not of -- the cancer from hepatitis B contamination, but I wasn't -- I don't think anybody was really aware of the long-term consequences of hepatitis C until Eric Preston published his paper in 1978, and I can't recall any specific questions from the haemophilia community with regards to that. So I don't think I would have told them about the long-term risk of

them getting a product contaminated with non-A, non-B.

MS SCOTT: Sir, those are the questions that I'm going to ask from the Core Participants.

Questions from SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: Thank you.

Just one question which comes out of the question you had early on in this session about confidentiality and what you said earlier about a description of a mother as "histrionic", you would accept, would you, that, a character assessment is not part of the proper function of a doctor whose job is to treat a patient medically?

A. I would agree.

SIR BRIAN LANGSTAFF: But that must then mean that comments about how nice a person is or how lively, et cetera, are unlikely to be of any clinical significance and should be omitted? Would you be happy with that?

A. That is correct. That is correct from the -- yes, that I would say. But, on the other hand, there is such a thing as developing human relationships and so one isn't necessarily effective in doing that if one adopts too objective an approach. But certainly in documentation, any judgementalism of that nature is inappropriate, and I actually think that that particular comment was unjustified and inappropriate.

So we learn as we go along.

SIR BRIAN LANGSTAFF: Well, you've made that perfectly clear, and I applaud you for it. The thrust of the question really is the number of letters which many will have seen from doctors which say nice things about a patient but they're not to the patients, they're not forming a relationship with the patient by doing so. They are really beside the point when it comes to medical treatment; is there really any place for them?

A. Well, I think there is, if it's not meant in a -- that sort of critical, judgmental way. I mean, doctors particularly -- or anyone who has face-to-face contact with people on that sort of medico-social basis, and who is describing, in a professional context, their experience with that, is entitled to put a human face onto the nature of their communications. And that, to be totally objective, could actually appear to be heartless and, in itself, therefore have regrettable consequences.

So, philosophically, I think we are dealing with people who have feelings, whether they're our co-professionals and, in particular, whether they're the people we have some responsibility for their care. So, consequently, putting that human face on our communications is, I think, an understandable and, on

the whole, so long as it's not overdone and so long as it's also honest, it is a justifiable approach.

SIR BRIAN LANGSTAFF: Well, thank you. Thank you for that. That's all that I ask.

Ms Scott?

MS SCOTT: Sir, Dr Boulton's legal representatives don't have any questions so it just falls to ask Dr Boulton whether or not he would like to add anything to his evidence.

A. Yes, thank you, I would. And I've got it written down, so I will be reading it out.

I'm profoundly sorry and deeply regret that my professional activities as a doctor during the period covered by the Inquiry led to the deaths and sufferings of so many people. In the late 1970s, I was responsible for the care of haemophiliacs in Merseyside and prescribed vials of commercially prepared Factor VIII concentrate, many of which happened to be contaminated with viruses and led to the development of hepatitis or AIDS, and sometimes both.

Within 10 years or so, many of these people had died, while others had to cope with the severe morbidity of chronic infection. AIDS was unknown at that time but almost certainly some batches of the commercial products given in the late 1970s were contaminated with AIDS

viruses originating from plasma bought by American fractionators.

On the other hand, potential contamination with viruses causing hepatitis was well recognised by professionals including myself, and not just in commercial products but also from donations to the UK Blood Transfusion Services. Although from the early 1970s, screening tests were applied to UK blood donations to prevent the transfusions of blood contaminated with what was thought to be the most common source of serum hepatitis (that's hepatitis B), it is recognised that these tests were unlikely to offer complete protection, even from hepatitis B, and, furthermore, that other hepatitis-related viruses, especially non-A, non-B, could not be detected even when present even NHS blood.

Nevertheless, the professional consensus was that such infections were usually mild, often asymptomatic, and short lived, so that the possibility of adverse consequences were often downplayed when advising the patients and their parents.

I should have done my best to ensure that everyone who received blood and blood products understood that there were risks of transfusion-transmitted infections in the products they were using. Although the degree of

those risks was unknown.

I was keen to extend the home therapy programme for the haemophiliacs in Merseyside and this was welcomed by the haemophilia community, especially the mothers of affected boys. Mothers, many mothers, on learning that they had carried the defective genes to their sons, felt guilty although such carriage was actually a form of lottery. Nevertheless, many were keen to be trained by me so that they could deal with the consequences of their parentage, and see the palpable relief of pain which would follow their administrations of Factor VIII or Factor IX to their young children. In no way can they be held responsible for the later sufferings of their children.

After I left Liverpool in January 1980, I never saw those people again. Although I note from some of the testimonies that the service to haemophiliacs in Merseyside may not have improved very much, if at all, until substantial developments occurred there under later haemophilia directors. The haemophilia community on Merseyside were great people, and I miss them. But it was proper to let my immediate successors take over from me completely.

I have felt since that I sort of deserted them in never having, for example, to conduct the personal and

difficult conversations, although I also recognise the part that I played in this tragic saga when I was at Edinburgh, and pay tribute to my Scottish colleagues who tried so hard to improve the testings for transmissible infections, to increase donor awareness, and hence to improve patient safety, as well as their pioneering efforts to inactivate the viruses contaminating the plasma while retaining the biological clotting activity.

The consequences of the contamination of Scottish Factor VIII concentrates revealed in November 1984 were permanent and will never leave the affected patients, their families, myself, my Edinburgh BTS colleagues and the Scottish Haemophilia Directors, and other people who administered the treatments.

I am therefore very pleased that this Inquiry is taking place and hope that those people and their families, who suffered and survived, and the families of those who died, obtain full recognition of their sufferings.

I extend this, of course, to any recipient of UK blood who has suffered from the contamination of that blood. I want no excuses but hope that everyone gets a clear explanation enabling them to develop an adequate sense of closure. Thank you.

SIR BRIAN LANGSTAFF: Well, thank you. What you've given us today has been really most informative, it really has and you haven't sought to make excuses, quite the opposite, in many cases. Perhaps living up to your name, you've been frank.

A. (Laughs)

SIR BRIAN LANGSTAFF: I hope you'll forgive me for that. But it is particularly useful, I think, for us to see somebody who has had experience from, as it were, both sides of the fence, both in the Transfusion Service but also as a treating clinician, and has had the experience of doing it both in Liverpool and in Edinburgh, and in dealing with blood supplies both in Edinburgh and in Wessex.

So you have the ability to give a comparison to us, which few others have, and I just want to thank you for that.

Now, I'll turn to Ms Scott and ask her what we have in store for us next week.

MS SCOTT: Well, sir, we sit again on Tuesday, 8 February. We start at 10.00 with a presentation about Wessex before Dr Boulton arrived in 1990, so the early years of Wessex, which will take us up until 12.00. And then we have the oral evidence, remotely, of Dr Huw Lloyd. He is abroad, and so he -- the plan is for his evidence to

begin at 1.

SIR BRIAN LANGSTAFF: Yes, he's in Canada, I think.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: So we will have -- we start him at 1.00.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Very well. 10.00, then, on Monday (*sic*). Thank you again.

MS SCOTT: On Tuesday, sir.

SIR BRIAN LANGSTAFF: On Tuesday, deary me! It's getting too late in the day, isn't it. But thank you for your staying power too, Dr Boulton.

So until Tuesday, 10.00, goodnight.

(5.17 pm)

(Adjourned until 10.00 am on Tuesday, 8 February 2022)

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