Tuesday, 8 February 2022

(10.00 am)

Presentation by COUNSEL TO THE INQUIRY about THE WESSEX REGIONAL BLOOD TRANSFUSION CENTRE

SIR BRIAN LANGSTAFF: Good morning, Ms Scott.

MS SCOTT: Good morning, sir.

SIR BRIAN LANGSTAFF: It's good to see you here in person.

MS SCOTT: Thank you, sir. It's very nice to be back.

SIR BRIAN LANGSTAFF: Yes?

MS SCOTT: This morning, sir, I am going to be giving a presentation on the Wessex Regional Transfusion Centre, from the date that it was established in 1970 until the time when Dr Frank Boulton took over as the director in September 1990.

You will recall, sir, that we heard evidence from Dr Boulton last week about what happened in the Centre from the time that he arrived in September 1990.

The first director of the Wessex Centre was Dr Donald Smith and he took the directorship from the establishment of the Centre in 1970 until stepping down in around, Dr Boulton thought, around 1988 or 1989, we didn't have a precise date for that. What Dr Boulton told us and what we see reflected in the documents is that, having stepped down, Dr Smith was

persuaded to remain for a couple of days a week as a locum medical manager and that is how he describes himself in some of the documentation that we see towards -- in 1989.

Then it looks as though he stepped away entirely at the end of April 1990, and we were certainly told by Dr Boulton that, by the time he arrived in September 1990, there was no director -- there had been no director in place for a little while. He wasn't sure how long. But it looks like that period was May to September 1990.

The Centre itself is based in Southampton and it covered a region which included Hampshire, the Isle of Wight, Dorset and part of Wiltshire. By 1984 we see from the documents that it served 11 district blood banks.

In terms of population, again, the documents tell us that it served a population of about 2.14 million in 1980 and that was rising through the 1980s to 2.3 million in 1987 and, by 1989, it suggested that a better estimate was 2.8 million.

If we can have, Sully, a document, CBLA0000391. We can have a look at a very simplified picture of the area that it covers. This document is the agenda and then the minutes of a meeting of the Blood Transfusion

Centre Directors, regional scientific advisers and Haemophilia Centre Directors for the supra-regional territory for which Oxford Haemophilia Centre had responsibility and it's from a meeting that took place on 26 July 1976.

We're looking here at the agenda but if we could turn, please, to page 3 of this document. We can see a map, and if we look down at the bottom there we can see that the Wessex RHA is depicted there and, we know from the documents, that the RHA and the Regional Transfusion Centre were not identical but that's the area we're, more or less, looking at; the transfusion centre did not cover the whole of the Regional Health Authority.

If we then turn over, please, to page 5 we get a little bit of information about who was attending this meeting and we can see, as we look down the list of attendees, that we've got an attendee from the Treloar Haemophilia Centre, so that was one of the Haemophilia Centres served by the Wessex Transfusion Centre, Dr Kirk, and we've also got there Dr Rainsford.

Then moving down the list, we can see there Dr Stern, from the Department of Pathology in Bournemouth, again another hospital and area served by

the transfusion centre.

Again, moving down we see Dr O'Brien from Portsmouth, again served by the Wessex Regional Transfusion Centre.

If we turn over the page we can see under "Regional Blood Transfusion Centre Directors" attendees, we see Dr Smith from Wessex and then at the bottom -- near the bottom, we see apologies for absence and we see the name there of Dr Chisholm who is from Southampton, again one of the Haemophilia Centres served by the Wessex Transfusion Centre.

Then, sir, if we turn over to page 8 of this document, we see recorded a discussion and a contribution from Dr Smith at the top of that page:

"Dr Smith said that he supplied cryoprecipitate to hospitals in Newport, Dorchester, Salisbury and Winchester. These are not Haemophilia Centres but Dr Smith felt confident that the patients were well cared for at these hospitals. Dr Smith said that he would ask at the next Regional Haematology meeting to see if the centres should be listed and designated as Associate Haemophilia Centres."

Then the view is expressed by Dr Rainsford and Dr Scott that:

"... it was not generally desirable for patients

to be treated at hospitals which were not haemophilia centres."

SIR BRIAN LANGSTAFF: Just on that, if we go back to the cast list on the page 5 --

MS SCOTT: Page 5.

SIR BRIAN LANGSTAFF: -- whereas Dr Kirk is shown as being at the Treloar Haemophilia Centre, the address given for Rainsford, who makes the point that you should only be treated at a centre, is shown as coming from Lord Mayor Treloar College. So he appears to give his address as the college not the centre.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: It just -- I don't know if anything turns on that point; it's one I will consider in due course, perhaps.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: Then if we turn to another document to give us a snapshot in terms of what was happening at the Centre in 1980, it's NHBT0110056. This is the annual report of the Wessex Transfusion Service for 1980, and we can see in the "Introduction" it says:

"This Service was set up by the Wessex Regional Hospital Board in 1970. The Region had previously received its blood supplies from the Bristol and

[South] London Transfusion Services. Some 55,825 donations were collected, processed and distributed in the first full year.

"At the re-organisation of the NHS in 1974, it was decided that the Bath and Swindon Health Districts would continue to be serviced by Bristol and Oxford Transfusion Centres: the distances involved made this a logical decision. This, of course, means that the Wessex Transfusion Service is serving approximately 2.14 million of Wessex's 2.74 million population."

Then the next paragraph, the second half of that paragraph:

"As will be seen in the body of this report, the total number of donations collected in 1980 was 86,926 with the plasma from about 38,000 going to Factor VIII and Plasma Protein Fraction production.

"In 1974 the service changed from bottles to collection of donations into plastic packs."

Then if we go down to the bottom of this page, in the last paragraph, halfway through that paragraph we see that a mobile centre was commissioned and had its first session on Monday, 1 September 1980.

If we go over the page then, please, we get told a little bit about the buildings, and so on. First paragraph:

"The increase in blood collection and handling has exerted considerable pressure on the space available in the Transfusion Centre. Two small extensions have been carried out, one to the Bleed Suite, the other to a prefabricated Class I Clean Room."

And we'll see reference to that in some of the documents we look at later.

And:

"A further two-storey extension is planned for 1981/82."

Then if we go down to the last paragraph, we can see that it's said that:

"The amount of Factor VIII ahf which is provided by the Blood Products Laboratory is insufficient to meet the Regional needs. The reason for this is the existence of the Lord Mayor Treloar Haemophilia Centre at Alton. Consequently, some 3.1 million units of commercial ahf will have been purchased in the current financial year. It is hoped that our plans for expanding our plasma collection will make significant reductions in this."

Then we can see at the bottom some of the names of the senior staff team. We've got: Dr Smith, medical director; Dr Barnes, who is deputy medical

director, and we will see quite a lot of correspondence from him later on; then we've got Mr Allison, senior chief MLSO; and Mr Duddridge, regional donor organisation; with Mr Grundy as administrator.

We know from other documents that by 1984, the Centre were holding 18 sessions a week and collecting 99,000 donations per year and ,for the transcript, the reference for that is NHBT0010821_009. Don't need to go to that.

And we also know that by 1987 there was a plasmapheresis panel and there seemed to be a preference at the Wessex Centre for manual pheresis rather than automatic.

Turning then to high-risk donors -- and again we don't need to go to this, but I'll read this for the transcript -- there is a reference in an executive committee meeting note for The Haemophilia Society of 9 December 1971, which for the transcript is HSOC0029691_142, and the note says this:

"Dr Smith has been very pleased at the interest shown in what he was doing."

And you will recall -- we'll see of course, sir, that this is a year after the Centre has opened, and

he goes on to say:

"The crews of many ships are volunteering as blood donors."

Now it is not clear whether those are naval ships or other kinds of ships but there is reference in this document which I think is worth going to, NHBT0108948.

So there is reference in this document we're just about to look at to naval donors, and we can see here it's a -- it looks likely an internal note from Dr Smith dated 27 June 1974, and he says:

"Please could you ask the team clerks, particularly at Naval sessions, to enquire if there is any history of jaundice even if the donor has previously donated. Anyone with a history of jaundice will not be accepted but I will always write to them and explain that they can go on our research panel."

So this document suggests that there were certainly naval sessions and we'll see some correspondence in due course between the Centre and a naval hospital. And I will come back to the question of the donor selection and criteria in relation to those who have had a history of jaundice.

We can also see from documents that there were collections from prisons. Could we have, please,

DHSC0100020_045.

So this is a letter from 9 May 1972 to "Dear Dr", and we can see it's from Dr Smith, and it's about a particular patient -- or donor, I should say.

"This donor attended one of our blood collection sessions at Camp Hill Prison on the Isle of Wight. Our routine tests showed that he had a positive HAA test and this was confirmed by the Portsmouth Public Health Laboratory. These facts were then communicated to the Governor of the Prison and the Prison Medical Officer who decided that for medical reasons (personality difficulties) it would be inadvisable to let Mr [X] know these results. Liver function tests were normal.

"I asked the Prison Medical Officer to let me know when this man would be discharged and he has now been in touch with me to say he will be going under the care of the probation officer, Borough High Street, London, SE1. I regret that we do not know the donor's address.

"I thought I would let you have this information so you will be warned if he attends one of your blood collection sessions."

So it looks, sir, from this that this is a letter that Dr Smith is sending out -- well, it's

not clear whether it's to one or more than one transfusion centres to warn them that this donor may attend a session, not knowing that he has tested positive for hepatitis B. Hepatitis B, or Hepatitis Australia antigen.

Can we then look at NHBT0108717_001.

Sir, this is a letter from, again, Dr Smith to, this time, Dr Maycock on 28 June 1972, and he says:

"I am enclosing information about the incidence of Australia Antigen in the prison and forces population in Wessex. It looks to me as if we shall lose our prison population of donors eventually."

Then he sets out the total tests and the antigen positives for the general public, HM Forces, and HM Prisons.

So he, at this point, sir, clearly considers that the number of antigen positives mean that they shall loose the prison population of donors eventually.

But if we look at a document --

SIR BRIAN LANGSTAFF: It makes the point beautifully, doesn't it, in terms of mathematics, because there are exactly the same number of antigen positive cases if you combine forces and prisons, combined, as there are in the general public. If you combine forces and

prisons in total numbers, it's just over 4,000, which, again, multiply by 10, and you get to 40,000. So it's ten times as likely, on the basis of this, very rough, to find someone who is antigen positive in the forces or in prisons compared to the public.

MS SCOTT: Yes. Yes, quite.

SIR BRIAN LANGSTAFF: I mean, it's only a snapshot and it's not rigorously statistical, but that's pretty clear.

MS SCOTT: Sir, just noting the date there, 28 June 1972, and the suggestion that it looks like they'll lose their prison population of donors eventually, if we then look at a document for September 1983, NHBT0008628_001. Ah, that document doesn't seem to be opening. I don't know whether it's worth pursuing that or whether the best thing to do is to come back.

SIR BRIAN LANGSTAFF: Well, yes.

MS SCOTT: I'm being told if we can wait 30 seconds it can be put up.

SIR BRIAN LANGSTAFF: Right. Let's wait. Thank you.

MS SCOTT: So, we can see here, "East of Scotland Blood Transfusion Service ... Scottish Transfusion Directors Meeting 13.9.83":

"Telephoned survey of England and Wales Transfusion Centres regarding use of prisons as

a source of donor blood."

If we look down, the fourth Centre down is Wessex and they say:

"It is several years since they stopped using the Isle of Wight prisons because.

"1) of increasing medical problems among prisoners, particularly related to drugs;

"2) the prisons cancelled sessions at 2-3 hours notice because of prison riots, demonstrations, etc.

"At present, they use Winchester prison, a short-stay prison for non-violent prisoners, once a year, but plan to withdraw this session in the near future."

So it seems from this that there were still some sessions being undertaken as of September 1983, albeit plan to withdraw those in the near future, whatever that means.

SIR BRIAN LANGSTAFF: What's the date of this, did you say?

MS SCOTT: September 1983.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: I'm now going to turn to a handful of documents to look at the issues that arose in Wessex for provision of plasma for fractionation. We know that in 1980, and we've seen documents relating to this in

previous hearings, that Wessex were providing plasma to PFL in Oxford for fractionation. There are a series of meetings and correspondence that takes place between PFL, BPL and Wessex as to whether and, if so, how Wessex can increase their supplier of plasma in return for more Factor VIII.

If we can pick this up at CBLA0001198. This is a letter dated 6 November 1980 to Dr Edith Bidwell and it's from Dr Smith. It sets out the history of this matter, and he says -- this the second paragraph down:

"Earlier discussions with Dr Lane and Dr Gunson, former Director of Oxford BTC, had been concerned with:

"Our desire to send more fresh plasma for fractionation to Factor VIII and Plasma Protein Fraction to help with the supply of Factor VIII to Alton [of course, that's the Lord Mayor Treloar's].

"Our 'sterile' room being at capacity ...

"Our wish to send single transfer packs of FFP.

"Our intent to have a Class 1 clean room ...

"After these preliminary talks and exchange of letters a meeting was held at Southampton and the statements below are extracted from the notes prepared by Dr Bidwell. The date of the meeting was ... 25th June, 1979."

Then it sets out what it was discussed at that meeting in terms of an agreement was reached about sending more packs each week to PFL in Oxford.

Then, if we turn over the page, we can see at the second paragraph down there:

"A meeting was arranged and held at Oxford on the 14th March, 1980. Those present were Dr Lane, Dr Bidwell, Dr J Smith, Mr B Grundy, Administrative Officer, Wessex ... Mr Allison, Senior Chief MLSO, and myself, and we were told that Oxford were unable to increase their handling of plasma to 600 per week [which is what Dr Smith thought had been agreed at the previous meeting] and that they were not entirely happy to process 500. Dr Lane stated that even if we increased our plasma supply to BPL in 5 litre pools, there could be no pro rata increase of Factor VIII, but in due course we would receive some PPF back.

"We had no alternative, therefore, but to cancel our arrangements about collecting more donations, for the revenue expenditure would have been about £170,000 with no Factor VIII return on the investment. Subsequent to the above meeting I wrote to Dr Lane and received a reply which confirmed our understanding of the points made above."

Then he goes on to say:

"As soon as the fractionation plants are able to receive extra FFP, even in 5 litre packs, we will plan again to increase our donor intake. This has always been made perfectly clear. We now have a Class 1 clean room in operation, but naturally, like everyone else, we would like to send single transfer packs."

So that was the position as at 14 March 1980.

Now, this state of affairs, ie Wessex wanting to send more plasma for fractionation, either to PFL or to BPL, was the subject of a letter that Dr Aronstam published in the BMJ, and if we can have a look at that it's RLIT0000667. It's dated 20 September 1980 and the letter is on the right-hand column, halfway down that page.

He's responding to some comments made by Dr Cash, if we could go up a little bit. It's not terribly good, yes, it's "Factor VIII supply and demand", "Sir". He sets out that he failed -- the reason he:

"... failed to mention the availability of plasma for fractionation as an important aspect of the problem of national self-sufficiency in blood products [was because the] Wessex Regional Transfusion [Centre] has recently offered to increase the supply of plasma to the Lister blood products laboratory, only to be

told that there was not the capacity to handle the extra plasma.

"I think it most important that ..."

I can't now read that.

SIR BRIAN LANGSTAFF: "... the repetitive cry ..."

MS SCOTT: Thank you:

"... the repetitive cry for increased plasma does not obscure the very real need for adequate fractionation potential in England today."

Now, that letter prompted a rebuttal from Dr Bidwell which we see at CBLA0001193. So she, in response to that, wrote a letter to Dr Aronstam, dated 29 October 1980, referring, in that first paragraph, to the letter we've just looked at. She puts a rather different -- has a rather different interpretation of events. She says this:

"The situation is that Wessex was unable to increase the provision of plasma to Blood Products Laboratory in the agreed form, namely 5 [litre] packs, in conformity with all the other Regional Transfusion Centres."

So that's slightly different from how Dr Smith was expressing himself in the letter he wrote to her.

The letter Dr Smith wrote to her is November 1980, so it is dated after this letter but it

recalls the events from his perspective prior to this letter being written.

She goes on to say this:

"The Plasma Fractionation Laboratory, Oxford, had begun to take plasma in single donations from the Oxford RTC in an effort to boost plasma intake from Oxford, in spite of the fact that the only method known to us of opening the present packs (developed at the New York Blood Center) had serious drawbacks, not least the exposure of staff to most unpleasant working conditions (handling packs immediately after immersion in liquid nitrogen). This method is difficult enough on the relatively small scale of our operation at Oxford and would be quite impractical on the scale of operation at BPL, Elstree."

Now, sir, my understanding of this is what she's referring to there as the 1 litre packs but it's not entirely clear:

"Pending the ability of Oxford RTC to supply plasma up to the limit of the capacity of the Plasma Fractionation Laboratory, I had the support of my staff in volunteering to accept sufficient single donations from Wessex to absorb our 'spare' capacity. This offer was made in the light of the long association between Oxford and Lord Mayor Treloar

College, and our appreciation of the special difficulties its situation causes the Wessex region -- not dissimilar to the special difficulties in Oxford.

"Our limited ability to open single packs was made clear to Dr Smith from the beginning. Nevertheless, as soon as we started to accept the single donations from Wessex, Dr Smith ceased to send any 5l packs to BPL, Elstree, and put the whole burden of fractionation of his plasma production for factor VIII concentrate on to this small laboratory at Oxford. It was hardly surprising that he rapidly out-stripped the small amount of spare capacity we had offered. Moreover, despite an initial undertaking to supply plasma from blood collected into CPD anti-coagulant, he switched to ACD, which gives a lower yield for the same amount of work from our staff. It was because he was offering plasma in a non-standard form, that he was told there was not the capacity to handle the extra plasma."

Sir, on that point there, of the lower yield using the anti-coagulant ACD rather than CPD, we don't need to look at this but there is a document authored by Dr Jim Smith, CBLA0012012, which says, in his view, that the loss of yield is 15 per cent. So Dr Bidwell there putting a rather different slant on this issue

than that reflected by Dr Smith in his letter we looked at.

SIR BRIAN LANGSTAFF: Can I just draw a breath there for a moment. I'm a little puzzled by the dates, because you began this plasma for fractionation by taking me to CBLA0001198 -- can we just have that back up again -- and the date of that is 6 November 1980.

MS SCOTT: Yes, yes.

SIR BRIAN LANGSTAFF: So if we -- all the documents you've shown me since came before that.

MS SCOTT: They do. So this document --

SIR BRIAN LANGSTAFF: So this is the last word, is it, for the moment?

MS SCOTT: Well, this is the last word and the reason I took you to it first is because it sets out two earlier meetings. It's the only record that I've found of those two earlier meetings. So --

SIR BRIAN LANGSTAFF: I see.

MS SCOTT: -- it sets out the meeting -- sets out earlier discussions, and then a meeting on 25 June 1979.

SIR BRIAN LANGSTAFF: If we just scroll down we can see that, perhaps.

MS SCOTT: We can see that halfway down, after (4), so:

"After these preliminary talks and exchange of letters a meeting was held at Southampton ..."

And that's 25 June 1979.
SIR BRIAN LANGSTAFF: I see.
MS SCOTT: Then if we go over the page to page 2, we can then see, the second paragraph down there:
"A meeting was arranged and held at Oxford on the 14th March, 1980 ..."
And then -- so that was the reason, sir, that I took you to that, to the --
SIR BRIAN LANGSTAFF: Right, so the dates in date order was 14 March 1980 is really where this particular exchange kicked off?
MS SCOTT: Exactly.
SIR BRIAN LANGSTAFF: Because that was interpreted, as it appears to be stated here, as saying: You can give us all you like but we can't cope with it.
With -- and some issue between the 5-litre pools and the 1-litre, but saying here, clearly, that: It doesn't matter if it's 5-litre or 1 litre, we can't cope with it.
MS SCOTT: Yes.
SIR BRIAN LANGSTAFF: And the correspondence then followed --
MS SCOTT: Indeed.
SIR BRIAN LANGSTAFF: -- arguing about aspects of that.
MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: I follow. Thank you for that.
MS SCOTT: Sir, the matter resolves itself after 1 April 1982, once the pro rata arrangements were introduced, and Wessex was able to send -- continued to send single donations to PFL, and received an assurance from BPL that if they sent plasma in 5-litre packs, factor concentrates would be returned on a pro rata basis. And we have -- we don't need to go to that, but that's set out and confirmed in correspondence between Dr Smith and Dr Lane, for example, in a letter dated 13 March 1982. For the transcript, BPLL0000901_001.
Then shortly after that, arrangements appear to have changed again, when Wessex stop sending plasma altogether to PFL, instead sending all their plasma to BPL.
And sir, we know from other material, and again we've looked at this -- some of this other material in other hearings, that the pro rata system was not applied strictly to Wessex because of the responsibility that it had for supplying the Lord Mayor Treloar school. So a special allocation was made to Wessex to account for this on top of what it received under the pro rata system.
Sir, if we then turn to NHBT0111301, we can --

have, again, another snapshot of what's going on in Wessex in 1988.
So we've got the date at the top there, 20 October '88. This is an internal memo from Dr Smith to: Dr Herborn, who we know from Dr Boulton's evidence was one of the consultant haematologists at the Centre; Dr Allison, who was the MLSO; and then Dr J Smith from BPL.
"The Use and Supply of Factor VIII"
And then it says there:
"An estimate of the clinical use of Factor VIII."
And then if we go down the page there, we can see a number of different Haemophilia Centres are set out there and, while it says it's an estimate at the top there, if one looks at the "NHS Factor 8Y [international units/per month]" has a star by it, as does "Commercial Factor VIII iu/month", has two stars by it, and if we look down the page we can see that that appears to be, rather than an estimate, a sample from the actual figures, January to September '88, calculated as eight months, and sample from first six months of 1987/88.
It's not entirely clear to me what "sample" means, because of -- the date of this document is

October 1988, presumably they had the actual figures. But it doesn't also seem to correlate with how one might describe an estimate.
Anyway, I think the point to take from this page, if we go back up, so we can see all of the different Haemophilia Centres, that the Lord Mayor Treloar school is by far the biggest user of Factor VIII, both in terms of NHS Factor VIII and in terms of commercial.
Then if we go down to the bottom of that page, we can see that the:
"BPL estimate we should receive the following amount of Factor 8Y ..."
And it's split in the months October '88 to March '99 between the Wessex RTC and Lord Mayor Treloar's, Wessex RTC getting the bulk of it, Lord Mayor Treloar's getting some of it.
So clearly quite a lot of Wessex's material would be going to Lord Mayor Treloar's in 1988.
Then if we turn over the page, we get some information about the policy:
"The aim would be, in the first instance, to wipe out the Commercial Factor VIII budget for all hospitals except Lord Mayor Treloar. If supplies of Factor 8Y increased further, the LMT budget could then

be reduced."

So we can see that the policy is: Lord Mayor Treloar's to remain on commercial longer than the other Haemophilia Centres. That's somewhat different from other policies we've seen where often children are given precedence for NHS factor concentrates. Here we have the opposite.

"If there is no further increase in demand for Factor VIII, we should be self-sufficient by December, 1988!"

Then it sets out what the stock is at present.

Moving on, then, to the arrangements for distribution of concentrates, we know from the documentation we've seen that prior to December 1976 BPL were sending concentrates directly to the Haemophilia Centres in the Wessex area. But from December, this was sent to the Wessex Regional Transfusion Centre. That was the plan. And we don't need to look at this but we can see this, for the transcript, from CBLA0004553, although of course the document that we've just seen from 1988 makes it clear that still some product was being sent directly to Lord Mayor Treloar's in 1988.

If we look at CBLA0001456, we can see a little bit more about this is.

So this is a document from the advisory committee on the NBTS, "Issue of Factor VIII via RTCs", and we can see at the top right-hand corner "AC [advisory committee] (81)", that's 1981, as we understand it, and then it's said to be:

"A summary of information received from Regional Transfusion Directors.Centres ..."

Sir, we've looked at this in previous hearings.

If we turn over to page 2, we can see the title there, "Issue of Factor VIII via RTCs - Summary information received from Regional Transfusion Centre Directors", and the regions set down on the left-hand column. "Transfusion Centre holds Factor VIII" is the first column, then "Other products", then "Whose budget", then "Comments".

If we go over to page 3 we can see what's said about Wessex. So under the column "Transfusion Centre holds Factor VIII", yes. "Other products", no. "Whose budget", RHA (Separate from RTCs)".

And "Comments":

"Encounter difficulties in coping with Haemophilia Centres Directors' individual preferences for particular brands of Factor VIII and getting Haemophilia Centres to operate within their budgets."

And the -- what precisely that means, we may

have a bit more information in relation to that if we look at OXUH0003752_005. No, that I don't think is the right ... No, I didn't mean to take that one up. Sorry, can we try this one, IPSN0000331_008.

So we can see here this is a meeting in 1978, so it pre-dates the document we've just looked at by a few years, but -- and it's the note of a meeting with Dr Aronstam by a salesperson, a sales representative from Hyatt, and what it says in the second paragraph is this:

"All orders for the Wessex area are processed through the buying office in Winchester" --

SIR BRIAN LANGSTAFF: Just pause. I was told, I think, during the Treloar's presentation, that this was a Speywood --

MS SCOTT: Ah.

SIR BRIAN LANGSTAFF: -- rep.

MS SCOTT: Can we go to the bottom of the --

SIR BRIAN LANGSTAFF: The initials "DW" may, I think, appear at the bottom, which would tend to confirm that. Can we have a look?

MS SCOTT: Yes, the initials are "DRW".

SIR BRIAN LANGSTAFF: Yes, that's the chief exec of Speywood.

MS SCOTT: I beg your pardon, sir. Yes. So ... yes,

"DRW", and CC'd to Mr D Heath. Yes.

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: I think the -- thank you.

So if we look at the second paragraph there, we can see, second paragraph from the top:

"All orders for the Wessex area are processed through the buying office in Winchester, but Aronstam makes the decisions, as he is by far the biggest user. His first requirement is convenience of administration, since they often have 15 infusions to give at a time. The six months study of all commercial concentrates last year showed Hemofil and Factorate to be better than Koate in this respect. In his opinion, solubility is slower with our product. It's worth going back, if we can provide evidence to the contrary."

So it may be that the reference in the table that we just looked at to having difficulties with Haemophilia Centre Directors -- let me just -- sorry, sir, let me just get the precise wording for that. We've lost the --

SIR BRIAN LANGSTAFF: It's CBLA0001456, page 3.

MS SCOTT: Thank you, sir -- the precise wording of that document, thank you.

SIR BRIAN LANGSTAFF: So CBLA0001456, page 3.

MS SCOTT: Yes, so encountering -- what's said in that -- in page 3 of that document is that the Wessex Regional Transfusion Centre appeared to be encountering:

"... difficulties in coping with Haemophilia Centres Directors' individual preferences for particular brands of Factor VIII and getting Haemophilia Centres to operate within their budgets."

It may be that that's a reference to Dr Aronstam, and we will see -- we can see from a document I'm just about to take you to that Dr Aronstam does indeed express difficulties -- that he is having difficulties in operating within his budget.

So we can see, if we look at OXUH0003752_005 -- this is the document I went to earlier -- it's a meeting from 19 June 1978, Haemophilia Centre Directors, Regional Transfusion Directors in the supraregion in Oxford, and we can see just second from the bottom is Dr Smith attending.

But if we go, please, to page 4 of this, there's a section which deals with supply of therapeutic materials, and we can see here, second paragraph down there:

"Dr Aronstam said that he was encountering problems because of the change of policy over ordering

50 severely affected haemophilic boys residing there.

"During 1973 this Centre used [900] units of Factor VIII ... approximately [650] units ... as Cryoprecipitate, 50,000 units as Fresh Frozen Plasma and ... 200,000 units as Human and Animal Concentrate."

SIR BRIAN LANGSTAFF: I think just for the sake of the transcript, the "900" is 900,000, isn't it?

MS SCOTT: Sorry, yes.

SIR BRIAN LANGSTAFF: The "650" is 650,000.

The reason I mention it is because it's comparing the 50,000 and 200,000 I think that you're going to take us to.

MS SCOTT: Yes.

"Our official supply from the Wessex Regional Transfusion Centre at Southampton is the equivalent of 10,000 bags of Cryoprecipitate or 182 bags per week throughout the year. I have been repeatedly told by Dr Smith that this is the absolute maximum production he is able to make available for me."

And then Dr Aronstam goes on to explain what he needs to do in order to find the excess material that he needs. He says in the next paragraph down:

"I have had to obtain these extra materials from a variety of sources often at very short notice and at

commercial F VIII. Initially he had ordered the commercial F VIII on prescription directly from the Commercial firms, but now he had to get it via his Regional Blood Transfusion Centre and budget ahead for how much he would need. He did not think that he would be able to manage within his budget."

And Dr Smith is then recorded as saying:

"... he did not think that there was any problem in the Wessex Region apart from the one at Alton ..."

Next page:

"... which was a special case because of the large number of haemophilic boys at the College. He was awaiting the DHSS's reply to a request for official recognition of the special situation at Alton."

And just sticking, then, with the supply to Treloar's, but going back to 1974 and seeing how the situation changed, if we could go, please, to OXUH0000652, we can see a letter 30 April 1974 to the Department of Health and Social Security. We don't need to look at it but we will see that -- when we go to page 2, that it's from Dr Aronstam, and it says this on page 1, it sets out on page 1 the background to Lord Mayor Treloar's, and notes that -- if you go to page 1 -- notes in that first paragraph there are

great difficulty to both myself and the sources. I have had to beg for materials from other transfusion centres ..."

And at the bottom of the paragraph:

"I have had to, when all else has failed, buy off the commercial market and have spent about £1,000 in the past year.

"This situation is quite impossible. We are never able to plan ahead and there is always the danger that our sources, entirely unofficial, will dry up leaving our large pool of haemophiliac boys without any reserve therapeutic materials for emergencies."

Then over the page he says that he has:

"... calculated that, on the commercial market, our shortfall of Factor VIII would cost £26,000 annually."

And that it's "imperative that our supplies are guaranteed" because they're "looking after boys from all over the country" and it should be regarded as a "national service".

So that was what Dr Aronstam was telling the DHSS in 1974.

If we then go on to 1978, to CBLA0000745, you can see a letter written from Dr Aronstam to Dr Stafford, a consultant haematologist at Plymouth

General Hospital, 14 March 1978, and he says this in the second paragraph:

"Your comments about the therapy which [X] enjoyed whilst he was with us provided much food for thought. You may be interested to hear that we now use prophylaxis routinely in many clinical situations, and we feel it can be of positive benefit when some of our boys are going through difficult patches.

"We are obviously more fortunate than you in that the Wessex Region is supplying us with all the material we need for our admittedly enthusiastic program. The climate with regard to prophylaxis appears to be changing and I do hope the wind of change blows your way fairly soon."

So we can see within that four-year period Dr Aronstam's view that the supply problems he's experienced in 1974 appear to be -- have sorted themselves even for what he describes as his admittedly enthusiastic programme of prophylaxis.

Sir, moving on, then, to the material that we have in relation to donor selection, with respect to hepatitis, we can see from NHBT0108678, that there is communication and correspondence between the Wessex Centre and the Department of Public Health at the city of Portsmouth. So this is a letter 25 May 1971 from

a Dr Roads, and he says this -- sorry, from Dr Smith to Dr Roads, and Dr Smith says this:

"I am pleased that you will be able to help us about cases who may be blood donors. Towards the end of this year we hope to start testing all our donors for the presence of Hepatitis Associated Antigen, and we may well be able to discontinue the request" --

Sorry:

"I am pleased that you will be able to help us about cases who may be blood donors. Towards the end of this year we hope to start testing all our donors for the presence of Hepatitis Associated Antigen, and we may well be able to discontinue the request that we have made to you."

And what I understand from the documents that this refers to, is the request made by Wessex for those that are investigating cases of notified infectious hepatitis to make enquiries as to whether or not they are blood donors, or indeed any of those that have been in close contact with them are blood donors, and then passing that information on to Wessex Regional Transfusion Centre.

We have examples of notifications being made by the County Medical Officer of Hampshire, so not just the city of Portsmouth Department of Public Health but

the County Medical Officer of Hampshire, and we don't need to go to those but, for the transcript, one such example is NHBT0108548.

Now we know from material that the Inquiry has seen and indeed looked at in previous hearings that the recommendation -- a recommendation was made by the -- in the second report of the advisory group on testing for the presence of hepatitis B surface antigen and its antibody with respect to the -- whether or not those with a history of hepatitis needed to be -- could in fact give -- remain on the donor panel as long as they had not suffered a bout of jaundice within the previous 12 months.

We know from -- and again we don't need to go to this but we know from NHBT0109112 that Dr Smith was notified about this recommendation by Dr Maycock on 13 June 1975.

Now, it seems that Dr Smith -- we have a memo from January 1977 from Dr Smith, which relates to this, and that's NHBT0108668. Can we go to page 5, please, of this document.

We have here Wessex RTC, "Donors with a History of Jaundice", and if we go to page 7, the end of that memo, we can see it's from Dr Smith, it's distributed to all team leaders, team clerks,

drivers/haemoglobinists and to medical staff, and it's dated 21 January 1977.

If we go then back, please, to page 5, he sets out the background that "We have ... been asked to change our procedure at blood collection sessions", and refers to the circular that appends the second report of the Advisory Group:

"... not to exclude from panels donors with a history of jaundice, provided the donor has not suffered from hepatitis or jaundice during the previous 12 months."

Then he sets out the background. He says this:

"Since 1963, as a precautionary measure, we have not taken donations from persons giving a history of jaundice or hepatitis (other than a history of neonatal jaundice or a history of obstructive jaundice) or who have been in close contact with a case of hepatitis in the past 6 months."

Then:

"Due to the discovery of a sensitive test for Australia antigen and a better understanding of the [illness] we have been asked to change our rules. Both types of hepatitis can be transmitted by transfusion, although Type A is usually spread by the faecal-oral route and Type B by injection of blood."

Then if we go over the page, halfway down that page, he talks about "Type 'B' Serum Hepatitis", and the incubation period. But if we pick it up at the end of that paragraph, we can see:

"We find that in Wessex about 1 in 2,000 donors have a positive test (Australia Antigen) with no history of jaundice.

"Only about 2% of persons will give a history of jaundice, and I would like to suggest that in the first instance, after you have considered this matter and if you are agreeable, that we should:

"1. Test for Australia antigen each prospective donor who gives a history of jaundice or hepatitis longer than twelve months ago. A 5 ml clotted sample will be required and a 2.5 ml EDTA sample will be taken at the same time to estimate the haemoglobin level", and then a finger-prick test.

Then if we go over the page:

"If the Australia antigen test is negative and the haemoglobin is satisfactory, the donor could then be called to a later session."

So those with a history of jaundice, more than 12 months ago, will have the sample taken from them and then if negative called back; those with a history of jaundice within 12 months will be deferred.

Then we can see that the procedure changes again in 1982, NHBT0144439, where in another internal memo it said this "Donors with a Medical History of Jaundice":

"The procedure dealing with potential donors with a medical history of jaundice or hepatitis has been reviewed and alterations have been agreed.

"With effect from 1st January, 1982, the practice of taking 'samples only' from these donors will cease, instead they will be regarded as ordinary donors and will be dealt with in exactly the same way as new donors, both at donor sessions and in the laboratories."

Then at paragraph 2:

"Donor selection will remain as it is, ie reject if a history of jaundice of hepatitis within the previous twelve months, or a history of close contact within the previous six months", otherwise treat as -- in exactly the same way as ordinarily donors.

Now, we know from a letter that Dr Smith wrote to the Lister Institute on 4 October 1971, which we don't need to go to but is NHBT0107890, that they started testing donations at Wessex for hepatitis B on the 4 October 1971. I think it is worth looking at NHBT0108997, which is a memo from Dr Smith to

Dr Barnes in relation to fresh blood labels, and it's dated 13 December 1971, and it says this:

"Until the testing of blood donations for HAA becomes more accurate and specific I do not think that we should alter the fresh blood group labels in any way. The test at the moment is only 40 per cent effective and I would not like the clinicians to believe that a patient could not contract transfusion hepatitis after being given HAA negative blood using our present test."

So it seems that an enquiry may have been made as to whether or not something should be put on the fresh blood to suggest that it had been tested for HAA, and Dr Smith is saying, no, because the tests are not terribly effective.

Sir, perhaps a couple more documents before perhaps we take a short break.

Moving on to the question of HIV, just looking at the information that we have about Wessex's experience of the first six months of the first AIDS leaflet, could we look, please, at CBLA0001820, and this again is a table we've looked at on number of occasions. We can see Southampton at the bottom column there. It says:

"Distribution method

"Distributed with call up cards [August '83 to February '84]

"now available at sessions

"[Number] used, 71,700 Stock 3,300."

Then under "Donor response Effect on Attendance":

"NIL."

On "Other Comments" it says:

"3 homosexual donors as for" --

It says "as for advice", I suspect it means "asked for advice".

SIR BRIAN LANGSTAFF: It looks as though the right-hand margin is missing further up the page --

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: -- so I think you're probably right.

MS SCOTT: Yes. We get a little bit more information about this from a letter sent to Dr Smithies from Dr Smith which is at DHSC0101658_014, and this is a letter dated 24 January 1985, and he says:

"We display a poster at our blood collection sessions together with a notice at the Team Clerk's desk and in addition we have altered the NBTS form 110 to draw attention to AIDS.

"I think a national poster would be very useful and when the new AIDS leaflet arrives we intend to

send this to all our donors with their call-up [card]."

Then lastly, sir, before taking a break, is a letter from Dr Smith again to Dr Smithies about HIV testing. DHSC0002285_013, and this is a letter dated 29 October 1985:

"Thank you for your letter about HTLVIII antibody testing of blood donations and blood components.

"Our stocks in the Centre and in the hospital blood banks were all negative for the above antibody on the 14th October 1985. This includes fresh frozen plasma and cryoprecipitate."

So he seems to be suggesting that they had tested all of those products by 14 October 1985, and then he goes on to say something about heat treated factor products:

"As you know we are only using heat treated Factor VIII for the treatment of haemophilia and I have mentioned to our local haematologists the problems that might be present with intravenous ... immunoglobulin."

Sir, that is the material that I want to draw your attention to in relation to the Wessex Centre.

After the break, I'm going to turn to the HIV

contamination incident and I know the Inquiry has heard some information and evidence in relation to that in previous hearings but I will go through the material that we have from the Wessex perspective in relation to that.

SIR BRIAN LANGSTAFF: Yes. Well, we'll take a break, then, and what do you suggest, quarter of an hour?

MS SCOTT: Yes, sir, that will be --

SIR BRIAN LANGSTAFF: So quarter of an hour, and I hope that gives those who are listening remotely time for a proper break.

So we'll come back, shall we, at 11.20.

(11.03 am)

(A short break)

(11.19 am)

SIR BRIAN LANGSTAFF: Yes?

MS SCOTT: Sir, I'm going to turn, first, to CBLA0000010_183. This, when it comes up on the screen, is a report dated 2 October -- we can see that at the bottom of the page, 2 October 1984, "BPL Internal Report", and if we go back up to the top of the page, we can see it is prepared by Dr T Snape, it's in relation to batch HL3186, it's a report from Dr D Smith of Wessex by telephone on 2 October, received by Dr Snape, and we can see the distribution

list of this report includes Dr Lane and Dr Smith. It says:

"Donor [was] admitted to Bournemouth Hospital with skin rash consistent with Kaposi's sarcoma, leukopenia and anaemia. Biopsy results awaited. Donor admits to homosexual activity but was VDRL negative when he donated blood several days ago (this donation was separated at Wessex RTC but plasma was not dispatched to BPL)."

Then it sets out the plasma donation number and when it was collected, 27 March 1984, dispatched to BPL on 6 April and the pack was used in the manufacture of batch HL3186. Then it notes that:

"No factor IX was recovered from the cryosupernatant.

"No fraction II was recovered from the A + I precipitate.

"Fraction V was recovered and is presently held as L938 and L939."

Factor VIII batch HL3186 has been distributed: on 10 August, 485 vials were sent to Wessex; and on 15 August, 400 vials were sent to Cardiff. There's some handwriting there, sir, which relates to the recovery of those vials, but we will look at -- that same information appears on documents we will look at

in a little while.

Then it goes on to set out what the actions were:

"Dr Smith (Wessex) was informed of the implication HL3186 [by telephone on 2 October] and was asked to recall all vials including any held by patients for home therapy.

"Dr Napier (Cardiff) was unavailable but Mr Booth [the senior MLSO from Cardiff] was informed [on the following day, 3 October, but again by Dr Snape] and was asked to recall all vials of HL3186, including home therapy issues.

"Both telephone conversations were [copied] in writing ..."

Then the fraction V concentrate was secured and labelled "HELD".

Then if we turn over the page, number 4, paragraph 4:

"Dr Smith ... was asked to report any plasma from this donor despatched to BPL (or PFL) within the last 5 years ([and it notes that] blood given by this donor on [7 September '83] and [21 November '82] was not used to supply plasma to BPL). Dr Smith was also asked to determine whether the donor had a history of attendance at local special clinics for venereal

disease.

"Dr Tedder ... was consulted but indicated that he did not wish at the moment to receive samples of plasma fractions since he did not feel test methods presently in use were appropriate. He did however ask to receive a sample from the most recent donation ... and this was arranged ...

"Dr Craske (... Manchester) was consulted and asked to be supplied with a list of haemophilia centres supplied with HL3186 in order to initiate follow-up studies on patients treated with the batch. [Dr Snape] to comply once data is received from Wessex and Cardiff, and given the confirmation of donor's condition."

The Medicines Division was informed of the situation by Dr Fowler, and Dr Snape would supply a copy of the summary report for the director.

Then a late telephone note from Dr Barnes in Wessex and, sir, you'll recall Dr Barnes is the deputy director from Wessex: the donation taken on 21 November '82 was taken at Leeds and time-expired plasma from this donation was sent to BPL on 11 January '83, and "Information on this is to be appended by SH".

Sir, that was the situation on 2 October 1982.

We can see, then, if we move then to DHSC0002247_090, we see a letter dated 4 October 1984 marked "Confidential" from the Wessex Regional Transfusion Centre, we'll see at the bottom from Dr Barnes, the deputy medical director. So we understand that Dr Smith was, in fact, on holiday at this stage. It's sent to the consultant haematologists in charge of the Haemophilia Centres, and then the Haemophilia Centres in the Wessex area are set out there.

It's headed "BPL Factor VIII Batch no HL3186" and refers to Mr Allison's telephone calls to their Blood Bank Chief "yesterday", so that would have been 3 October:

"... asking for the above quoted batch of Factor VIII to be re-called and returned to us."

Then it says:

"The reason for this is that one of the donors whose plasma was incorporated into this pool is now thought to be suffering from AIDS. Investigations are being carried out and the diagnosis should be settled, one way or the other, within the next week or two. In the meantime, may I confirm", the request to re-call all the batches to the Centre.

Then he says this:

"In order to prevent undue worry to your

patients, may I ask for your discretion here and, for the time being at least, to keep this new [I think it should say 'news'] to yourself. When any definite information does become available, either Dr Smith or myself will let you know."

Also on 4 October, could we look at CBLA0000010_209, which is a letter again from Dr Barnes, this time to Dr Snape at BPL, and he sets out the background to the events, and he sets out what's known about the previous donations.

If we could go down the page, please. We can see one from 21 November 1982 taken in Leeds, time-expired plasma pooled and sent to BPL; one from 7 September '83 in Bournemouth, sent to a Portsmouth hospital and not returned, and we'll see what happens to that in due course; 27 March 1984 in Bournemouth, fresh frozen plasma sent to BPL, 6 April 1983, plasma reduced blood sent to one of our Portsmouth hospitals and not returned; and 25 September 1984, Bournemouth plasma separated and frozen, red cells destroyed and then aliquot has been sent to Dr Richard Tedder.

Then it says, in relation to donations 2 and 3:

"We are not getting in touch with the clinicians involved until the diagnosis is confirmed."

Then, if we go over the page, we can see:

"There is also a possibility of a donation before November 1982 in this region, which we are attempting to trace. I will, of course, contact you again when [definitive] information is available."

We'll look at this letter later but I'll give the reference for the transcript now, DHSC0001690, it's a letter from 5 November 1984, which makes it clear that they haven't found any previous donations before 1982.

Now, information about the donor's diagnosis came on 16 October 1984, so some days later, and we see this at DHSC0000247_093.

Sorry, DHSC0002247_093. We can see that this is again a letter from Dr Barnes, 16 October, to all directors of Haemophilia Centres in Wessex, and he says, with reference to the earlier letter we looked at, 4 October and his telephone call of yesterday "my apologies to those I could not contact personally":

"I am extremely sorry to have to tell you that the diagnosis of AIDS has now been confirmed. I understand that Dr Snape ... will be writing to all of us within the next day or two, and that further contact will be made by Dr Craske on the follow-up of your patients. In the meantime, I have been asked to

suggest that a policy of discrete surveillance be pursued."

We can see there the list of the Haemophilia Centre Directors to whom this was sent.

Sir, it is not entirely clear what Dr Barnes was suggesting there by a "policy of discrete surveillance".

On the same day, a letter was written to the Surgeon Commander of the Royal Naval Hospital in Haslar. If we can look at that, please, it's DHSC0002247_094. This relates to one of the donations we saw in the earlier letter where it was said that the clinicians were not being informed about this incident until more information was known. So this is taking up -- this is the letter informing the Surgeon Commander about the donation:

"To confirm my telephone call of yesterday, I regret to inform you that a blood donation taken from a donor now known to be suffering from AIDS was sent to RN Hospital, Haslar, earlier this year, was not returned to us, and presumably has been transfused into a patient."

Then details are set out. Then he was informed that Dr Tedder is aware of the situation, and pleased to carry out virological studies of the patient and

that Dr Craske is carrying out follow-up of patients who have received plasma or Factor VIII from the donation and is very willing to offer advice.

So that, sir, is the information we have in relation to what the dissemination of information about the incident to clinicians, in the immediate aftermath.

Turning then, to the action that was taken in relation to re-call of the product, can we turn, please, to CBLA0000010_211. This is a letter of 8 October 1984, again from Dr Barnes to Dr Snape, and he says that he confirms an earlier telephone call and the number of vials of Factor VIII batch HL3186 sent to the Haemophilia Centre in Wessex, and sets out there the Haemophilia Centre that had received batches and the number that had been returned.

So you'll see, for example, that 70 were sent to Salisbury, they've had none returned; 22 to -- Lord Mayor Treloar College, 200 sent to them, 33 returned, and so on. So out of the 485 --

SIR BRIAN LANGSTAFF: Sorry, 22 to Lord Mayor Treloar College?

MS SCOTT: Sorry, 200 were sent to Lord Mayor Treloar with 33 returned.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: Out of the 485 vials sent, they've had, by 8 October, 99 returned.

We move then onto 23 October, DHSC0001111. This is a memo, a report, if we go over to the second page, please, a summary -- another report from Dr Snape and we can see from the bottom that this is dated 23 October 1984, and he sets out the history, and so on.

Can we turn, please, to page 4 of this report. We can see there the "Results of factor VIII recall", so this is 23 October 1984.

"The 400 vials of batch HL3186 despatched to Cardiff break down ..."

Recovered: 101 out of 150 vials for Heath Park, Cardiff; 51 out of 60 for Morriston; and Carmarthen, 36 out of 40; and, altogether, they know that nine patients have been treated with the product in Cardiff. So a total of 338 vials were recovered with nine patients receiving the batch, and that's the situation in Cardiff.

In Wessex, there's no information given about how many patients have been treated, but they know that, out of the 485 vials, 187 have been recovered by that time: so 105 out of 200 from Lord Mayor Treloar; by now they know that Salisbury and Winchester had

used all the vials that they had been sent; but Bournemouth had returned, for example, 60 out of the 60 that they had been sent.

If we can then turn, please, over the page to page 5 of this report, it's worth noting what Dr Snape is saying on 23 October about the observations on the incident. He makes two observations. At 5.2, he says his:

"In this particular instance, the last (and most damaging) donation was received at BPL on 6th April 1984, pooled for fractionation on 17th May 1984 and issued for clinical use on 10th August 1984. This timetable is consistent with the five week period of quarantine presently supportable for fresh frozen plasma and the irreducible six to eight week delay from pooling plasma to release of Factor VIII concentrate for clinical use.

"Enforcement of a three month quarantine period would not in this instance have avoided the loss of resource resulting from the plasma pool being compromised by a single donation; it would almost certainly have avoided patient exposure to the product however.

"Enforcement of a six month quarantine period

would have prevented release of the batch for clinical use; it would also have allowed the donation to be included before pooling, thus avoiding a very expensive reject situation.

"This incident must be an extremely cogent argument for the establishment of cold-storage facilities capable of supporting a six-month quarantine of fresh frozen plasma."

He also makes this observation in relation to the follow-up:

"The appearance of this donor at three different Centres within two years clearly underlines a fundamental problem when carrying out follow-up of donor incidents of this sort. Surely central co-ordination of donor records is unavoidable."

Now, a copy of this report was sent to the DHSS on 24 October '84, we don't need to go to that but, for the transcript, that's PRSE0001658. Can we, though, turn to CBLA0000010_188, which is a document that deals with the follow-up undertaken by Dr Craske of those who were treated with the infected donations.

So we have here the front cover, and we can see it's in relation to batch HL3186, and it's Dr Craske's letter to Haemophilia Centre Directors, dated 20 November 1984. We can see the list of Haemophilia

Centre Directors that it's sent to, so those in Wales, and so we've got Swansea there, Carmarthen, Cardiff, as well as those in the Wessex area. It's CC'd to a number of different individuals, including Dr Rizza, Dr Lane, Dr Snape, Dr Smith and the Wessex Regional Health Authority.

If we turn then to the page 2, we can see the letter itself, and it says in the second paragraph down:

"I have responsibility for the epidemiological follow-up of recipients of that is batch to confirm whether any hazard exists, and to assist in the investigation of patients where required. I hope that we can obtain the maximum information from this unfortunate incident, and devise methods for the prevention of the disease. We also need to confirm the association of HTLV-3 infection and transfusion of factor VIII concentrate."

Then, under "Risk to the patient", he says this:

"From the foregoing discussion you will see that it is difficult to be certain of the precise risk of any recipient contracting AIDS, but the following facts may help you to appreciate the position."

Then he sets out, on the following page, six facts:

"1) Only a proportion of the patients transfused with an infected batch are likely to contract HTLV-3 ...

"2) Some patients who have received commercial factor VIII since [1 January 1980] will already have contracted HTLV-3 infection from other infected batches.

"3) The proportion of patients who are infected with HTLV-3 who will eventually contract AIDS is unknown ...

"4) The long term program notice for patients with HTLV-3 verification is unknown ...

"5) There is evidence that HTLV-3 infection can be transmitted by sexual contact. Therefore some sexual partners of recipients of factor VIII contaminated with HTLV-3 may [now] be at risk.

"6) We cannot yet distinguish those patients who are likely to transmit infection, or who are likely to contract AIDS by means of laboratory tests."

Then he says this, under "Methods of Investigation":

"With the above facts in mind, I propose the following strategy. [First of all]

"(a) Identify all patients who have received factor VIII batch HL3186 ...

"(b) Follow up of patients.

"Patients identified should be followed up at least at four monthly intervals for six years."

Then he sets out details of how that should be achieved.

If we go over the page, please, he also provides them with simplified records forms for the follow-up to be provided to him. It says halfway down that page:

"Follow up should be carried out even if a patient is found to be positive for HTLV-3 antibody in the first specimen tested", ie prior to receipt of the infected batch.

He then sets out that four monthly review and how that should be completed, and that the form should be sent to him in Manchester. He says this:

"The follow-up may be carried out using an alternative of two different strategies:

"i) If the patient has been informed of the risk associated with this contaminated batch of factor VIII, testing could be carried out on each specimen as it is obtained at each four monthly review. In addition, it would be wise to warn the index patient that his spouse may be at risk from contracting HTLV-3 infection as a result of any sexual

contact. A test for HTLV-3 antibodies can be offered [it says] to Directors at the time of follow-up of the index case. Follow-up can be arranged by the Director or in collaboration with the GP as thought necessary."

So that's for those cohorts of patients who have been informed of the risk associated with the contaminated batch and then, on the following page, he sets out an alternative strategy:

"An alternative strategy would be not to tell the patient of the risk involved but to observe him at regular clinical review four monthly, to collect serum specimens for HTLV-3 antibody examination and send them to me at Manchester. These would not be examined until two years after the initial exposure, or until the patient develops clinical features suggestive of AIDS, or testing is [required] by the Haemophilia Centre Director."

Then it says, the next paragraph:

"The ethical problems involved in these two alternative methods of follow-up are discussed in an appendix at the end of this letter."

If we turn to page 6, we can see that appendix, "Ethical Problems Associated with HTLV-3 Infection in Haemophiliacs":

"1) Informing the patient and his family of the

risks."

He sets out the benefits of this:

"[It] allows information of the development of HTLV-3 infection to be available to the caring physician as soon as possible, and thereby to identify and treat all complications as they arise where treatment is available.

"It also allows the patient's spouse to be informed of the risk [and to take precautions].

"It also maintains a trusting relationship between the physician and his patient which is essential if difficult problems arising from HTLV-3 infection are to be surmounted.

Then the alternative which is entitled "Restricted follow-up":

"In this strategy, the identification of patients who contract HTLV-3 infection will not be made for 2 years or at the request of the Centre Director. It will be impossible to warn spouses and advise preventative measures to limit the transmission of infection, since it will not be known when the index patient first contracts HTLV-3 infection. If a patient develops AIDS related illness it will be too late, as the period of maximum infectivity will already have passed.

"Any benefit or peace of mind for the patient will be temporary if any other persons exposed develops AIDS. If the patient finds out that he has had this batch, then the trust of the patient will be lost, and the Haemophilia Centre Director placed in a delicate situation.

"It is quite likely that any patient who has received commercial factor VIII since 1980, and thus had already possibly been exposed to HTLV-3 infection will not have a greatly increased chance of contracting AIDS, compared with the patient who has received only NHS concentrate until now."

Then he says:

"In my view option (1) is the only one tenable on moral and ethical grounds."

So then if we turn back to page 5:

"Should the patient be told?

"Ideally I think he should, but this will depend on many factors, including the amount of anxiety concerning AIDS there is already present at the Centre, and the degree to which the patient is capable of understanding the situation. Every effort should be made to encourage the patient to discuss the problem with his spouse and help them to face the problem together. The General Practitioner should

also be informed by letter."

And then:

"Other preventative measures

"1) When a patient is told of the risk to exposure to HTLV-3 infection he should also be warned that his sexual partner might also be exposed to infection."

Then it goes on to discuss barrier methods of contraception.

So that is the letter that was sent in November 1984 to all the Haemophilia Centre Directors.

We don't have very much information about how that was received save for a couple of documents I can take you to.

Can we turn, please, to -- oh, in fact, before I do that I'll just take you to HHFT0001026_004.

So this is a letter dated 20 November 1984, so a few days -- the same day, sorry, as the Craske letter we've just looked at. It's a letter from the Wessex Regional Health Authority, and we can see at the bottom the circulation is to those Haemophilia Centre Directors who have received the Craske letter. It is a letter from the regional medical officer and it says "Dear Doctor".

First of all it sets out in that first paragraph

the background to the contamination incident.

Second paragraph relates to the working party being set up by the DHSS to look at the questions raised for the Blood Transfusion Service and the recognition of AIDS, and it's the third paragraph that's of particular relevance:

"I have discussed the subject of AIDS with two members of the Working Party and feel that in the first instance it would be strongly advisable for the patients who received Batch No. HL 3186 of Factor VIII concentrate, or their parents, to be told, with the emphasis of the benefits of treatment by Factor VIII far outweigh the small risk of the patient developing AIDS. I hope you will agree to do this now and let me know thereafter."

Then he goes on to say:

"The public interest in this matter will almost certainly lead to further Press inquiries in Wessex before long. I would like to be able to say that all patients have been informed and that the situation is being closely monitored."

So turning, then, to the material that we have to understand how this was received and what the Haemophilia Centre Directors actually did in terms of telling patients, can we turn to CBLA0000010196.

Now this is a letter written from -- CBLA0000010_196.

This is a letter written from Dr Green, from the Portsmouth Haemophilia Centre, to Dr Snape, and it's in response to a letter written from -- by Dr Snape to the Haemophilia Centre Directors prompting them to provide information about follow-up to Dr Craske.

And Dr Green says this:

"I object to the tone of your letter. I intend to follow up the patients affected by the transfusion of HL3186 and I reserve to do this in my own time and in my own way. If you had taken the trouble to enquire from Dr Craske you would know that he is in possession of samples from some of my patients and in due time he will be in receipt of samples from all of them."

Then he complains:

"It has taken [Dr Craske] seven weeks to supply [him] with the results of the tests he does" --

I think it should say "have":

"... and I only got them by 'phoning him. Things I dare say will work out in their own time."

This doesn't help us very much with understanding whether Dr Green has put his patients in the first or second category, ie told them about

what's happened -- well -- told them about what happens other than that he has asked Dr Craske to test the samples that he sent him, which would suggest that those patients at least should have been told. But it certainly gives the impression that there isn't much urgency in times of the time that seems to be taken both by Dr Green and possibly by Dr Craske in understanding whether or not these patients had in fact been infected with HTLV-III.

In August 1988, Dr Lane wrote to Dr Craske -- we don't need to go to it but for the transcript it's CBLA0000010_200 -- wrote to Dr Lane asking him whether a final report had ever been written by Dr Craske resulting from the follow-up that he had undertaken of those patients who had been -- who had received the infected products.

We can look at Dr Craske's response. That's CBLA0000010_202.

It's a response dated 23 September 1988, and he says this at paragraph 2:

"The follow-up we were doing eighteen months ago of this incident was bedevilled at that time by the reluctance of Haemophilia Centre Directors to cause, what they considered to be, an unnecessary worry to their patients, so that a follow-up of the recipients

who received this product has not been carried out in the formal sense."

Then he says at the fourth paragraph down:

"Your letter prompts me to re-open this enquiry, as we do need to know the outcome of patients who received this and other batches which may have been contaminated with HIV. I will consult my files and let you have a report as to what is known at the present time."

So Dr Craske's analysis of the response from Haemophilia Centre Directors is that they did not want to cause unnecessary worry to their patients, suggesting perhaps that in fact patients weren't told that they had received contaminated product.

SIR BRIAN LANGSTAFF: Well, it looks as though, on the face of it, they've adopted the first of the -- was it the first or the second of the two options?

MS SCOTT: The second.

SIR BRIAN LANGSTAFF: The second of the two options which Craske had put out in his letter, and they've adopted the course which he regarded as morally and unethically unacceptable.

MS SCOTT: Sir, it may be that they haven't even gone that far, because that second option did include follow-up in a formal sense. It did include taking samples and

sending them to Dr Craske. It looks from this as if they haven't even gone down that route, they simply haven't done any follow-up. It may be -- well, sir, you'll have to decide, but it may be that Dr Craske here is saying he hasn't actually had many samples, at all.

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: Even ones that he can't test for the two years or until some other event happens.

Now Dr Craske there suggests that he will do a final report but the Inquiry has not found a final report from Dr Craske.

So lastly, then, what does the -- what do we know about what happened to the patients? Can we turn, please, to DHSC0004180_050.

Sir, this is a report that's neither dated nor authored, but it does give us some more information about the incident in itself and about what happened to the patients, albeit we don't know where it comes from -- we don't know who wrote it, I should say.

So it sets out the background to the donor becoming ill in the first paragraph, and second paragraph sets out what was found and that the diagnosis of AIDS was confirmed. It sets out the donation history and his blood group.

"21st November 1982. Leeds BTC. Red cells unused, time expired plasma sent to BPL ... Two batches of PPF were made and held."

Then:

"14th February 1983. Birmingham ... Whole blood donation transfused. Further information from Dr Ala."

And we don't, I think, have any further information in relation to that.

"26th August - 10th February 1984. Wessex BTC. All regular donors sent AIDS leaflets. An AIDS leaflet was received by the donor early in 1984.

"7th September 83. Wessex BTC. Whole blood transfused to Mr (SR) following prostatectomy for benign hyperplasia. Later anti-HTLV-III found in serum. Patient later died ... from neoplasm of rectum."

Then over the page:

"27th March 1984. Wessex BTC. Plasma reduced red cells transfused 2nd April 1984 to patient ... for bleeding peptic ulcer. Follow up ... anti-HTLV-III detected in his serum early November 1984."

And that, we can see, is the Royal Naval Hospital in Haslar.

Then it goes on to discuss the HL3186

Factor VIII batch:

"7,000 plasma donations in the pool. 9 patients transfused in Wales and 29 in Wessex. Other units immediately re-called, total batch compromised 485 vials sent to Wessex and 400 sent to Cardiff RTC. A total of 338 vials were recovered from Cardiff and 9 patients received the batch. In Wessex a total of 187 vials were recovered and 29 patients received the batch."

Then they set out below the breakdown of where those 29 patients in Wessex were treated, and we can see that eight of those were in Lord Mayor Treloar and eight of those were in Southampton, with Dorchester, Salisbury, and Portsmouth also -- and Winchester also having patients.

Then if we go over the page, we see:

"25th September 1984. Wessex BTC. Informed by hospital that donor has AIDS. Donation tested and found HTLV-III Positive by Dr Tedder."

And the donation was discarded, and then we see that the donor died on 5 November 1984.

So that gives us a little bit more information.

We also have a few other bits of correspondence. So we can see from a letter written from the Southampton Haemophilia Centre to Dr Snape,

29 January 1985, CBLA0000010_194.

We have a letter saying:

"Dear Dr Snape,

"Thank you for your letter ... regarding follow up of patients treated with Factor VIII Batch HL3186. All eight patients exposed to this batch at Southampton have been informed of the problem and sera from seven of these patients have been sent to Dr John Craske."

And one of those patients has been followed up at Lord Mayor Treloar.

So that's a letter from a Dr Bell, 29 January 1985.

Now, we know from another letter written by Dr Bell to Dr Aronstam -- which we don't need to go to, but it's TREL0000110_040 -- that one of those infected from Southampton was Gary Bennett, who has given evidence to this Inquiry, and so I think it's helpful to remind ourselves of what he told this Inquiry in his written statement about being informed about the contaminated product.

We find his written statement at INQY0000325.

Sorry, I've given you the wrong account, WITN -- WITN0297001. Thank you.

That's the story of -- that's the first page of

the witness statement. If we could go, please, to page 5. It starts at para 18:

"I had to go to class room 2A. There were about ten or 11 of us in this particular age band. The nurse and Dr Wassef came in and said have you all got a pen and paper. He then told me personally, if you have such and such a batch number, and he read the numbers out. He said you have permission from the headmaster and I need you all now to use the public phone outside our dormitory's office and ask your parents to check if they have that batch number at home. Not to use it but to return it to your hospital. That batch number that was read out was at home, we had got it from Southampton General. Dr Wassef then left the room. I remember getting off the seat walking down to our dorms and we were all lined up in a row outside our dormitory to see our dorm master, Mr Eggins. He knew why we were there."

"19. I rang home and learned that I had one of the batch numbers at home. I spoke to my Dad. They didn't tell us why we had to check these batch numbers. It was a long time ago but looking back, the first part I can actually remember. I left college and went to my hospital to see Dr Chisholm. She knew my brother and me as we had being seeing her for

years.

"20. I can remember in 1985 I went and saw her and she changed her tune as I think she knew there was a crisis as she wasn't laughing anymore. She knew all of us but her demeanour had changed to a more serious one. I think she knew and it was as if she was thinking you don't realise what has happened.

"21. Tony and I learnt at the same time about the batch numbers. Looking back they had hammered us with bad batches."

If we go over the page:

"I remember Mum and Dad sitting me down in the front room and saying you've been infected with HIV since 1982. This was around 1986. It came through in a letter to my Mum and Dad from Southampton General. They received nothing from Treloar, ever. We were told via a letter from the hospital despite going there regularly, they never told us face to face."

Sir, you will have to marry up this account of being told -- or when Gary Bennett was told about the infection with the letter we looked at from Dr Bell to Dr Snape of 29 January '85 in which he said that all the patients had been told of the problem.

Sir, those were the documents that I want to draw your attention to in relation to the contaminated

product incident.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: And that brings to a conclusion the presentation on the early years of the Wessex Regional Blood Transfusion Service.

SIR BRIAN LANGSTAFF: Thank you. So, we take a break now, do we until 1.00?

MS SCOTT: Yes, 1.00, and Dr Lloyd will give evidence at 1.00.

SIR BRIAN LANGSTAFF: And we start at 1.00 because Dr Lloyd is joining us from Canada, and they are five hours behind us.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Very well.

So 1.00 for Dr Lloyd. We'll take -- those of us who want a lunch break now will have it now.

MS SCOTT: Thank you.

(12.03 pm)

(The Short Adjournment)

(12.59 pm)

SIR BRIAN LANGSTAFF: Dr Lloyd, can you see me? Dr Lloyd, can you hear me?

THE WITNESS: Ah, I can now. Good afternoon.

SIR BRIAN LANGSTAFF: You can see me?

THE WITNESS: I can.

SIR BRIAN LANGSTAFF: Good. Well, that's the start we want, at any rate. It's 8 o'clock with you, is it, in the morning?

THE WITNESS: It is, yes.

SIR BRIAN LANGSTAFF: Well, thank you very much for joining us, either after or during breakfast, and here, as you will know it's 1 pm, in the afternoon. Ms Richards will ask you the questions in a moment or two. You are talking to a very small number of people here in a large hearing room in Aldwych. For reasons of Covid, which affect us as they do you, we have no others of the general public or people who are interested watching directly but they are watching online. So you will have an audience of about 100 or more people who very much want to hear what you have to say.

In a moment, I'm going to ask Mary to invite you to take the oath, the affirmation and, after that, Ms Richards will ask you the questions.

Mary, please.

DR HUW LAWRENCE LLOYD (affirmed)

Questioned by MS RICHARDS

MS RICHARDS: Dr Lloyd, can you see and hear me?

A. I can. There is a slight delay in your voice but, yes, I can hear you clearly, thank you.

Q. I'm going to start by just getting an overview of your medical career. You took up your first house officer post in 1975; is that right?
A. That's correct, yes.
Q. Then, between 1975 and 1979, you had various house officer and senior house officer posts with no particular emphasis on haematology or transfusion?
A. That's correct.
Q. Then, in 1980, you had your first placement at the Northern Regional Transfusion Service from 1980 to 1981, as a locum registrar; is that right?
A. That is correct, yes.
Q. What led you to that post?
A. I was following what would be considered a traditional medical career, working my way up the ladder, I guess, and at that time working in neurology at Newcastle General Hospital, I felt that a career in what one might call the traditional medical format was not for me. I watched some of my colleagues trying to move through the grades doing research jobs, for which they were neither qualified nor interested, and I decided to look for something different, and it was very much by chance that I came to the Blood Transfusion Service.
Q. In the course of the year or so that you were there,

at that stage, you spent, I understand, some time in each department of the Centre and you've explained you would review donor information and also you became involved in blood banking and component production and the introduction of automated blood grouping, amongst other tasks?
A. Yes, that's right. I can't remember the exact moment when we started work on the automated grouping. It might have been while I was still in the locum position it might have been after I obtained a substantive registrar position. But it was about that time we were trying to move from manual operations to a little bit of automation.
Q. Then from 1981 to 1983, you were a registrar in blood transfusion and haematology and, as I understand it, that involved receiving training and experience in haematology, pathology and microbiology at the Freeman Road Hospital; is that right?
A. Yes, and some clinical biochemistry. So it was all the pathology departments in a big general hospital.
Q. You also, during that period, had a secondment to PHL; is that correct?
A. Yes, I went to the Public Health Laboratory Service, which had laboratories actually based in the same building as the Transfusion Service in Newcastle, and

that was mainly to look at virology.
Q. You also, during this period, had a further period of time at the Regional Transfusion Centre; is that correct?
A. Yes, that's right. It was officially a rotation, so I came back into the transfusion centre.
Q. Can you remember of that period '81 to '83, can you remember approximately when you were back in the transfusion centre, which year it was?
A. It was likely at the end of that rotation, so probably 1983. I think I would have started off the rotation by going to the Freeman hospital, and then coming back to the transfusion centre at the end of the period.
Q. You tell us in your statement that your time at the haematology department at the Freeman Road Hospital provided insight into hospital blood banking, use of blood products and clinical issues arising from transfusion. What kind of issues arising from transfusion do you recall encountering during that period of your work?
A. Well, the Freeman Road Hospital housed Newcastle's cardiothoracic unit, so there were a lot of patients receiving fairly high volume transfusions and platelet transfusions and support for their coagulation status. So the issues that arose, we would see quite a lot of

patients with non-specific reactions to transfusion, raised temperature, perhaps rigors, and so on. So there would be some investigation to make sure there wasn't an obvious serological reason for it but I don't recall any other really major issues.

I think we had one case of a major transfusion reaction and, I think -- and I really only think -- that that was a case of a unit of blood being incorrectly -- being given to the incorrect patient and caused a major reaction.

So we saw some serious things. I do not recall anything that was related to non-A, non-B, for instance, but then that's -- I don't think people were looking as hard for it as they might.
Q. We'll come back to that at a later stage of your evidence, that issue.
A. I'm sure.
Q. 1983 to 1987 you were then a senior registrar in transfusion and haematology, spending time in each of the three main teaching hospitals in Newcastle. So would that be Freeman Road, Newcastle General and the Royal Victoria Infirmary?
A. That's correct.
Q. You had a period at the Haemophilia Centre, the Newcastle Haemophilia Centre, at this time. Can you

remember which year that was?
A. No, I can't now. It would have been at my -- towards the -- in the latter half of that period, because I think I started at the Freeman Hospital then the Newcastle General, and then the Royal Victoria Infirmary, and it was while I was at the Royal Victoria Infirmary that I would have had a period working in the Haemophilia Centre. So yes, towards the -- in the second half of that period.
Q. How long, very roughly, were you at the Haemophilia Centre?
A. Very roughly -- very hard to remember now -- probably four weeks. I doubt whether it would have been longer. There were so many other things to fit into that period of time.
Q. And you had then also during this period of your work, a further period at the Regional Transfusion Centre?
A. Sorry, you froze then but I think you were asking if I had a further period at the transfusion centre?
Q. Yes.
A. And that's correct, yes.
Q. And you did the second part of your MRCPath exam having done the first part earlier in the 1980s.
A. Yes, yes.
Q. Then in 1987 you took up a post as a locum consultant

haematologist at the transfusion centre, and then June 1987 to October 1988 you were a consultant haematologist at the transfusion centre.
A. Yes, that's right.
Q. What, in broad terms, did that role as a consultant haematologist entail?
A. I had obviously -- sorry, I shouldn't say obviously. I had quite a number of -- I spent quite a lot of time with interactions with the individual haematologists, particularly when products were requested. It was not unusual for there to be shortages of platelets, particularly, and so we'd be discussing how --the condition of the patient, their platelet counts.

I also looked at information from donors. At the blood donor sessions there was a book which was used to make notes about any particular donor. If there was something that the clerical staff or the nursing staff felt warranted further investigation, a note would be made and each day that list would be looked at and I took my turn at doing it and sometimes would discuss with others who were doing it what was found, were the donations that they had made suitable for use? And obviously in some cases we felt unable to use them.

I also became perhaps more involved in

management than would be normal for that position, including sitting as the Centre's representative on union negotiations with staff over changes that we were hoping to make.
Q. And then November 1988 you became the director of the Northern Regional Transfusion Service. I think your title at that point --
A. Yes.
Q. -- was medical director and then later became chief executive?
A. I think I was medical director and general manager.

Excuse me. Sorry, this is a problem I have.

I was director and general manager from the beginning. It was some years later that we ...[frozen screen]...
Q. Sorry, you froze then, Dr Lloyd, and we lost the last --
A. Sorry.
Q. No, no, not your fault at all. We lost the last bit of your answer.
A. Yes, I was medical director and general manager from the beginning, and then it was several years later that we reorganised a bit and I became just the chief executive. We also of course at that time, around that time, were able to appoint a new consultant to

become the head of our medical services.
Q. And when you took up the role as director in November 1988, your predecessor Dr Collins moved to the clinical haematologist role; is that right?
A. That's correct, yes.
Q. I want to ask you next a little about the Centre, its facilities and its arrangements. I've just mentioned Dr Collins, that was Dr Anne Collins, and prior to her --
A. Yes.
Q. -- appointment, it was Dr Sheila Murray. Who was director; is that right?
A. That's right. I met her on one occasion in 1980 just as the transfer from herself to Dr Anne Collins took place.
Q. In broad terms, what was the geographical reach of the Northern Regional Transfusion Service?
A. It had a very wide geographical area to cover, one of the largest in England and Wales, with some large areas of low-density population and a few very highly dense pockets of population. So it covered -- it actually took in a little piece of North Yorkshire, which was not part of the Regional Health Authority's remit, the Northern Regional Health Authority's remit. It then, from there, went up to the Scottish border

and, across to the west side, it took in most of what's now called Cumbria. We did a little bit across the border and I think we sort of snuck into Gretna, but we did not -- there was a small area of south Cumbria which we did not cover. Transport links were very poor and it was covered by the sub-centre at Lancaster.

Q. Now the centre which you first worked at in 1980 was based in the Institute of Pathology in Newcastle General Hospital, and I think had been since the 1950s.

A. Yes.

Q. Can you describe to us the facilities there and how adequate or otherwise they were for their purpose.

A. Yes, that building I believe was opened in 1956. One floor was dedicated to the transfusion service and that would have been at a time when there was very little in the way of processing blood into components, and very little testing -- I think probably only the syphilis test -- and so there was not a lot of space.

By the time I arrived there, several things had happened to that facility. The basement, which had never been intended as a laboratory area, part of that had been converted to make a facility for processing blood into components.

A second -- and it only came back to me the other day -- there was a second laboratory annex, a wooden structure, elsewhere on the site, Newcastle Hospital site, which was being used for the infectious disease testing, at that time hepatitis B and syphilis, but also had a facility for producing cryoprecipitate.

Then there was a second hut which housed the donor services department, where all the donor records were kept.

So when you look at it, it -- to me, even then, it was a very old-fashioned set-up, a little bit sort of cobbled together with these sheds, these huts, and the basement facility.

The laboratory equipment was generally old, and laboratory benching -- by today's standards, you know, one would be horrified at the wooden benches and people actually brewing up tea in a laboratory, I recall.

The other facility was a garage housing the vehicles. The vehicles were old, not in great condition. Some of them the refrigeration systems were very basic as well for transporting the blood. So it was ...[frozen screen]... in the 1980s.

Q. Again, I'm afraid we lost a few seconds then,

Dr Lloyd. You said it was, and then we missed a little and then you said, "the 1980s".

A. Okay. I think it was -- yes, I said something like: it was pretty outdated, even by the standards of the 1980s.

Q. An adjective a use in your statement to describe it, in fact, is "Dickensian"?

A. Yes, sorry about that. Yes, it was in some ways. The thing that sort of struck me was that we would see blood grouping being performed and the results were transcribed by clerks sitting on high stools at wooden benches with great big ledgers. The entries being made in pencil, which of course would be a complete no ...[frozen screen]... after doing repetitive tasks, which did give you that feel of a Dickensian office.

Q. I'm going to ask you to look at a document with me, Dr Lloyd, just so that I can pick up one point from it.

Sully, can we have NHBT0101335_052.

A. Sorry, can you say that number again?

Q. NHBT0101335_052, it should come up on your screen.

A. I was trying to pull it up, but a little too fast for me there.

SIR BRIAN LANGSTAFF: It's still not there for us.

MS RICHARDS: Have you got it, Sully?

A. No, say it again? 0101?

MS RICHARDS: Sorry, we're just having to reload it on to our system here, Dr Lloyd. NHBT0101335_052.

A. 052. Is that going to come up for me?

Q. It should come up on the screen in front of you, Dr Lloyd. Can you see it now? It should be displayed on the screen on which you're talking to me?

A. Yes, it has. Okay. Right, I --

Q. It should now be in front of you. So it's a letter --

A. Yes --

Q. -- from you, June 1987 to the regional scientific officer at the Regional Health Authority. I needn't trouble you with most of the letter, I just wanted to pick up something on page 3, please, Sully, bottom half of the page.

Sorry, we're having our own problems with documents here, Dr Lloyd.

I actually only need a single sentence, so what I'm going to do --

SIR BRIAN LANGSTAFF: We're there, I think.

MS RICHARDS: I might just read it.

SIR BRIAN LANGSTAFF: It is there, it is up.

MS RICHARDS: It's not on my screen.

SIR BRIAN LANGSTAFF: Well, it is on mine.

A. I do have the document in front of me, page 3, so

please go ahead.
MS RICHARDS: I'll read it. My screen is not working, although if everyone else's is, that's fine. I've got a hard copy.
The paragraph towards the bottom of the page beginning:
"Finally, the concept introduced" --
A. Yes, I have it.
Q. "-- that the Centre was designed and commissioned for 200,000 donations per annum shows a lack of understanding of current blood transfusion practice."
This was the sentence I wanted to ask you about:
"The original submissions for this building of a new Transfusion Centre was made in the 1960s, at which time 200,000 donations seemed appropriate. When this Centre was actually planned, transfusion practice had changed dramatically, but to avoid major delays it was decided not to make a new submission to the DHSS. A decision was made to go ahead and build within the confines of the original schedule of accommodation."
Now, as I understand it --
A. Yes.
Q. -- the service moved in 1985 to a new purpose-built centre but do we understand from this that it was a purpose-built centre based upon designs and thinking

from decades previously?
A. No, that's not quite the case. I think in this document and this paragraph, what I'm saying is the Regional Health Authority to allow themselves to go ahead and build a new centre at that time, what they felt was fairly quickly, they didn't want to go back and make a whole new submission to the DHSS.
So they went ahead using the original envelope of the submission, but what was produced internally had no bearing on the original -- I never saw the original submission, but the new building was, to my mind, well built. I thought the design was very good. There were a few little bits you could argue about but, in general, it was well built, well designed.
The architects spent a lot of time on trying to make sure that the flow of people and materials within the building were logical. They grouped departments next to each other where material was required to move between them. So, for instance, the donor services department which didn't actually handle the physical -- you know, the material, the blood, was on an upper floor. The dispatch department was fairly close to, you know, the loading bay.
So my feeling was that it was well designed, it was up to date and this particular phrase I can

understand does give a slightly strange impression of the building.
Q. We can take that down, thank you.
Do you have any knowledge of why, it apparently having been identified in the 1960s, that there was a need for a purpose-built proper centre, why it took until the mid-1980s for that to be realised?
A. No, I have no idea. The only thing that comes to mind is one of the documents that you submitted in that final group was a document from Dr Sheila Murray to, I think, Mark Sackwood, the Chief Medical Officer at the RHA, in which she discusses issues of introducing more plastic bags and producing more cryoprecipitate. So maybe that was a time when there was a sudden push to produce more cryoprecipitate and, also, you know, platelet transfusion was presumably starting to become a possibility, but maybe that was a bit later.
So it may have been, and I only say may have been, that Sheila Murray was pushing for a better facility to produce particularly cryo.
Q. If I can ask you next to look at -- and again it should, I hope, come up on the screen in front of you -- TYWE0000052_005.
A. I'll get that up for you. No, sorry it's not coming up on mine --

Q. Don't worry, it should, I hope, come up on ours shortly.
A. -- and it hasn't come up on the screen yet.
Q. Our document system is struggling today. TYWE --
A. Yeah, I did -- yeah.
Q. Ah, it should I hope be on the screen in front of you now, Dr Lloyd, on our screen?
SIR BRIAN LANGSTAFF: It is on mine.
A. Oh yes, this is one of --
MS RICHARDS: Dr Collins's letters.
A. -- one of these poorly legible.
Q. Yes, it is. I'll read out the relevant passages. So it's from Dr Collins, it's dated 3 October 1986.
A. Yes.
Q. So, by this time, the service has moved into the new centre. It's addressed to Dr Donaldson --
A. Yes.
Q. -- the Regional Medical Officer at the Northern Regional Health Authority, and I'm just going to read out the first four paragraphs.
"Dear Liam
"Your letter of 24th June requested a comprehensive survey of modern Blood Transfusion medicine, as well as complex information not readily available from our many complete but manual recording

systems. Getting it out is very laborious.

"As you are aware, we are understaffed at senior level and now have no purely scientific staff. This means that the increasingly complex clinical and scientific problems have to be handled largely by myself. Being virtually single handed during the summer I have not had sufficient time to devote to this report.

"However, Dr Lloyd has rejoined us on the Senior Registrar rotation and is well experienced in the workings of the centre from within and also as a user of the Service.

"I have discussed all these matters with him and he has been working hard compiling this preliminary report."

The question I want to ask you rising from this document is really about the staffing situation by this time, 1986, and you obviously then returned full time to the Centre in 1977. What do you recall about the staffing problems that Dr Collins is referring to here.

A. The problems, I think, were quite significant. Anne Collins, as the director, I don't think -- there was no other full-time consultant. There was some clinical assistants -- I think they called them

clinical assistant grade -- but their ability and their knowledge range was extremely limited. So really, she was working very much on her own. The support from the others there at the time, the other medical staff was really -- didn't touch on what I would call significant clinical issues or the, sort of, management of the Centre.

So yes, she had a difficult time. Very little support.

Q. Then if we look at a report which may, I think, have been the report produced that's referred to in this letter. It's NHBT0101 --

A. I can tell you, NHBT -- (overspeaking) --

Q. -- 332_045.

A. 332 -- that is the one, you're correct.

Q. Good. So hopefully it will come up on the screen again in the not too distant future.

Yes, NHBT0101332_045. Thank you.

So we can see there a page which has various sections set out. If we go over the page, we can see section 1 is "Major products and services provided by the Northern Regional Transfusion Centre", and then we can see it's red cell products, fresh plasma products, time expired plasma, platelet concentrates, reagents, and then reference to the transfusion laboratory and

antenatal laboratory.

A. Yeah.

Q. Then if we go to the next page, I wanted to ask you about this next section. So headed "Whole Blood":

"This region has a relatively high demand for whole blood. There are many periods during the year when whole blood is not available in the quantities requested, despite some whole blood being returned 'out-dated'.

"Reasons:

"(a) Previous patterns of use. Whole blood has tended to be freely available.

"(b) Many surgeons and anaesthetists find it easy to have whole blood available for operations. Plasma blood is available in most cases.

"(c) Hospital blood banks maintain stocks of whole blood for emergency use for major trauma and massage haemorrhage."

Then there are "Comments", four comments:

"(i) Pressure of reduced whole blood supply will force some change in use.

"(ii) Education at hospital clinical meetings may help accelerate the changes.

"(iii) Changes in hospital blood bank policies in consultation with clinical departments can reduce

the level of requests.

"(iv) Optimal additive red cells provided acceptable alternative to whole blood in most instances."

Then you go on in the next part of the document to talk about the optimal additive red cells.

What essentially was the issue here that you were recounting in 1986 about the use of whole blood?

A. Well, if you looked at the amount -- the percentage of donations that we produced that were issued as whole blood, it was high compared to other parts of the country.

I had a chance to look at some figures from elsewhere around the country so I was aware that we were, if not at the top, very close to it. I think we probably were the highest issuer of whole blood, and that sort of seems to go back -- when I was in the old centre in the early part of the 1980s, the laboratory manager always pushed very hard for us to -- for whole blood. To the extent that the Centre production staff were sometimes unoccupied because blood that was expected to be converted was not being converted, it was being left as whole blood.

It was a strange situation. We were collecting blood into multiple bag packs designed for producing

multiple components, and yet we left it as whole blood, clipped off the extra blood packs and threw them in the waste.

So there is a long history in this Centre of using whole blood, issuing it. And if you look at that, the Centre really, I don't think, had an opportunity to discuss these issues with the hospitals. But also, most -- many to the hospitals outside sort of the two bigger centres, sort of like Newcastle, had no haematologist. The blood bank and haematology was operated by -- was overseen by a pathologist. So that was not their specialty. And there was a big push by Professor William Walker at the Royal Victoria Infirmary to get haematologists into all the hospitals in the region and that was successful.

So it would have been hard to make a change at that time and we were putting out lots of whole blood.

A second point, and that comes up in another article -- another document, is that -- and I think it was from Anne Collins -- that we are trying to produce blood -- optimal additives or sometimes referred to as SAG-M, saline-adenine-glucose-mannitol, the optimal additive, saying you don't give us -- you have the money to produce this product on a regular basis.

This product is a good alternative to whole blood, but if we can't produce it on a regular basis, on a consistent basis, then the individual hospital users are not going to change over to it.

So we had a sort of a little bit of a chicken-and-egg situation there. And so yes, it was a lot of whole blood, and the demand appeared to be there but that's possibly because the education hadn't filtered through that whole blood is not a good product for many patients.

Q. Just picking up --

A. I hope that answers your question.

Q. Absolutely. Just picking up your reference to the document from Anne Collins, CBLA0001800, please, Sully.

This is a report by Dr Gunson. If we go to the second page -- if we just go a little closer, please, Sully, into the table.

A. I know the document.

Q. So we've got the reference there: Northern Regional Transfusion Centre:

"1984-5

"- Does not expect to separate more plasma than 1983/4. Cannot obtain finance for SAG(M)."

And then "1985":

"Has been unable to initiate discussions on plasma supply with RHA. Could not in any case increase supply in present premises. New RTC should open in 1985/6."

Then:

"Confidence ... in ... achieving target.

"Not hopeful of obtaining necessary funding."

A. Yeah.

Q. So that would suggest --

A. I'd say that -- if I might say, there is another document where Dr Collins specifically mentions the problem of erratic supply of optimal additive, or SAG-M, so there is another document, and I'm sorry I can't remember it, but I have seen it. So yes, there's more than one reference to this problem.

Q. And then if we pull up CBLA0002392.

A. Oh, yes.

Q. And if we could go to page 165, please, Sully.

This is a document you drew attention to in a recent addendum to your statement, Dr Lloyd.

So we've got table 11:

"Number of units of red cell products made in 1985/86."

Then if we look at the regions on the left-hand side, as I understand it region B is the Northern

Region, is that right?

A. In this table. It's different in different tables. So you can't use B across everything.

Q. Well, that's useful to know, thank you, Dr Lloyd.

And we can see there highlighted for us on the screen the relevant figures, which show, if we look at the figure under the heading "SAG(M)" a very --

A. Compared to most of the other centres.

Q. Exactly, a very modest use compared to the other centres.

A. You know, it's not only a modest use, it is -- emphasises the fact that you couldn't provide this product on a regular basis. If you only make 2,000 in a year, you can't offer it as an alternative to whole blood.

Q. And if we go two pages further on, please, Sully, to page 167.

This is the second table you referred into your addendum statement, Dr Lloyd. Table 13. I think this is -- region B is still the Northern Region in this table, and we can see there the percentage --

A. Yes, a little group.

Q. Yeah, "Percentage of Red cell products issued", and we see there, with the exception of region J, which is apparently not offering any --

A. Yes.
Q. -- the Northern Region is offering a modest amount indeed compared to --
A. 2 per cent.
Q. -- other Centres.
A. Yes, region J was East Anglia for some reason. I don't know why they didn't use optimal additive.
Q. Then I'll come back to how things changed in due course, Dr Lloyd, but I'm just trying to get a sense of what things were like in the first half of the '80s through to sort of 1986 or thereabouts.
Sully, could we go back, then, to NHBT0101332_045.
A. What page would you like to look at on that?
Q. Page 8, please.
A. Yes.
Q. In this report, Dr Lloyd, I'm saying this for the benefit of others, really, you give a snapshot of the position in relation to the range of different products used. I'm not going to go through the detail of it but I mention that so that others listening can look as appropriate.
But I just wanted to pick up the figures in relation to cryoprecipitate at the bottom of the page. You say there:

"There has been no significant change in total usage of this product."
Then we've got the figures from 1982 to '85. The units showing a fall in '83, a slight rise again in '84, and then a slight rise again or a further rise in '85. But not a huge variation.
A. There was -- those numbers -- the differences in those numbers are not significant. I mean, they are very, very small differences in the overall picture. And I think even if you -- I did present a chart with some other years -- and again, for quite a period we were running along at around that ...*[frozen screen]*...
Q. I'm sorry, you froze again, Dr Lloyd. The last we got was you said, "for quite a period we were running along at around that"?
A. Around about 5,000. So it stayed at about that level over quite a long period of time.
Q. If we go to the top of the next page or the first half of the next page, we can see it says:
"This, however, hides an underlying trend. The major users were the haemophilia units at Newcastle and Middlesbrough. The use of cryo at the [Royal Victoria Infirmary] fell significantly in 1983 and 1984, probably due to a reduction in surgery on haemophiliacs due to HIV/HTLV III positivity. It

seems likely that orthopaedic surgery will increase again as arrangements are made to carry out surgery on HIV/HTLV III positive patients."
Then we've got the figures for the Royal Victoria Infirmary's cryoprecipitate use for that same period, 1982 to 1985 and we can see there the reduced usage. Then, if we just go a little further down the page, under the heading "Major Users of Cryo", we then see the other users: Middlesbrough Group, QEH and North Tees.
I'll come back and ask you a little more about issues relating to the Haemophilia Centre in a little while, Dr Lloyd.
Can I then, just in terms of an overview of the Centre's work, pick things up with an inspection report in 1989. NHBT0006234, please, Sully.
I'll just get my own copy.
So we can see the date of the inspection by the Medicines Inspectorate was July 1989, so you were, by this time, in post as director and we can see it's a routine reinspection and the date of the previous inspection was March 1987.
If we can go, please, to page 3, Sully. Under the heading "Introduction", we can see here the move has taken place:

"The Northern Regional Transfusion Centre is housed in a purpose-built building, opened in 1985 ...
"The Centre serves a population of nearly 3.1 million over a wide geographical area, collecting around 120,000 donations annually and employing a staff of 220."
Then we have the staff list there set out. I'm not going to go through the details of that.
If we go over the page, to page 4, we've got a list of the products being produced as at -- for the period April '88 to March 1989. Then, under the heading "Inspection", I just want to pick up a handful of points with you there. It says:
"There is a plasmapheresis clinic in the Centre equipped with 8 Haemonetics machines, the donor panel currently numbering around 1000. However, apart from very occasional walk-ins, normal donations are not collected at the Centre and all normal donor sessions are mobile. A visit was made to a mobile session held in Whikham Community Association Hall."
Then the next paragraph tells us that:
"Donor records are not computerised, the 101 card system still being used", and there is then a description.
Then the next paragraph:

"If a donor reports having had a recent illness or course of medication, brief notes of this are written onto a page of a duplicate notebook, alongside the [donor] number, and at the end of this session, this sheet, known as the 'Illness Sheet', accompanies the blood to the Blood Components section, where it is used to identify unsuitable donations."

Can you just tell us a little bit more about how that latter procedure operated: the illness sheet and identifying unsuitable donations?

A. Sorry, I lost that little piece.

Q. So, in relation to the procedure described in that paragraph I just read out, the completion of the illness sheet and then its use to identify unsuitable donations, how did that work in practice? Who would identify them as unsuitable and what kind of information would lead to that conclusion?

A. Okay, this was the -- I mentioned this earlier in my evidence today -- that at the sessions there was a book, as it mentions here, a duplicate book, and if there was something that sort of fell outside the normal or the -- that the clerk, who was clerking them in wasn't, sure about, that information would be written on the illness sheet, and if one of the donor attendants or the team leader or, indeed, the medical

officer at the session felt there was some piece of information about which they weren't sure ...[frozen screen]... written in this illness sheet, it came back to the Centre.

Then every morning, the next morning after the day's sessions, the illness sheets were passed to one of the medical staff whose job it was to go through all the illness sheet information, compare it to the known criteria for donation, in some cases to put the donation on hold while further enquiries were made of the donor's general practitioner. Sometimes there'd be, you know, if it was a more junior member of staff doing it, they might refer it to perhaps myself or Dr Collins.

So a decision was made whether or not that donation was suitable. Sometimes the donation was considered suitable for plasma but not for red cells. It varied. Unfortunately, there were -- it highlights an issue that we tried to deal with later which was that we were taking donations from people where we weren't sure if their donations were going to be suitable for full use, which we felt later -- when we came to this issue, we tried to change that round and say we shouldn't take a donation from someone unless we're sure that their donation is suitable for use.

But this is how it had worked for -- I mean, that illness sheet book, that duplicate book, they had been in use for years, and years, and years. That's how it worked.

Q. Then if we can go to page 9 of this document, I just want to ask you about another aspect of the Centre's operations. So under the heading "Despatch":

"Orders for blood and products are generally telephoned in to the Despatch department but there is also a 'milk run' of set journeys to a number of hospitals. Telephoned orders are first noted onto a piece of scrap paper and then transcribed onto an official order form."

Then it goes on to talk about the orders being put together, the donation numbers, et cetera, all recorded manually "in the Blood Issues Request/Despatch Book. There is a system of using different coloured ink for each type of product but this not always adhered to."

Then if we just go to the fourth paragraph, we can see there it explains what happens with returned packs:

"... (of which there are many) are logged into a Returns book ..."

Then it says:

"... the task of tracing the fate of an individual pack would be extremely laborious and, in some cases, impossible."

Can I just -- again, this is obviously pre-computerisation and we'll come on to the changes that were made over the following years. The process, first of all, of dispatching products, leaving aside the milk run, which presumably was essentially a set of standing orders to different hospitals --

A. Mm-hm.

Q. -- to what extent were you able to deal with the *ad hoc* orders for blood and products being telephoned in or did it give rise to shortages?

A. The telephoned orders, requests for blood, didn't specifically give rise to shortages. The shortages were more of a structural issue with the way that the Centre was -- you know, how much the Centre was producing. So the ...[frozen screen]...

Q. Sorry, Dr Lloyd, you froze again?

A. -- throughout the day but also in the evenings -- yes.

Q. Not your fault at all. You were telling us that it was a structural issue with the way the Centre was -- how much the Centre was producing.

A. Yes, and so whether there was enough blood to, you know, fulfil the regular orders on what's here

described as the "milk run", although that's not a phrase I ever heard any of our staff use. The orders that came in for *ad hoc* were promptly, dispatched whether it was during the day or whether it was in the middle of the night. They didn't specifically of their own give rise to shortages.

What I can say is, and this is also touched on in the records storage report prepared by the CMO office, DHSS, and you have a copy of it, it's a rambling report but it does say that hospitals that they went to often exaggerated the demand -- exaggerated their order because they knew that their transfusion centre would issue less than the amount they'd asked for. And that was absolutely classical of the Newcastle Centre; people ordered twice as much as they wanted, as they needed, because they knew their order would get cut back, and then one day they would make that large order and it wouldn't be cut back, because there happened to be enough of it around.

So it was a very poor system, a lack of cooperation -- perhaps not cooperation, a lack of understanding between both sides. And that was one of the things we did try and change, was to say our job is to issue what you asked for, not issue what we

think you should have.

So, yes, it was a difficult time, and it required a lot of change to move from it.

Your other issue is -- that was brought up on this is, of course, that everything was manually recorded, and everything -- virtually everything in that Centre was manual.

Q. Then the paragraph I read out relating to returned packs included the phrase in brackets "of which there are many".

A. Yes.

Q. Is that accurate, and why were there many? Was that a feature of people asking for more than they needed?

A. I'm not sure I can give you a definitive answer on that. There certainly were many. The amount of blood that was returned to the Centre unused was considerable. It dropped off later, I think, as demand increased and supply didn't increase a lot, and also with better arrangements between the Centre and the hospitals.

But if you go back into the 1960s and 1970s, you see vast quantities of blood being returned from hospitals unused. You know, thousands of units were being returned unused, which was why the Centre spent a lot of time collecting outdated plasma to be sent to

BPL in Elstree. So yes, there was a lot of ...[frozen screen]... was the regular delivery runs, which I think -- I only say I think -- well, particularly for the hospitals outside Newcastle, were pretty much a fixed quantity of each blood group. To the extent that the delivery drivers sometimes had difficulty delivering the order. Northallerton hospital, for instance, I recall it was often mentioned that our delivery to them they couldn't fit it in all into the fridge. So there was a big disconnect there between what we -- the Centre was doing and what hospitals actually required.

Q. And I know, Dr Lloyd, that you weren't involved in the formal hepatitis C look-back that was initiated in 1995 because that coincided with your departure from the Centre. But we can see here a reference to the difficulties in tracing the fate of individual packs.

Prior to the -- this becoming a fully computerised system, was that your experience on -- or were there occasions when you did have to trace the fate of packs and were unable to?

A. We didn't have to trace packs very often. You know, if you go into the HIV era, the number of HIV positive donations in the Newcastle -- for the Newcastle Centre and its catchment area was very, very small. I don't

recall not being able to trace it.

I mean, this is a report from an inspector. What I would say is that although the Centre had an incredibly manual system, it was a system that had been in place, you know, from almost time immemorial, if I might say, and so people did know how to use it.

It was slow. It was slow. I mean, it could take you days to find out what had happened to a donation. What we did have more of was donors who would phone in after they'd donated, perhaps a week later, and say, "Look, I've come down with a cold", or something, and you would try and -- you needed to retrieve that donation, which had been issued perhaps in two or three parts to hospitals. It could take, you know, a couple of days to actually trace that going back through manual records.

But I think it was ...[frozen screen]...

Q. I'm sorry, Dr Lloyd, we lost a few seconds again.

You said it could take you a couple of days to trace going back through the manual records?

A. Yes, and it was difficult, it was slow, and obviously, as it says there, extremely laborious. But it was possible.

Q. Now, we saw from the beginning of this document that there'd been an inspection in 1987. This was

a routine re-inspection in '89. Do you have any idea whether there had been inspections in the first half of the 80s, and if so, how frequently they'd taken place?

A. No, I have no recollection of previous inspections.

The '87 one -- maybe I wasn't in the Centre but I certainly don't recall it. And of course, we have to recognise that this was at a time when the Health Service operated under crown immunity, and therefore whatever the inspector might have said or might have recommended, there was no sort of requirement on the centres for or their management, in this case the RHA, to actually get things changed.

So yes, we do -- you know, it is -- I don't recall them inspecting before, but obviously, as they said, they had.

Q. You tell us in your statement, it's WITN6935001, page 11, so it'll be on your screen, Dr Lloyd. You tell us there --

A. Okay.

Q. -- about the introduction of the Blood Management Computer Network System. I'm not going to ask about the details of that because you very helpfully set it out in your report, and the Blood Donor Management System, and then the CDIC.

At the bottom of the page, you explain that you asked Birmingham University Health Services Management Group to carry out an assessment of the management of the Centre and develop a programme of predominant development.

What had prompted you to ask for that assessment, and what, again, in broad terms, was it designed to address?

A. Well, you have to understand that, you know, myself and, you know, I had a medical training. None of my training included anything on how to manage, which was, you know, a shame. And I became director quite suddenly. There was no opportunity to take any additional sort of training courses. I started to read quite extensively on how to manage, and management issues, and I think together with my senior managers we realised that we did need to improve what we were doing. We needed to become more professional in how we operated and so the -- I had been to a two-day -- a weekend course arranged for new consultants, arranged by the Regional Health Authority, presumably when I first became a consultant, and they -- that little course was run by the people from Birmingham University. And so I sort of knew what sort of style they had, and felt

that they might be able to help us and we -- I, in my humble opinion, yes, it helped.

Q. Now one of the --

A. And if you want to know more about it --

Q. No, I think that's fine, thank you. We can take that down, thank you, Sully.

Your statement tells us you made a number of organisational changes to the Centre as director. I'll pick up one in relation to donor services later but there's just one I wanted to pick up now. That was the testing of donations for infectious diseases, consolidated through the usage of a single manufacturing system. Now, we'll talk about hepatitis C screening and its introduction at a later stage of your evidence probably tomorrow, but in broad terms what was this single system, and what was its advantage in your view?

A. Okay. Before we introduce that, we were testing -- you know, for hepatitis B and HIV, and there were two different systems. So we were using completely different mechanics, equipment, for each test. That gave rise to data transfer issues, so you now have to develop two systems of data transfer, two systems of data validation, two systems of authorisation of the transfer of records into your main system.

You also have a training issue. You now have to train your staff on two different systems. You have to -- I mean, it goes on. I keep saying two. But whenever you're using two different sets of equipment it gives rise to a multiplicity of issues. You have to do everything twice. Your quality control is going to be different, your quality assurance programme for it is going to be different, your training is going to be different. It makes it more difficult for staff to change between one machine, one test and another.

So we moved to a single system offered by the Abbott Plc, I think the official company we dealt with was based in Germany, but it's an American corporation and they produced equipment which had a much higher level of automation than the equivalent other companies offered. So it integrated a lot more of the quality control into the system, automatic pipetting and delivery of samples.

But basically they're using the same system to do different tests, and then the test results come together, and they had one module which brought the test results together, which allowed you to do one authorisation process to release the results into the general computer system or wherever.

So it gave you a lot of advantages, not only in

mechanics of running it, the training staff ...[frozen screen]... run systems.

Q. I'm sorry, Dr Lloyd, we lost you again.

So we last had it when you said it gave you a lot of advantages, not only in the mechanics of running it, the training of staff ...

A. And things I've already mentioned. So the quality control and the single authorisation of results before they're transferred out for use by the rest of the system in *...[frozen screen]...*

I have to thank the staff who worked there for really bringing a lot of that to my attention, and helping recognise that there were some good alternatives out there.

Q. Can I then ask you a little about the relationships that you had with other bodies and organisations. So first of all, relationship with your Regional Health Authority. How would you characterise the relationship that you had or, to your knowledge, your predecessor had?

A. I'll start with my predecessor. Dr Collins did appear to have difficulty with the Regional Health Authority and her dealings with it. My understanding from talking to somebody at the Regional Health Authority was that they were to some extent unhappy that when

automated blood grouping was brought in, Anne Collins would not reduce the staff commensurate with that automation.

We had dozens of junior at the time called technologists or technicians, which we didn't need once it became automated in that particular department. So I think there was sort of a little bit of a stand-off about that. So I think, you know, she did have difficulties with her dealings with the RHA, and I am sure we will come back to the RHA's view on plasma production later.

When I took over, I got along reasonably well with the people at the Regional Health Authority, initially the regional scientific officer, Mr Geoff Whittaker and, as time went on, the Regional Health Authority changed its -- you know, who I dealt with. I got moved to deal with somebody who dealt with a number of regional services, Mr Tony Garland, I think. I'm not great on names. But I was sort of moved and I got along with them. I wouldn't say, you know, that every communication was wonderful but, you know, we got along quite reasonably and they did seem to start responding to issues that we were able to bring up.

And as time went on, I found that some of the

more senior staff at the Regional Health Authority, particularly Liam Donaldson -- now, I think Sir Liam Donaldson, you know, he understood issues. He did. He was -- he understood health care, and I found that I was able to, you know, we did manage to get things done. So it became a reasonable relationship.

In the early days there was -- as I mentioned in my witness statement, there was a lot of detailed stuff coming from some of the lower areas -- levels of the Regional Health Authority. And some of that got pretty tedious, asking us to produce flowcharts and I think something called a Gantt chart, all sorts of bits and pieces which really I felt weren't necessary to the running of the Centre and weren't helping us to move forward, and there was a lot of detailed stuff.

But as time went on, that became less, and part of that was of course the move to separate us out into a clinical agency of the Regional Health Authority.

Q. Now, in terms of relations with other directors of Regional Transfusion Centres, you were present at what turned out to be the last Regional Transfusion Directors meeting in January 1989. It wasn't clear to me whether it was also your first meeting as a Regional Transfusion Director, I think it might have been?

A. It was.

Q. So your first last and meeting, and I won't display the minutes because we've looked at them on a number of occasions but you'll recall, and you note it in your statement, it suggests that the decision to disband the meetings was unanimous. Your recollection --

A. Yes.

Q. -- I think, is different?

A. Yes, recollection is always a tough thing. Sometimes you recall what you want to recall. But I do note the informal minutes of that meeting, I think, produced by Dr Ewa Brookes, which said that the announcement or the decision to end the meetings was met by universal silence, and that there had been no discussion about ending the meetings. So ...[frozen screen]... myself, you know, my first meeting, I'm the junior, very much the junior, I'm sure I wouldn't have stood up -- I think you've lost -- I'm sure I wouldn't have --

Q. I can hear you.

A. I'm sure I wouldn't have stood up and said, "No, don't do this" because, you know, I was -- (a) I wouldn't have got anywhere because everyone else seemed to be okay with it and, yes, I was very junior, in terms of the number of years that all -- most of the others had

served as ...[frozen screen]... Yes, I probably acquiesced, let's put it that way.

Q. We lost you a couple of times there, Dr Lloyd, but it was clear, I think, what you were saying.

A. Okay.

MS RICHARDS: Sir, I note the time. I've got couple of documents I'm going to want to look at, so perhaps do that after the break?

SIR BRIAN LANGSTAFF: Yes, okay. That's a good idea. Let's take a break now, what shall we say, 25 minutes?

MS RICHARDS: Yes, that would be fine.

SIR BRIAN LANGSTAFF: So 25 minutes. Let's come back at 2.40, our time, and that's 9.40, thank you. Your time.

A. 9.40.

SIR BRIAN LANGSTAFF: Let me say to you what I say to all witnesses at this stage, if I haven't said it previously, and it's this. You're giving evidence. You must not talk to anyone until you've finished giving evidence about the evidence you have given or anything you think you may be asked to say in evidence but you can talk about anything else you like.

A. I understand that, sir.

SIR BRIAN LANGSTAFF: 9.40.

MS RICHARDS: Thank you, sir.

(2.15 pm)

(A short break)

(2.40 pm)

MS RICHARDS: Dr Lloyd, your arrival as director largely coincided with the creation of the National Directorate. What was your experience of the National Directorate and its ability to coordinate or take decisions?

A. Well, if you look at some of the documents that have been submitted in my correspondence with the National Directorate, I think that speaks to the fact that I did not have a very high opinion of that organisation. I felt that they were poor at making decisions. We know from Dr Gunson's own statements that he felt that he had no authority, and that's the case. He was not -- the National Directorate wasn't set up to have a line of authority.

On the other hand, if you had recognised that, you could have worked with people to get agreement, and what we saw, as we mentioned earlier, as you brought up earlier, there was the last of the Regional Transfusion Directors meetings. And, in that -- in dissolving that meeting, you removed a degree of coordination which would have been possible, bringing all the directors together with the national director,

and together with people from the Department of Health, DHS, DHSS as what it was at different times, and a representative from the Scottish Blood Transfusion Service.

And that is -- I mean that's mentioned by Dr Ewa Brookes in her informal minutes of that meeting saying, you know, you may come to rue the moment you agreed to this meeting ending.

So the National Directorate, to me, had ended up severing certain lines of communication, so that -- I don't know how other directors felt but I felt that I was, sort of fed, you know, small snippets of information and really didn't have a lot of input; and sometimes that meant that you didn't understand the context of some things that were happening.

So, yes, the National Directorate, to me, was a poorly put together ...[frozen screen]... It could have functioned a lot better within the confines of what it was given. Sorry, I rambled a bit.

Q. That's quite all right a bit.

I want to ask you to look at a document which was produced by you in March 1991, so approximately three years into the life of the National Directorate, NHBT0001864. So the document should be on your screens, Dr Lloyd. It's "Framework for a National

Directorate of the Blood Transfusion Service in the post White Paper Era", and it's dated on page 6 --

A. Right.

Q. -- 14 March 1991. You say in the "Introduction" that:

"Since the creation of a National Directorate there have been significant changes in the NHS."

You describe links with Regional Health Authorities starting to weaken, and then you say:

"That raises the question of a future role for a National Directorate."

You suggest that:

"... there is an important and valuable role for [it], covering in particular the areas of information on Transfusion Medicine and Transfusion Management and the provision of a public face ..."

Then if we just go to page 4, if we pick it up halfway down the page, under the heading "The authority for a National Directorate", just wait until we get there.

SIR BRIAN LANGSTAFF: Are we on the right page?

A. (Overspeaking).

MS RICHARDS: Yes, we're on the right page but we need the bottom half of the page.

Yes, so "The Authority for a National Directorate".

A. Oh okay.
Q. You say:
"At present the National Directorate is officially working to a brief dating from 1998. That brief is out of date ..."
Then skipping over a couple of lines:
"It's long term role appears uncertain unless a clear role can be developed that fits with the current White Paper philosophy."
Then you refer to the National Directorate and the CBLA and then, over the page, next page, you set out "A Proposal for the way forward". I'm not going to through the detail of that but just pick it up at the "Summary", bottom half of the page:
"A re-definition of the role of the National Directorate, with a clear brief to support the UK Transfusion Centres and to provide cost effective information, public relations and certain coordinating functions is proposed."
Now, we know this isn't what happened and, in due course, we have the National Blood Authority, which I'll come on to in a couple of minutes, but what was it that led you to advocate this redefined role for the National Directorate? What were you hoping it would achieve?

A. Goodness, yes, I was obviously ...[frozen screen]...
I was trying to look for something that didn't require the National Directorate to be completely brief, redeveloped. In other words, you didn't want to have to go to the Department of Health and say, you know, "Create a different beast". So what could the National Directorate do that would deliver, you know, value to the transfusion centres? So I'm looking at certain things.
As an individual transfusion centre director, I was obviously heavily consumed in running, you know, what was then a multimillion-pound operation. And the amount of time available to do some of these things was limited. So, you know, the time to travel to, you know, international meetings and get a good understanding of what was going on from around the world, you know, that would have been something that the National Directorate could have done because the National Directorate doesn't have to actually manage anything other than a handful of people in an office.
So I was looking for things that they could deliver, which would help the Transfusion Services, and so I think that's sort of where it -- where I was going. Gosh, it's a long time since I wrote this. I don't know, is there anything else you'd like to dig

into on it?
Q. No --
A. Just to say, I was just flying a kite.
Q. We know there was then a consultation on forming a National Blood Authority, and there's a response to that consultation by the Northern Region Blood Transfusion Service at DHSC0004584_039.
If we go to the third page, under the heading "Introduction" picking it up in the third paragraph:
"In essence the NRBTS believes that strong local management with local accountability provides the best option for the future. This option is outlined in the section 'Preferred future management arrangements'. Central coordination is available through a small organisation operating on behalf of Regional Transfusion Centres."
Then the next paragraph:
"It is accepted that the strongly independent stance that we would like to take, whilst possibly appropriate for ourselves will not be suitable for a number of Transfusion Centres. It is also accepted that BPL requires more support to survive."
Then if we just keep the whole of it on screen, Sully, I think it's fine.
The next paragraph:

"We have assessed various options against the standards that we believe appropriate for a Transfusion Service in the United Kingdom ..."
You refer to a proposal put forward by the Transfusion Centre Directors and Managers. Then you say:
"The NBA proposal as presented in the consultation paper does not meet our criteria on a number of important points. These are amplified in the section 'Perceived problems in the NBA proposal'. It does however address the national co-ordination question, the need for a national image for the NBTS and the link between the NBTS and BPL. We therefore support the formation of an NBA but believe it should be in the form of revised proposals from the Transfusion Centre Directors & Managers."
I'm not going to go through the whole document, Dr Lloyd, but can you tell us essentially what it was that you were proposing and why you were not supporting the idea of an entirely National Blood Authority, essentially a single transfusion service?
A. Yes. As I said in that document, you know, what we were proposing may not have been entirely appropriate for every transfusion centre. I'm certainly aware that quite a number of transfusion centre directors

strongly wanted a central service -- organisation.

I guess I had found that I had a really good group of staff in the Transfusion Centre, at many levels, and we were able to work together to make changes. And we could make them quickly. Relatively quickly. Some of them we could make very quickly.

So you can get things done with a good management team and good staff. You can get them done locally. Once you become national, particularly in the early years, you've got an enormous task to try to bring disparate organisations together. And certainly from my point of view, and it's mentioned elsewhere, I didn't really want to be in a position of just being told what to do.

You know, one was aware that the NBA changed some of things we did quite quickly, perhaps stupid things -- changing telephone systems, you know ... which removed direct outside lines into our dispatch department, apparently. And I quote that from someone who worked there after I left.

You know, so I'm not a lover of big organisations, I have to say. I'm not a lover of the big bureaucracy. So yeah, I pushed for something to keep us independent, but not ...[frozen screen]... standards. How you meet them doesn't matter. It's

meeting the standard. And if you can meet that standard, or exceed it, then that's good. So it's not saying, "Let's just forget about standards and we'll do our own thing", it's, "We'll do our own thing and meet what is appropriate."

So yeah, you see me being pretty clear on (unclear).

Q. And I understand from your statement that the establishment of the NBA in the form it ultimately took was a factor in you deciding to leave your post and move on to pastures new?

A. I have to put it in context. When I became director I had said to myself, and I think I've written that in my witness statement, that I didn't want to stay in that position for too long. One of the reasons for that was that I had met a number of other transfusion centre directors, and sort of felt that perhaps, you know, they'd started off with great ideas and, and so on, but had rather stagnated, and I didn't want to let myself get into that position.

So once, you know, by the time the NBA came into ...[frozen screen]... so the combination of my own idea, that I didn't want to stagnate, and the fact that the NBA would really take away my ability to get things done that I wanted to do, and I'd be subject to

an organisation, this sort of rather unknown organisation, you know, yes, that gave me the impetus to put my CV, my résumé out there.

Q. Now I'm going to ask you next about the relationship with Haemophilia Centres.

Just before I ask you about that from your perspective as director of the Regional Transfusion Centre, can I just come back to the short period of time you worked at the Haemophilia Centre during your registrar years.

Do you have any recollection of what Dr Jones' approach to treatment or treatment philosophies were, based on your own very short time there?

A. Yeah, very short time. I mean he was a great advocate for home treatment. And having, you know, knowledge of what haemophilia had been like for individuals prior to the availability of factor concentrate and then prior to the move to home treatment, you realise that home treatment offered a terrific -- potential terrific improvement to life. Now we know what happened.

But just the very fact of -- you know, he wanted patients to live a more normal life, if they could. So yes, home treatment was, I think, the bedrock of what was done at that Haemophilia Centre. But

I didn't have time to go into, you know, what his philosophy was and how long he'd gone down that path. So I -- and after that, it becomes hearsay.

Q. One of the documents in the 80s tell us -- tells us that the haemophilia patients in the Northern Region area were all managed from the Newcastle Centre rather than their own more local unit. Do you have any knowledge as to why that was the case?

A. I really don't, no. I mean, I know that there were some sub-centres but I don't even really know how they were staffed or managed. It did seem to be that Newcastle was the -- you know, the Centre that managed and offered management to patients in the whole region.

Q. Now I'm going to look in a moment at a letter that you wrote at the time of the HIV litigation, but before we do that, just in broad terms, as I understand the position, in relation to commercial concentrates, the Regional Transfusion Service had nothing to do with the ordering or stocking or supply of commercial concentrates. That was all dealt with directly by the Newcastle Haemophilia Centre; is that right?

A. ...[Frozen screen]... Haemophilia Centre and their pharmacy organisation. We did not order, choose, supply any of those commercial products.

Q. In relation to the NHS concentrates, the BPL products -- and we'll explore issues of plasma supply a little later on -- but, as I understand it, the Regional Transfusion Centre did have a role there, in the sense it received those products from BPL, and it supplied those products to the Haemophilia Centre?

A. Yes. Without going too much into semantics, when we say "supplied", I mean that was just an issue of -- a matter of transferring the product. We had, you know, we had a truck that went down to Bio Products Lab, BPL, with plasma, it came back with finished product, the Factor VIII was put into refrigeration, and then it was for the Haemophilia Centre, the RVI, you know, to collect that product.

I don't recall them actually ever ordering it. They didn't sort of say, you know, "Can you supply us, you know, ten boxes", it was a case of "We've got the product from BPL, come and get it".

Q. If we look then at the letter from the time of the HIV Litigation, TYWE0000064, please, Sully. If we go to the second page, it's a letter from you to a Mr Slack of Crutes Solicitors, heading "HIV Litigation", you say:

"Attached is a fairly brief set of answers to the questions put by you recently ... As I only became

Director/General Manager in late 1988 my involvement with, and hence knowledge of, certain aspects of this Litigation is limited."

You then refer to having gone a through large quantity of files created by Dr Collins and some files dating back to Dr Murray, and you say:

"... clear from my examination of the files that very little was put to paper by the previous Director, or if it was, no copies now exist at the Transfusion Centre."

If we go to the next page, there is a heading at the top of the page, "BTC Responsibilities in Relation to the Haemophilia Centre":

"The Transfusion Service responsibility to the Haemophilia Centre in this Region is little different to its responsibility to any other Health Service Department or Unit. We provide, within our capabilities, the products that are requested by the Haemophilia Centre. Some of the products we provide are locally produced, including cryoprecipitate and individual packs of fresh frozen plasma.

"As far as the supply of Factor VIII and Factor IX are concerned, we have acted purely in a handling intermediary position between the Blood Products Laboratory at Elstree and the Haemophilia

Centre. Because we have a vehicle travelling to Elstree carrying raw plasma to that factory, and the van is then returning to Newcastle, we bring back all the Factor VIII and Factor IX allocated to the Northern Region and then despatch it to the Haemophilia Centre. At various times we have held some of this product in stock, awaiting instructions from the Haemophilia Centre to have it sent across. As mentioned elsewhere, there have been times when it has been necessary to remind the Haemophilia Centre that supplies of NHS Factor VIII are available and awaiting collection."

Just pausing there in relation to that last sentence, Dr Lloyd, you refer in your statement to Dr Collins showing you boxes of Factor VIII in a walk-in fridge that Dr Collins told you the Haemophilia Centre was reluctant to take; is that right?

A. Yes, that's correct, and I think you have also supplied a document which is a letter from Dr Collins to Dr Jones, in which I think she uses the phrase "embarrassingly large supply that hasn't been shifted".

Q. Yes and we well just look at that --

A. *(Overspeaking)*

Q. -- TYWE0000015_002. If we just zoom in on the text, please, Sully.

It looks like it's 26 August 1983 but I'm not 100 per cent sure.

A. Yes, that's what I thought.

Q. It's from Dr Collins.

Thank you, Sully, I think that's right.

It's from Dr Collins to Dr Jones:

"Dear Peter

"We have an embarrassingly large supply of BPL Factor VIII in stock. How about it?"

It would appear from what you -- from what Dr Collins related to you, I think, and what you relate in this document, that the Transfusion Service's understanding was that the Newcastle Haemophilia Centre used, to a very substantial extent, commercial concentrates; is that correct?

A. As far as I know, they did. We know, and I'm sure we'll get into this at some stage, there was very limited supply of BPL Factor VIII. It would not have met the regional demand, particularly once you start a fairly aggressive home treatment policy. But, despite that, you know, there were still -- obviously there were still some products not getting used immediately. So yes, they used a lot of commercial

product -- concentrate, and you see that in other documents that have been submitted.

Q. If we go to the next page of this document, just pick up an answer you gave to one of the questions. So it's TYWE0000064, and it'll be page 4, please, Sully.

So paragraph 5 says:

"To what extent were there shortages of Factor VIII?"

This, as I understand it, was part of your answer.

"Factor VIII has, since the 1970s, been produced by the Blood Products Laboratory at Elstree in quantities less than those required for the treatment of the haemophiliacs in this country. The level of shortage in each region has varied because of the supply of raw plasma, from which Factor VIII is made. As mentioned elsewhere, I believe that this Region took a decision in the 1970s to purchase Commercial Factor VIII rather than invest in the transfusion centre, with a view to producing more plasma."

Can you recall, Dr Lloyd, what the basis was for your understanding that there had been a positive decision by the Regional Health Authority, I assume it's the Health Authority you're referring to there, to invest in --

A. Yes.

Q. -- commercial concentrates rather than rebuilding the transfusion centre?

A. Okay, at the time I wrote that, I would have been fairly heavily influenced by comments made by my predecessor, Dr Anne Collins, because I wrote that before I was director, and I would have had -- I wouldn't have seen some of the documents that you now have given me access to over decisions by the Regional Health Authority.

So I am here, I think, pretty much quoting the view that came from my predecessor without having sort of hands-on evidence to support that -- those statements.

Q. And I should say, I'm not going to go to it now, sir, but we do have a draft statement from Dr Collins produced I think, again, for the purposes of the HIV litigation.

A. Yes.

Q. I won't take time with it now, but for the transcript it's TYWE0000022. I may come back to it in the course of Dr Lloyd's evidence. But we do have Dr Collins's input there.

A. Yes. I have read that.

Q. There are a couple of comments that -- actually,

having said we won't look at that document, I'm going to suggest that we do.

Sorry, Sully, could we have TYWE0000022.

So this is the draft statement from Dr Collins. I just want to pick up on what she says at pages 4 to 5 and then ask if you have any observations or any reflections of your own based on your conversations with her.

So if we go to page 4, please, thank you.

If we pick it up halfway down the page:

"A further difficulty arose from the arrangements which were made from about 1980 onwards with the distribution of Factor VIII. The system introduced at that time was known as the 'pro rata' arrangement, by which [RTCs] were intended to receive back amounts of blood products in proportion to the amount of blood plasma sent by Regional Transfusion Centres throughout England and Wales. Because some Regional Transfusion Centres, such as the Leeds Centre, sent a disproportionately large amount of blood plasma, the northern transfusion service 'lost out', even when the amount of blood plasma sent to Elstree increased."

Do you have anything or any particular insight into or understanding of what Dr Collins had in mind

there, this sense that the pro rata system somehow was stacked against the Northern Region in some sense?

A. Well, not particularly against the Northern Region, it happen to act against the Northern Region.

If you look at some of my -- one of the charts I presented in my witness statements showing the pro rata distribution of products in general to the Northern Region, it shows that over a period of a number of -- I think it was actually only couple of years this data relates to, I just didn't happen to have a larger range of data, but you can see that in that chart that the amount of plasma being sent to BPL from the Northern Region stayed the same, but the amount of product that came back diminished.

And that was a fact -- that's how the pro rata system worked. You took the total quantity supplied by all transfusion centres and you, you know, divvied it up, accordingly -- the production accordingly.

So if some centres produce more but others stay the same, the ones who stay the same are going to get less product back. And that's what Dr Collins is referring to here. And as I say, I did produce a small chart showing that in operation.

Q. I'll certainly come on to some of the charts that you've produced, Dr Lloyd, in the course of the

afternoon.

Then if we just go to the next page, page 5, so still in Dr Collins's statement, picking it up in the second paragraph she says:

"It became apparent that there was a preference at the Haemophilia Centre for commercially produced Factor VIII blood product for the following reasons ..."

Then she sets out three: solubility, allergic reactions, and a more attractive presentation of commercial Factor VIII.

A. Mm-hm.

Q. Now that's what Dr Collins was saying.

Do you have any direct evidence or information of your own as to what might have been the preference of Dr Jones for commercially produced Factor VIII product? Is it something you ever discussed with him?

A. I mean -- no, I don't think I discussed it with him. I mean, I was certainly aware, because whilst I was a senior registrar at the Royal Victoria Infirmary, we often treated haemophiliacs who came in after hours when the Haemophilia Centre wasn't open, and we used the product that was allocated, you know, for that patient. If that patient was on a certain commercial product, that's what we used.

And it's true, the commercial Factor VIII was more easily soluble. In other words you could put the distilled water in -- I think it was distilled water -- into the vial, and dissolve it much more quickly than you could the BPL product. So I actually, you know, have experienced that.

I don't know really enough to say about the allergic reactions, the rate of those. But, you know, obviously Dr Collins had some knowledge of that. But I don't know what specifically Dr Jones was saying about that. But, you know, it is the case that that product, the BPL product, was less easy to use, and it wasn't presented, if you like, in a nice package. It didn't come with its -- with everything together. So a little more difficult to use.

Q. And then just before we move more generally to issues relating to plasma supply, whilst still on the topic of haemophilia treatment, can I ask you to look at NHBT0078890_022.

When it comes up, Dr Lloyd, you'll see it's a letter from you. So it's dated 13 November 1986.

A. Yes.

Q. It's addressed to the parents of a boy with haemophilia.

A. Mm-hm.

Q. And it refers to the possibility of collecting plasma from the parents to provide cryoprecipitate for treating their son.

Now I'm not going to ask you anything about the individual family concerned, but just as a broad topic, this idea of what I think you refer to in your statement as "family-specific cryoprecipitate", did that take off? Was that something that was done, and had it ever been contemplated before this?

A. I don't recall it being done at other times. You know, I read this letter and it -- you know, it obviously brought the issue back to mind, but it wasn't something that I was aware of as a -- certainly wasn't a major component of what we were doing in the transfusion centres. We were obviously prepared to do it, but I don't recall it becoming a frequent -- certainly not a frequent issue. We might have done others but I -- honestly, I'm sorry, I can't remember now.

Q. Do you know whether what had triggered this possible arrangement was concern about viral infection, or whether it was unrelated to that issue?

A. No, I don't know. I didn't deal with the parents, and certainly, you know, it was Dr Jones who worked with the parents to get a suitable means of treatment.

So I don't know what discussions took place to come to this conclusion. So I'm sorry, I can't help you further on that one.

Q. Thank you. We can take that down, Sully.

I'm going to ask you now to look at three documents, all of which, I'm afraid, predate your time as director, but they're three short documents relating to issues of plasma supply and meeting targets, and so on. Then I want to ask you about some observations you make in your witness statement.

So the first document is DHSC0002247_077. This is a letter dated 18 October 1984 from the regional general manager at the Northern Region Health Authority to the Department of Health. We can see it's headed "Supply of Plasma to the Blood Products Laboratory".

A. Yes.

Q. It says this:

"Your letter dated 10 August 1984 on this subject was discussed by the Regional Health Authority at its recent meeting when commitment to achieving the target for this Region was reaffirmed but only a qualified assurance with regard to timing could be given in the light of additional capital and revenue resources required and more particularly the need to

build up the number of plasma donors in the Region. In this latter connection, the recent closure of factories in the Region has had a considerable effect on the ready availability of blood donors."

So I appreciate you wouldn't have seen this letter at the time, Dr Lloyd, and, indeed, it doesn't even appear to have been copied to Dr Collins. But it suggests an in-principle commitment to meeting the targets and, presumably, the ultimate objective of self-sufficiency but not an equivalent guarantee of being able to do so. Is that, more broadly, a fair reflection of your understanding of the position at around this time, and the position you then inherited later in the '80s?

A. Yes, I think so. I think there's another document also from the Regional Health Authority probably from, was it the Regional Director of Resources, which I think may have followed up this letter, which you also, you know -- I didn't see at the time, which gives it perhaps a little more background to it. But, yes, my understanding was that we're not going to put a lot of money into the Centre. It's going to be expensive. We have limited resources, and so, at the moment, yes, we'll -- when you read it, you say: yes, well, we -- we'd like to go along with you, but

"I will let you know when any agreement is reached."

So it would appear that Dr Collins is effectively awaiting approval from the Regional Health Authority to take the steps outlined, fairly modest steps, potentially outlined in the third paragraph of her letter.

A. Yes, yes. She wasn't -- she felt, you know, she couldn't -- you couldn't -- you can't spend money that you don't have, you know, you don't have the authority to. And so the two things there, the bags containing the optimal additive, SAG-M, were more expensive and, of course ...[frozen screen]... expensive operation. There was a small plasmapheresis centre in the new building with a small number of units. We saw that in the Medicines Control Agency Inspection Report earlier, where I think they mentioned eight Haemonetics machines, although that might have been a little bit later than this.

Yes, it was the next year, wasn't it, that report.

So she had -- she couldn't go ahead with some of the things that she would have liked to have done because she didn't have the funding to do it.

Q. Then I think we see that perhaps most starkly in the

actually we're not going to. Haha.

That's what it appears to say. And the little bit about the closure of factories, and so on, is just a little bit of icing on the cake to try to show that, you know, it was going to be difficult.

Q. Then I'll just pick up two other documents, they're not, I think, the one you're referring to, but I'll try and find the reference to that later.

So the second is a letter from Dr Collins to the DHSS, May '85, DHSC0002269_021, so 1 May 1985, headed "Plasma Procurement for BPL":

"I am sorry for my late reply to your letter re Plasma Procurement for BPL. The matter was raised at the recent [Regional Health Authority] meeting, members being advised that additional finances would be required for the proposed plan and that information was still being collected.

"I am therefore not in a position to assure you yet of any increased supply from this region.

"The new Transfusion Centre building should become available later this year, thus resolving one constraint upon us. The proposal being considered comprises a small increase in routine blood donations, use of SAG-M for a proportion of donations and the shortfall being made up by plasmapheresis.

third letter I wanted to ask you to look at briefly, it's TYWE0000051_004. It's almost illegible but I'm going to read it out. It's Dr Collins to Dr --

A. Dr Jobling.

Q. -- Jobling, a pathologist --

A. Jobling.

Q. -- at the Preston Hospital, and it's December, 9 December 1985, I think.

A. Yes.

Q. She says:

"I must point out that the Regional Health Authority does not fund this service to be self-sufficient in plasma products."

Then she says:

"However -- there has been recently a shortfall in supplies of processed material from BPL, and we will now be able to let you have a small additional number of units, as they are correcting this."

So again, I think it's fairly obvious what Dr Collins is saying in the first main paragraph there: insufficient funding for self-sufficiency.

A. Yes.

Q. So those letters really then lead, I think, to some observations you make in your witness statement, Dr Lloyd. So if we could have on screen, please,

Sully WITN6935001, and we go to page 39. So paragraph 29 says "Barriers to achieving plasma targets", and you identify three points there:

"Prior to 1985 -- limited and outdated facilities", which you've already told us about in the course of your evidence.

A. Yes, yes.

Q. Then "The Centre's belief that a large proportion of whole blood was required by the hospitals it supplied", is the second bullet point.

A. Mm-hm.

Q. Does that take us back to the issue you referred to earlier about the very substantial proportion of blood or -- or products being supplied in the form of whole blood rather than, for example, the use of the red cells and SAG-M?

A. Yes, yes. I mean, when I started -- as I'm just reiterating what I said before -- the Centre seemed to think, at least its laboratory staff at that time -- not later, but at that time -- seemed to believe that what the hospitals needed was whole blood and that's what we were going to give them. And the -- we didn't fractionate -- sorry, not factor -- we didn't separate a lot of the whole blood into components as we should have done and, of course, you couldn't put it into an

optimal additive because we didn't have the bags and the money to, you know, buy them.

So that's definitely what I was talking about and that's what I'm talking about here.

Q. Then the third bullet point, "Prior to 1988 the RHA's approach to funding plasma collection", and that's really the point that emerges from the correspondence we've just looked at; is that right?

A. Yes, yes. Yes.

Q. Can we then just look at some of the graphs that you've exhibited to your statement. If we start with WITN6935013, so this is the supply of fresh frozen plasma from the Northern Region to BPL, 1981 to 1985. Can you just -- well, I think this is probably one of the pieces of information you were referring to earlier.

A. Yes, it is.

Q. The amount in terms of volume supplied remains relatively static during that period. There are increases and decreases year in, year out --

A. Yes.

Q. -- but there's not a huge difference. But the percentage, in terms of the percentage contributed by all centres, we can see significantly reduces over that period, which results, under the *pro rata* system,

with a Northern Region receiving less by way of BPL factor concentrates; is that right?

A. Yes. Yes, I mean, you're talking about a close to 50 per cent reduction in products sent back to the Northern Region from whatever BPL was producing at the time. And the Northern Region hadn't done anything other than stood still. The rest of the world had moved on.

Q. And then, if we turn to WITN6935003, we have, I think, now, information about the same thing, in the sense it's plasma dispatched to BPL. This is purely relating to the Northern Region. And it's now for the period from the '85/'86 to '93/'94, and we can see a very significant increase in the amount of plasma being dispatched to BPL over that period.

A. Yes.

Q. We'll look at a handful of further documents, Dr Lloyd, but essentially, how was that achieved, that increase?

A. Okay. My -- if I may start with what I was thinking at the beginning of that period, perhaps just before I became director, which was that probably the only way to get a major change in plasma production was to go full force into plasmapheresis, as the way some other centres had done -- Leeds has been mentioned

before. But once I got into the job, you know, I realised that we had a terrific opportunity to separate a lot more blood, and instead of sending out whole blood, we would produce products where we were able to salvage the -- remove the plasma for this purpose and send the hospitals either concentrated red cells or we'd reduce that, or we sent them something in an optimal additive. So we did change our view.

We ran a small plasmapheresis operation within the Centre. We were able to do that with very little extra cost because we had the facility. We still had -- we had the machines there, and ... you know, it needed a bit of staffing and organisation. And that produced about 4 tonnes of plasma per year throughout this period.

So the bulk of this change is just by changing the amount of blood that is processed and how we processed it. So one of the things we did was we organised meetings with the haematologists and their senior blood bank staff from across the region, and they all came to the Centre for a day, and we were able to present information showing them how much whole blood they were using and how that compared to the rest of the country, how much whole blood was being returned unused, and we initiated a discussion

with them. And I have to say they were extremely cooperative. I mean, you know, the haematologists across the region understood that whole blood is not a good product to use, you know, generally. A few specific cases, maybe ...[frozen screen]... concentrated red cell products, and using plasma products and so on as needed was something they recognised. And they were able to change and deal with their staff and surgeons, anaesthetists and so on at the hospitals, and allow this change to happen. And I think we did it in two stages. We sort of set a target and then we went to a second stage after a further meeting and said, "Well, can we reduce this further?" And they said yes, of course. And by the end of that period, whole blood was a rare beast. I mean, less -- well under 1 per cent of our output was whole blood.

So most of this was done by working with the hospitals, with people who understood, you know, transfusion and blood banking.

And we also changed our manufacturing techniques to allow us to produce more plasma per pack. We became probably the biggest user of an automated or semi-automated system for separating blood, the Optipress system from Baxter Corporation, which

allowed us to eke out, you know, that extra 10, 20ml of plasma from a lot of the products we produced, at the same time as improving the quality of the product. So it was a multifaceted change, but it was done with very little in the way of capital investment.

Q. If we look at one further graph on this topic, WITN6935002.

This is, I think, a visual depiction of what you've just told us. So percentage of red cells issued as whole blood --

A. Correct.

Q. -- for the period '85/'86 to '93/'94, and we can see its decline too, as you just indicated, and there being a tiny proportion, if any, being issued by the time we get to '93/'94.

A. Mm.

Q. Is there any reason why this could not have been done significantly earlier than it was?

A. Oh, it could certainly have been done earlier. I mean as I said, when I -- just before I started as director, my views were different. I didn't really appreciate the extent of what we could do. It did take a year before I -- well, before I really got into it. So yes, it could have been done. Of course it could have been done. Newcastle was -- even before we

moved to the new centre, we were at the top of the league table of producing whole blood. So other centres were able to reduce it, reduce the use of whole blood, so there's no reason why we shouldn't.

I would say that I think, and I don't have terrific information, the Northern Region probably had fewer haematologists in post, particularly outside the -- you know, a couple of the bigger centres, which would have made it more difficult to do. You know, you need a good haematologist, with good transfusion knowledge, who can talk as an equal to the surgeons and the anaesthetists about this. So yes, we could have started -- it could have been started earlier. It would not have been as easy for me to do at this time with so many haematologists in post.

Q. You told us a few moments ago that when you started out as director, at the forefront of your thinking had been using plasmapheresis more. I'm not going to go to the document because you've explained what happened in relation to that, but for the transcript there was a report which you produced in around I think 1988, which is at NHBT0001580, which had a proposal at that time for increasing plasmapheresis.

If we just go, however, to the graph --

A. Correct, yes.

Q. -- which you produced relating to plasmapheresis donations, which is WITN6935012.

We can see from this an increase in plasmapheresis donations again over the period 85/86 to 93/94. So would it be right to understand although this wasn't the central plank of your strategy for increasing the supply of plasma, nonetheless you were able to achieve a significant increase in plasmapheresis collection?

A. Yes, yes. We got us a small plasmapheresis unit, got some great staff together to run it, and got it up quite quickly to producing the 4 tonnes, and we sort of left it at that, because we seemed to be able to produce plasma from other sources. And plasmapheresis plasma is more expensive. The physical location within the Transfusion Centre had originally been designed as a location for blood donor sessions, so we -- with a very small pheresis section at the far end of it, with room for two machines, I think -- I think that was in the original plans drawn up by FaulknerBrowns. So we did a bit of a remake, turned it over to plasmapheresis, and then somewhere in the middle of that, with a lot of help from the staff running that unit, we remodelled it to increase its efficiency, using some ideas that they came up with.

Q. And I think we can get a snapshot of the plasmapheresis facilities at NHBT0003365. This is a short note from Dr Gunson, 14 August 1989, "Notes on Visit to Northern RTC".

He discusses issues relating to the plasma targets and the core records in the past of the first section.

And then section 2, "Plasmapheresis", we can see:

"2.1 Plasmapheresis centre in RTC.

"2.2 Eight machines in operation."

He gives then details of the staffing.

And then 2.4:

"Currently there are 1000 donors on the panel which have been recruited in the last six months."

Prior to the new centre being opened in 1985, would plasmapheresis have been possible in the old Regional Transfusion Centre?

A. I don't think so. I mean that facility was crammed, physically not set up for this. I'm trying to think -- I'm trying to reimagine the building. I really cannot think of anywhere in that building where you could have set up plasmapheresis. You know, you might have built another shed, another hut, in the grounds and used it as a plasmapheresis centre but not

in the existing structures. I don't think so.

Q. Then if we look at WITN6935024.

Now this is just on the topic of autologous transfusion. I don't think we need to look at anything other than the first paragraph, which explains that there's a:

"... pre-deposit Autologous Transfusion service for hospitals within the Northern Region. This service is provided on request and aims to ensure that any patient due for planned surgery and for whom there is a likelihood that blood will be required will be able to benefit from [it] ..."

Was there the potential for any wider use of this, as a method of collection?

A. Yeah, autologous is an interesting topic. I think -- and there is some documentation earlier than this date where I actually sort of say I don't think it's really a very good idea -- or not that it isn't a good idea, but it probably isn't necessary from a safety point of view. Perhaps by this time I was -- I'd got to a point where, "Mm, perhaps I shouldn't be quite so sure of myself."

And there were patients and their physicians -- sorry, their doctors, who really felt that they wanted their patients to have autologous transfusion for --

particularly for planned surgery. So we were fortunate in being able to offer it. It was a small operation. But I was very concerned that if autologous transfusion was carried out locally with poor control, you had the risk of blood going to the wrong person or not being stored properly, not being labelled properly, and that would negate the benefit that autologous transfusion was bringing to you.

So we did offer it. It didn't have a great uptake. I think it's -- at the end of the contract there's a list of hospitals who that used it in the previous year and I can't remember if it's six in this document or nine. But, you know, it's a small number and a small number of units. But it was an option for people, and, you know, once you've realised -- particularly once you start thinking beyond HIV, then autologous certainly makes more sense. If you only think of HIV, then, because of the very low incidence in the Northern Region, it was hard to make a case for it. But certainly with non-A, non-B, and then hep C, the balance does, I think, change.

Q. We can take that down, thank you, Sully.

A. We should have done more earlier.

Q. That leads neatly to my next question for you, which was about your understanding of hepatitis. Before we

look specifically at non-A, non-B hepatitis, if you can go back to your training years in the 1970s, Dr Lloyd, what can you recall being taught about the risks associated with blood and blood transfusion, in particular the risks of viral transmission?

A. I trained at the Royal Free Hospital which was the centre of liver disease treatment and investigation. So we knew a little bit about it. I was, I think, aware that there was a problem with patients undergoing cardiac surgery. There was a big cardiac surgery unit in the south of England, in Hertfordshire perhaps? I can't remember now.

So we were aware of a problem but at what point between -- you know, during my training I became aware of that, I'm not sure. It sort of sits somewhere back -- at the back of my mind that there was this issue. So yes, there was -- I had some understanding and then, obviously, as I went through my -- particularly my senior registrar training, where I had to read extensively on transfusion issues, it became much more apparent.

Q. We heard evidence a few weeks ago from Professor Marcela Contreras and she told us of writing on chalkboards in the classrooms of medical students the words to the effect "Blood can kill", and

obviously there may be a range of reasons why that might be the case not limited to, but including, viral transmission.

A. Mm-hm. Okay.

Q. Was that sense of needing to be aware of the dangers of the use of blood and blood products very much part of the thinking at the Northern Regional Transfusion Centre in the '80s or was it not?

A. Ooh, I'm trying to think what it was like before I was director, when I was just around as registrar. I don't think -- it wasn't a terrific sort of -- I don't sort of see that message up on the chalkboard: it's dangerous. Certainly, it was being used relatively freely, and we were still seeing units being given -- you know, single unit transfusions, and the like. So I don't think there was quite as strong an emphasis as Dr Contreras showed where she was teaching students. So perhaps not as significant, no.

Q. Then non-A, non-B hepatitis, can you recall, as it were, the evolution of your understanding of non-A, non-B hepatitis, both in terms of its incidence as a risk of transfusion, and as to its seriousness?

A. Taking the risk of non-A, non-B, a lot of what I knew in the earlier days was material that came from the States, and certainly was aware that there were a lot

of differences in the way that, you know, donations were collected in the States, the separation between the voluntary side, under the umbrella of the ABB, and the commercial side. So you got a sense that maybe we're not in as bad a position as they are. And of course, we probably weren't, but it wasn't -- it wasn't a panacea. We weren't wonderful, by a long way.

And so you saw that. It then gradually, you know -- there wasn't a -- one of the documents that has been presented to me was a journal article which studies non-A, non-B in the States, I think, in -- certainly in two areas: Texas and New York, I'm not sure.

Anyway, it's an article that you presented. And, you know, you read that article and you see people have taken care to develop a study over a long period of time, they've got good information, they've used an independent panel to assess the recipients of blood to see if they had hepatitis and whether it was significant, and they were able to test large numbers of donations that went to these patients, and they used some fairly sound statistical analyses which showed that there were, you know, the link between the blood and the hepatitis and the patients, you know,

there was a link. It was statistically significant.

I don't recall seeing that sort of information coming out in the UK. We had some studies but they were underpowered. They weren't powered to give us the real knowledge we needed. And they didn't make that firm link with patients who were getting hepatitis. So my knowledge of it, sort of, developed, I think, relatively slowly, and so I got to a point where I -- and I put it in my witness statement -- you know, should we have been doing ALT testing, for instance? Yes, I think we should have been. Was I standing up there shouting from the rooftops, saying should we do it? No, I wasn't, and probably should have done more. But, yes, it took the UK -- for some reason, the UK seemed to have this attitude that this was not a serious disease, and we didn't need to do much about it.

We've seen documents, articles, which seemed to imply that it's not a cost effective thing to do. There's a lot of information about, oh well, we're going to lose too many donors. Well, heck, that's the transfusion centre's job, is to replace the donors with safe donors. That was what we should do and, you know, if we lose 1,000 donors we can replace them. You take the Northern Region, we lost thousands and

thousands of wonderful donors because the factories, the shipyards, the steelworks, closed down. We lost those donors, but we made them up. We made up more numbers from those losses than we would have had to have made up from starting the ALT testing. You know, we should have been there.

As to its severity, I didn't do a lot of work clinically to actually see it, and obviously you'll read it, but I was very surprised by Dr Gunson's comment around the time of HCV introduction saying that non-A, non-B or hepatitis C, this hepatitis was not a significant disease. I mean that really surprised me, even then.

Q. I'll pick up on some of those issues again tomorrow, Dr Lloyd, when we look in more detail at the introduction of hepatitis C testing.

Hepatitis B. Now, obviously testing for hepatitis B had been in operation long before you joined the Centre. Can I just ask you couple of questions about --

A. No, sorry. Sorry, can I -- can you --

Q. Yes?

A. Sorry, can you clarify that? You said hepatitis C testing.

Q. B, hepatitis B.

A. Oh B, oh yes.
Q. I'm moving to hepatitis B, my apologies. So I just want to ask you a couple of questions in relation to hepatitis B testing. If we go to NHBT0072680. This is a letter you wrote in May 1992 to Dr Castervan at the Freeman Hospital, and it looks like you've been asked a question about --
A. Can I just point out, sorry. Please note that that is not his correct name, that is an error on that letter, it is Dr Kesteven with a K. But anyway, thank you Patrick Kesteven, yes, I do recall this.
Q. Thank you. Yes, so you'd obviously been asked a question about the position in 1974?
A. Mm-hm.
Q. You say:
"According to our records for the whole of 1974 we were still testing for Hepatitis B antigen using an electrophoretic method."
And then you explain it was definitely less sensitive than the assay brought in in 1975, probably missing as much as 20 per cent of the hepatitis B positivity in the donor population.
Can you recall what had prompted that enquiry? It looks as though it may have been a case of someone, a recipient, getting hepatitis B.

A. Yes, I -- no, I've read this letter. I can't remember what the -- you know, what letter was sent, you know, came through or question was sent to me about this. I mean, you look at that, and say maybe Patrick was being asked to, you know, make a witness statement for, you know, for litigation. But it goes back, you know, obviously a lot of years. But no, I don't recall. I'm sorry.
Q. When you first started work at the Centre in 1980, do you recall what form of hepatitis B testing was then in use?
A. No, I don't. I couldn't tell you what the technology was. I mean I did go into that lab and see it being done but I can't remember the exact test that was ...*[frozen screen]*...
Q. Then if we could look at TYWE0000067, please.
This is another letter to Crutes Solicitors, and it refers to you having returned a witness statement, which, if we go to page 3, we can see the statement.
For present purposes I just wanted to pick up on something you say on page 7, but if we start at the bottom of page 6, you -- and this was about Dr Jones again and his choice of commercial produced Factor VIII. So you've said:
"As I understand it, the reasons why Dr Jones

may have preferred commercially produced Factor VIII were ..."
Then we've seen two of the points already discussed, the reactions --
A. Yes.
Q. -- and solubility.
Then over the page, (c) is about the characteristics of the commercial product, (d) about purity. It was (e) I wanted to ask you about. You say:
"Dr Jones may have considered that the methods of testing for the presence of the Hepatitis B virus were better in the United States."
A. Yeah.
Q. Now do you know where that thought came from? Was that your own thought you were attributing to Dr Jones or was that your understanding of his actual thinking?
A. I mean, I say there "may have considered", so I can -- I don't recall Dr Jones ever saying that to me. But what was my reason for saying that? It was probably -- and I only say probably -- from discussion with Dr Collins about this. But I don't have any -- I don't think I had anything really firm that I could -- now that I could say that's why I said that. And I don't think I can really, you know, say much

more on that point.
Q. And do you recall whether -- at any point in the 1980s or first half of the 1990s when you were at the Centre, do you recall any cases of transfusion-transmitted hepatitis B being drawn to your attention?
A. I don't remember any. And I know we have two areas there. One is patients who received blood and regular blood products, and I don't recall having to do any hepatitis B, you know, look-backs. I might be wrong. And probably the cases of hepatitis B in the haemophiliac population, one suspects that, you know, that was more an issue with the fractionators rather than the Centre. And obviously the Centre produced the plasma but the fractionators converted it into the finished Factor VIII, Factor IX.
So I would imagine that the haemophilia population who developed hepatitis B, that information would have been sort of fed back to the -- to, say, BPL or, if they received commercial product, to the commercial people, manufacturers, and so you may have seen a difference in hepatitis B rates between the two groups. But I wasn't a -- certainly not party to that information.
Q. Then in terms of transfusion-associated hepatitis more

generally, so leaving aside whether it's hepatitis B or non-A, non-B hepatitis, was there a system for such infections being notified to the Centre or did it just very much depend upon whether a clinician who had a patient who might have a case of transfusion-associated hepatitis, whether they happened to tell you?

A. Yeah, I don't think there was any sort of proper set-up -- a sort of -- there wasn't like a sort of a document that said, you know, "You will inform us". So I suspect that it would have been very *ad hoc*.

And it's quite possible that, you know, they just -- if it was a non-A, non-B hepatitis, then, well, you know, there's was no point in telling the Centre because they're not testing for it. And, you know, it is something that could have been done but no, we didn't do it. But there was certainly non-A, non-B hepatitis around, and you saw that in one of the documents that was presented which references an article by another Dr Collins, at the Freeman Hospital, Dr Collins and James and a couple of others, who actually followed up a number of cardiac surgery patients who developed hepatitis.

So it was around, and I don't recall that information sort of flowing back into the Centre.

Q. And if cases of hepatitis or transfusion-associated hepatitis were reported to the Centre, was there anybody or organisation to whom the Centre then had a reporting obligation, as far as you can recall?

A. Not that I recall. No.

MS RICHARDS: Sir, I'm going to move now to a different topic of -- in relation to the donor selection, and donor arrangements. So I wonder whether if we take our second break now, and then I can pick that up after the break.

SIR BRIAN LANGSTAFF: Well, let's do that shall we and come back at 4.20. So 4.20, if you please.

(3.59 pm)

(A short break)

(4.19 pm)

MS RICHARDS: Dr Lloyd, I'm going to ask you a little bit now about the arrangements at donor sessions. You tell us in your statement that the donor sessions --

A. Sorry, I don't have sound at the moment. I don't have sound at the moment -- should be all right --

Q. -- can you hear me now?

A. -- but I can't hear anything.

MS RICHARDS: Hmm, sir, shall we break for a couple of minutes.

SIR BRIAN LANGSTAFF: Let's do that.

THE WITNESS: I don't know if the technical people can assist for a moment.

MS RICHARDS: We'll try and get that resolved if we break for five minutes.

SIR BRIAN LANGSTAFF: Okay, break.

(4.20 pm)

(A short break)

(4.28 pm)

MS RICHARDS: Dr Lloyd, can you hear me now?

A. I can hear you clearly, sorry for the interruptions.

Q. Thank you. I'm going to ask you next about the arrangements for donor sessions and then look at questions relating to donor selection.

You tell us in your statement that, in broad terms, the sessions historically could be divided into the general public sessions and industrial sessions; is that right?

A. Yes, correct.

Q. The general public sessions would take place in village halls and community centres and the like; is that correct?

A. That was the usual arrangement, yes.

Q. Prior to the new centre opening in 1985, were blood donor sessions ever held in the old centre?

A. I don't think so. I don't think there was a facility,

a room in the old Centre that would take it but, no, I don't recall it.

Q. Then once you had the new Centre, is it right that there were some blood donor sessions that together place in the new Centre but it wasn't a major part of the Centre's use?

A. No, it wasn't. The drawing has been shown as a donor facility, a donor room was given over to plasmapheresis, so we allowed -- I say allowed -- we accepted occasional walk-in donors who just thought: well, here's the Transfusion Centre, I'll donate blood. We would take their donations in the plasmapheresis unit.

But we did hold some, sort of, full-blown sessions by clearing out the dining room and using that as a site, and we'd bring up a set of beds that would normally be used on a mobile session and we'd set up almost as though it was a mobile facility that happens to be in our building.

Q. In terms of the geographical reach of the donor sessions, is it right that the sessions took place all over the area but there were fewer sessions in Cumbria because of, I think, transport and road links?

A. Yes, yes. The road link from Newcastle into the Cumbria area, even to Carlisle, remained sort of --

a city in that area -- was one road, the A69, and a big stretch of it was not even divided. It was just single track in each direction. And we ended up -- the arrangement was that the team would go out on one day and then they'd be put up in a hotel, and then they would run the session the next day and perhaps stay overnight another night, do another session, and then come back. So it was complicated. It was time consuming. It was expensive. So the Cumbria area was underserved.

Q. You told us in your addendum statement that there was a satellite office in Middlesbrough, known as the Teesside office. Did the donor sessions in that area take place at the Teesside office or was it a question of mobile questions going out from the Teesside office?

A. No, it was mobile sessions. The sessions essentially organised the same as the rest of the area, except that the Teesside office did two things: one, it looked after the donors in that area, parts of North Yorkshire, Durham and surrounding areas around Teesside, Stockton -- anyway; and they also managed, as I mentioned, the voluntary team of donor attendants from the British Red Cross and the St John Ambulance Brigade, somewhat unusual, but interesting.

Q. Then you told us in your main statement that you thought there was an area just north of the Scottish border which was supplied by the Regional Transfusion Centre and you didn't recall any blood donor sessions being held there but, in your addendum statement, I think your recollection now is that you didn't supply that hospital but you did hold donor sessions in that area; is that right?

A. Yeah, I mean that's -- boy, I'm sorry, that's really rusty. I think we did hold a session, perhaps in Gretna. I really can't remember. It's so minor, it's a very, very minor issue. You know, we also crossed into the Yorkshire Region's area and supplied a hospital. These are, in the big picture, very minor.

Q. Then, in terms of the general public sessions, were they based upon donors being called up from the panel or were they drop-in sessions or was it a mixture of both?

A. We called people to the general public sessions so they were invited by letter. And so, you know, we had statistics that showed, you know, how many people we invited, and how many turned up. We're very proud of our statistics until we introduced a new computer system and found out that, actually, there were quite

a lot of walk-in donors that we hadn't invited turning up. So it's interesting what you find out when you start getting the information. But, yes, public sessions were by invitation.

Industrial sessions were mainly the individual companies organised, you know, who would come at what time, and so we didn't actually send them out individual letters, and you'll see that factor comes into play when there was the -- when AIDS leaflets were to be sent and distributed.

Q. Then, if I can just ask you to look at one document from 1988, NHBT0059596_001. So this is a meeting, 12 January 1988 at which you were present and this is from the point in time at which you were a consultant haematologist at the centre but not the director.

If we just go to page 5 and pick it up under "Any Other Business", the second paragraph refers to you presenting the donor panel statistics for 1987. You note there'd been a continued fall in the intake of blood and the number of new donors attending had fallen still further. Relative decline in the value of the publicity budget was also noted. Then there's a further discussion about rejection of donors.

Then if we go to the next paragraph, it says:

"Dr Lloyd pointed out that for the recruitment

of new donors we needed additional funding and this had been requested in the short-term programme for 1988/89. He also felt that if any savings were to be obtained from reorganisation within BTS then a significant part of these resources should be applied to the donor sessions to make them more attractive. Some discussions followed on ways of improving the appearance of donor sessions. It was generally felt that the use of rather dingy church halls left us with an image that was very similar to that seen in the 1950s. It was clear however there was no easy answer to this problem as good quality accommodation was extremely limited."

Then there's a later document, I won't go to it, but there's an article from 1989 which quotes you talking about difficulties in attracting donors given the lack of standards.

Do you recall what was -- whether you were able to do anything about the issue here of not being attract donors because of -- well, described here as "rather dingy church halls" and not being attractive accommodation or "good quality accommodation" to hold the donor sessions in?

A. I mean, we did make some changes in our donor services department, and tried to focus, get some people in to

focus on different types of sessions, so that they had more chance of trying to get better accommodation. It was certainly difficult. You know, we were competing with other organisations. If you have an organisation that wishes to use a nice community centre and they're going to use it once a week, then we want to come in on one of their days but only twice a year or four times a year, it -- you know, it's a difficult issue.

So you can't -- it's hard to get better accommodation. It certainly was. Once you have the accommodation available to you, then you can perhaps start trying to make the session run more effectively. But that's obviously another issue.

Q. Do you know what consideration was given when the general public sessions were being held to creating opportunities for privacy, so that donors could speak in confidence perhaps to the medical officer, especially if they're being asked questions about high-risk activities?

A. No, it wasn't good. I think we used to use an area -- we had a screened area in our sessions, which wasn't sort of wonderful, but you could take the donor out of the main area and into this -- an area with screens around. I think it was sometimes used for someone who wasn't feeling very well, as a recovery. And there

was also a screened-off area where they did some work on the bags after collection. So donors could be taken out of the main area. Certainly not perfect but they weren't being -- when you got away from the initial questioning to go into something more detailed, there was an opportunity to go to a slightly more private area.

Q. In terms of the workplace or industrial sessions on which you've already told us the region was very heavily reliant, was any consideration given to concerns that a workplace donor might not be a truly voluntary donor because they may feel pressured to give blood if their employers had arranged a session?

A. Yes, I mean that's a valid concern. I don't recall that we did anything to try to alter that. The donors in workplace sessions, I don't know how much in the -- they were put under pressure. It's hard to tell. You know, perhaps some confidential surveys might have been a good idea. But, yeah, there's always a risk in any group, whether it's a family, you know, members of the family or extended family donating, pressures there. Pressures of work, certainly possible.

We never tried to pressure the workplace to, sort of, push people into donating. It was very much, you know, you'd bring as many people as you can, but

if the numbers dwindle we're not going to sort of say, "Hey, you must, must, must get more people!" But, yeah, it's a valid concern, I agree.

Q. Do you know whether, in the workplace sessions, again, whether there were opportunities for donors to be able to speak confidentially, again in the context of discussions about high-risk activities in particular, it may be particularly problematic for a donor if their colleagues are within earshot, to be candid in response to questions asked.

A. You had the same physical set-up with the screened area so that's sort of really as good as it got.

How close other donors would have been to that would perhaps vary from session to session. You know, in some of the shipyard sessions, you could have difficulty talking to people, they were so far away. You know, a great big hall ...[frozen screen]... where the accommodation is certainly tighter. So -- but the screened area, you know, was available. Not perfect, certainly.

Q. Then I'm just going to ask you to look at couple of the graphs you've exhibited to your statement on the donor numbers. If we start with WITN6935008, please.

Oh no, sorry, my fault, Sully. I've given you the wrong reference. WITN6935006, I meant to start

with, sorry.

So this gives an overall picture of donor numbers from 1947 to 1994 in the region and we can see, obviously, a significant increase overall, but it looks like it remained relatively stable from really the 1970s onwards, some increase when we get on to 1993, with a drop in '87 and, I think, '88 in particular.

A. Yeah.

Q. Do you have any recollection as to what caused that particular drop?

A. Yes, I think there's another chart I've produced which shows employment rates. If you knew the north east at that time, the number of shipyards closing down, you know, steelworks closing down, steel fabricators, it was a very difficult time. We lost -- yeah, we lost a lot of people. And it's very hard, if you lose your job, to bring yourself to come back and donate and do something voluntary would be hard.

Q. Then I won't go to the charts but there are two charts which look at registered donors and industrial donors and then the employment rates, and for the transcript they're WITN6935008 and WITN6935009.

Can I then ask you little about the process for donor screening. I'm going to start by asking you to

look at a national document, CBLA0002307, please.

Oh, no, that's not the document I had in mind at all.

A. Probably not.

Q. Okay, let's try a different version. DHSC0046337.

Okay, so this is the 1985 version of the "National Blood Transfusion Service Guidance for the Selection, Medical Examination and Care of Blood Donors", and if we go over the page, we can see there it starts with a section on the "Selection of Donors".

Now, Dr Lloyd, we've got a version from 1977, a version from 1984. This one is 1985.

A. Yes.

Q. We've got later versions from '87 and 1990. Until you introduced your own selection booklet, was this the guidance that was used, do you think, some form of -- one of the --

A. Oh yes, yeah.

Q. -- versions of this?

A. I mean, this document is very familiar to me. I mean, you could pull up several from different years and they don't change a lot, but this was the base for the selection of donors that we used. I mean, we didn't deviate particularly from this, it's just that we tried to make something that was easier for our staff

to use so that they could be more effective in selecting donors.

Q. And if we go to the next page, please, this sets out the questions that the donor session clerk should ask about medical history. And then we've got a number of conditions listed. We can see AIDS would lead to disqualification.

Blood transfusion in last six months is referred to the medical officer. Can you recall what the practice was in the Northern Region if there was someone with a blood transfusion in the last six months?

A. Well, they would be deferred, as far as I can recall. For some reason I thought it was longer than six months, but yes, we deferred blood donation within the last six months. I see there in that document it says, "Blood donation within 4 months", "Action: Wait", which is don't take. In six months, presumably meaning between four and six months, "Refer to MO".

I'm not sure why there was that distinction between four and six months. I'm not sure what the logic behind that was. But this is the sort of document we would have used, and so we would have followed, you know, that instruction, "Refer to MO".

Q. Yes, if we go then to the bottom of page 6 because you'll see it says, "See note ix", and then --

A. Okay.

Q. -- note ix is at the bottom of page 6:

"Transfusion of blood or blood products received in the last six months."

Then it says:

"6 months minimum depending on nature of disease or injury."

A. Yeah.

Q. In any event, if we then go back to page 4, please, I just want to pick up a couple of other conditions or situations.

So the third item down here is "Drug abuse ... Disqualify." Can you recall what procedures were to try to assess whether somebody fell into that category? Were there specific questions that were asked or was it very much dependent upon that information being volunteered?

A. I don't think people are going to volunteer to answer and say, "Do you abuse drugs?" Looking back on this, you think that perhaps the wording being used was not really appropriate.

"Am I drug abuser? Oh no, but I did use drugs once. You know, I did inject myself at that party."

Is that person a drug abuser? Do they consider themselves to be a drug abuser? So I think, you know, our wording is not that -- was not very good. I think it changed later. But as to weeding out who might be at risk, I don't think we -- we probably didn't do a great job at it.

Q. Then if we look further down the page, we've got:

"Hepatitis ... Refer to MO ... See appendix 1"

And we see the same at the top of the next page, it says, "Jaundice ... Refer to MO ... See appendix 1".

If we just go to appendix 1, page 12, please. So we can see it's the fifth paragraph down, headed "Hepatitis".

A. Yes.

Q. "Individuals who give a history of jaundice or hepatitis or in whose blood anti-HBs is present may be accepted as donors providing they have not suffered from jaundice or hepatitis in the previous twelve months, have not been in close contact with hepatitis or received a blood transfusion of blood or blood products in the previous six months ..."

As far as you can recall was that the practice at the Northern Region, that someone with a history of jaundice or hepatitis could donate if it was more than

12 months ago? And subject obviously to the HBsAG --
A. I mean, at that time, you know -- at that time I don't recall that we would have done anything other than follow this. I certainly don't recall anyone saying we should have a different arrangement. We followed -- you know, in this case we followed these guidelines as they came out every few years. Yeah. I think that's -- I mean, I don't have documentary evidence to say that we did anything different. So yes, we would have followed this.
Q. Then if we come to guidance produced by the Northern Region itself, if we start with NHBT0007497, we can see a letter from you to Dr Gunson, January 1994 saying:

"I know you are now getting reasonably close to producing the Selection of Donors booklet. I thought you might like to see the version we have introduced. The main aim in producing this booklet was to put all the possible information together into one alphabetic section. This means staff are less likely to have to jump from one section of the book to another", and so on.

Then if we go on to NHBT0007498, we've got the booklet or a version of it dated December 1993 --
A. Yes.

Q. -- so probably what you were referring to in your letter to Dr Gunson?
A. Yes.
Q. If we go to page 5, we can see, under the heading "Introduction", it provides:

"... the information required to assist staff of the Northern Region Blood Transfusion Service in the process of selecting Blood Donors and Donations with regard to both the safety of the donor and the safety of the donations for transfusion and for further processing into plasma derived products."

Do you know whether there have been any -- or can you recall whether there was any earlier version of a locally produced booklet or was this the first time that one had been produced?
A. I think this was the first one. It is marked as Version 1. So I think don't think we produced an earlier one of this. It took some time to produce this and, as I say, it was part of our -- what we were trying to do was make it easier for the staff to get the information and use it. This was probably introduced at about the same -- I think we introduced the information on medication, might have been a bit earlier but, yeah, I don't think we did anything separate prior to this.

Q. Then if we look towards the bottom half of this page, "Rationale":

"There are two major considerations with regard to donating blood. These are:

"(i) That all care should be taken to protect the voluntary donor from harm, and.

"(ii) That the blood or plasma collected should be safe for its intended use.

"In addition to this it is the policy of the NRBTS not to take donations of blood or plasma from donors unless at the time of collection, it is believed that the donation is suitable for use. It is unethical to accept donations from donors in the knowledge that the donation is unlikely to be used because it does not meet specifications. Unusable donations also represent waste of materials, money and the time and effort of members of staff."

Had that always been the policy of the Northern Region or was that a shift which you introduced?
A. That was a shift. Perhaps not as massive as it looks there. But we did collect ...[frozen screen]... it was --
Q. I'm sorry, Dr Lloyd --
A. -- remember we had -- sorry?
Q. You froze there for a moment. Sometimes when you

freeze I don't think we're losing what you're saying but I think we might have done there.
A. Okay.
Q. So the last we heard was you said, "But we did collect", and then we lost you.
A. Okay, yes. We did collect donations that we couldn't use. Our statistics, as we gradually built up our information systems in the centre, we realised that we were taking a lot of donations that weren't either being used at all, or were only being partially used. And we felt that was not good for the Centre and it wasn't good for the ...[frozen screen]... medical staff meeting, there was a question about someone who was homosexual and, you know, should we take a donation from them just, you know, so it looks nice and then throw it away? Well, no, we shouldn't.

So it was a change. We were trying to do what we said in this document and, obviously, we hadn't done it before this time.
Q. Then if we go to page 7, we've got the heading "Medical Assessment":

"In practice it is impossible to perform a complete medical and physical examination of every prospective donor. A significant part of the assessment procedure will usually rely on answers to

simple standard questions relating to general health, past medical history and medication. This is combined with simple visual assessment of the donor and selected testing of samples collected at the time of donation."

Then the next paragraph refers to donors undergoing medical investigations. Then this:

"Where doubt exists, the donor should be deferred and permission obtained to contact the Donor's [GP] or other appropriate Medical attendant."

Then:

"Any active and/or chronic disease which may be transmissible, should be a reason for permanent exclusion."

In terms of the "Where doubt exists, defer and seek permission to contact the GP or other" --

A. Lost you. In terms of these?

Q. The paragraph which begins "Where doubt exists, the donor should be deferred" --

A. Yes.

Q. -- was that a shift in policy at this time?

A. I think we were moving more to excluding, if we were in doubt, rather than collecting the donation and perhaps following up afterwards. Now, in terms of the safety of the blood we collect, you might argue that

that doesn't make a big difference, as long as you have a doubt, and that is acted upon, donation is put on hold, and then we follow it up. That's probably not a dramatic change because we were all -- you know, we'd always done that. But what we're trying to do is actually not take the donation in the first place.

Q. We can take that down. Thank you.

What systems or processes did you put in place to try and avoid donors whose donation might well end up getting rejected from attending in the first place? How did you tackle that issue?

A. I mean, two things. One is with a document like the selection document you've just seen, and working with the staff to -- who went out and did this work, to try to, you know -- when I started, there were very few training sessions for anybody. So, you know, we gradually introduced more training, gradually introduced standard operating procedures, which staff were required to read and understand and be shown to understand. So that we were trying to get the session staff to understand what we were trying to do as an organisation.

So we did a lot more training and I think for the first time we started having training sessions back in the Centre for the medical officers. I don't

recall that ever having happened in the past and so now we were bringing medical officers in for -- whether it was a day or an afternoon, I can't remember -- but we had training sessions. So we -- you know, trying to change the, sort of, attitude and our approach, and it's very hard to know if we were successful.

Q. You talk in your statement about trying to ensure that donors were informed about donation criteria before attending, to avoid them wasting their time if they turned out to be ineligible.

A. Mm.

Q. Was that done by sending out standard literature with the call-up cards, then?

A. Well, in one of my documents that I attached to my witness statement, you'll see a leaflet that we produced. You'll see it stands out. It's white with a lot of red lettering on it and most of the text is blue with headings in red. I can't remember what number it was but we produced -- that was one of the things we produced and sent out with all the call-up. And that --

You know, the thought process, if you've come to a session it's taken you a long time, perhaps, to get there. You may be with a family member or a friend,

and then we go into the peer pressure thing, and you're presented with an AIDS leaflet at the session, that's a little bit late, a little bit harder to get out. If you've had that in the privacy -- you know, a letter sent to you personally, you might be able to make an informed decision prior to making -- going out to a session. So try and give them more information.

And it wasn't just about, sort of, the safety issue it was also about looking after the donors and making things easier. There were a lot of simple things where donors are not able to donate, so -- and they only found that out after they'd come to the session. So give them that information before the session, it may save them the journey to a church hall, which might be, you know, a few miles away. And so it will save them time and effort and hopefully mean that if circumstances change they'll be more prepared to come back again.

Q. The letter that you referred to that you exhibited to your statement is WITN6935020.

A. Yes.

Q. It's not, I think, dated but I think it must be after 1989 because, if we just look at the letter on the right-hand side:

"Dear Donor,

"On behalf of the Blood Transfusion Service in the North East and Cumbria, I would like to take this opportunity to thank you for your willingness" --

A. Yes, we put a date.

Q. -- "to help us by donating blood.

"During 1989 there was an increased demand for blood and blood components and I am very pleased to say that many more donations of blood were given, helping us to meet that need. This year it is clear that even more blood is being used and still more donors will be needed."

Then the next paragraph talks about the value placed upon the voluntary nature of the donation. Then if we just go, next paragraph down:

"In this leaflet there is information about donating blood which I hope you will find useful. In particular it is designed to help avoid the annoying situation where after going to a blood donor session you find that your donation cannot be accepted because you may have taken some tablets recently, or perhaps you have travelled to certain foreign countries recently."

Then there's an opportunity to telephone a number for further information, and then the next paragraph says:

"... I hope that this leaflet will help you avoid a wasted journey or a long wait at the session."

I'm going to ask you separately about some specific issues relating to the AIDS leaflets but, in terms of this kind of letter, this personal letter being sent out to donors, was this the first time that this was done in 1990, probably, I think, or was this something that had been done earlier, do you know?

A. Oh dear, I can't remember. I happen to have a copy of this leaflet in one of my old files here. So, you know, it sort of brought it back. But I can't remember -- it's the sort of thing that we would have -- we were trying to do. So I wouldn't be surprised if we hadn't done it a little bit earlier but, you know, 1990, did we do it before 1990 ...[frozen screen]... first.

Q. I'm sorry --

A. -- given the timing -- and, oh --

Q. We missed a bit there. So you said --

A. Okay.

Q. -- you asked the rhetorical question: did we do it before 1990? Then we lost it for a few seconds.

A. Okay. Looking at the timing and thinking back about our thought processes of changing how we, you know, dealt with donors, this is probably the first one we

put out.

Q. Then, if I can ask you to look at your statement, WITN6935001, page 10. It'll be the bottom half of the page, please, Sully, when we get to it.

So, in that long paragraph at the end, just over halfway down, you say:

"In the past many donations were labelled for 'laboratory use' because of limitations in the donation process."

What kind of limitations were you referring to there?

A. The donation process doesn't mean, in that context, just putting the needle in the arm. It's the whole process of the session, and selecting the donor and -- so it is the whole process. So -- and then it refers to the fact that new documentation was produced to support the clerical staff, providing clear information.

So we -- this is part of this process: let's not do what we did in the past and collect blood for which we really had no use.

Q. We can take that down --

A. It's not fair to the donors.

Q. And then what, if any, systems were in place at the Northern Regional service to ensure that a donor who

had been excluded from giving blood in your region would not give blood in another region? Was there any way of ensuring that?

A. Oh no, no, I don't think so. If we excluded someone, I don't think there was any -- I don't recall sort of a system of broadcasting that information to other transfusion centres.

Q. And do you recall any occasions in which your service was notified by another regional service of a donor who'd been excluded? Or deferred?

A. I do not recall that happening. It's a lot of years ago, but I don't recall it, no.

Q. I just then want to pick up on a couple of what might be regarded as high-risk groups. So prison donations, first of all. If we look at NHBT0008628_001. This is a document that was put up together for a Scottish Transfusion Directors' meeting in September 1983. It says:

"Telephoned survey ..."

A. Yes.

Q. "... of England and Wales Transfusion Centres regarding use of prisons as a source of donor blood."

A. Yes.

Q. I think this may have been an exercise undertaken by Dr Brookes, but I --

A. I think it probably was.
Q. And obviously it sets out the position in relation to a number of regions. But if we go over the page, the second region is yours, Newcastle.
"Long ago stopped holding session is Durham and Northallerton but continued to use an 'Open' prison in West Cumberland which housed 'civil crime' prisoners (bigamy, fraud, etc).
"Latterly they had noticed an increase in incidence of hepatitis B markers and discovered that prisoners from Walton Jail (Liverpool) were being sent there for their pre-release 6 months.
"This session has now been dropped, so that Newcastle now holds no prison sessions."
Now that's as at autumn 1983. Do you know yourself how long before that this practice had been dropped?
A. No, I don't. I mean, I do -- you know, I recall, and I think I said it in my initial witness statement, that I thought we didn't hold sessions at prisons, in my time, and I mean by that going back to 1981, 1980/81, when I first worked in the transfusion centre. But then I saw this, and obviously it makes it possible that we held sessions at that facility in Cumberland after 1981, but prior to ...[frozen

screen]... Dr Anne Collins telling me that they had stopped -- actually telling me this information: that they had stopped taking blood from prisons because of the higher rate of hepatitis B markers. So she did tell me that. And she would have ...[frozen screen]... one maybe, you know, I can't be absolutely sure but it was in that early phase when I was first starting working there, and I recall her telling me about this.
Q. We lost you for a couple of seconds, a couple of occasions, Dr Lloyd. I'm just going to read back broadly what you said and see whether we caught all of it.
So you said it may be "possible that we held sessions at that facility in Cumberland after 1981". Then you referred to Dr Collins telling you that they'd stopped because of the higher rate of hepatitis B markers.
A. Mm-hm.
Q. Then you say you can't be sure but it was in that early phase when you first started working there and you recall her telling you about this.
So is it right to understand it's in the 1980/81 period that is your best recollection of when she told you this?

A. That's my best recollection. I sort of feel that it was something that she told me early on, certainly when I was still a registrar, or locum registrar. So it's the '80/81, possibly '82, but I sort of feel that it was probably in the earlier part because I do recall, you know, this thing: we don't do sessions in prisons anymore. And that came from other people as well.
Q. You tell us in your statement this, you say:
"I recall from informal discussion with staff in the Centre that it was known that prisoners were given privileges for donations such as cigarettes. This went against our policy --
A. Yes.
Q. -- of not offering inducements to donate."
A. Mm-hm.
Q. Were you being told or led to understand that that was something that was being given out by the Transfusion Service or by the prison?
A. I mean, first of all, that was not -- those sessions weren't occurring at the time. This was a historical information. But those -- the cigarettes were given out, as far as I -- you know, they were given out by the prison staff. We didn't -- unless I'm extremely mistaken, we didn't supply cigarettes. But I think

the prisoners would get a benefit of some cigarettes for donating. And that came from the prison.
Q. And then do you recall whether the Northern Region collected blood from military institutions, barracks or Air Force bases or the like?
A. Yes, we did. I'm pretty sure that we went to Catterick barracks, near Northallerton, actually in north Yorkshire. And we also went to a small -- I think it was -- I can't remember if was run by the Royal Navy or the Royal Air Force, a munitions depot in the Carlisle area. So we certainly did those two. The munitions depot would have been a slightly different beast to the Catterick garrison, but yes, I believe we did.
Q. And were there any US bases where donation sessions were held?
A. No, as far as I -- well, I know we didn't do any sessions at US bases, and I don't know that there were any US bases in our region. There might have been an Air Force base and some facilities around the North York Moors, but no, we didn't do any sessions at US bases.
Q. Can you recall whether any active consideration was given to the position of those donating at military sessions, that, again, they may not be truly voluntary

or it may be even more difficult for them to admit to high-risk activities than it might be in other settings?

A. Yeah, yeah. Yes. No, I don't think we did give consideration to it. I don't recall us discussing that. So yes, they -- you know, "You, you and you will donate today". It's certainly possible.

Q. And then you referred earlier to the position of people coming along with family members to donate and the difficulties that might arise there.

A. Mm-hm.

Q. I just want to pick that up by reference to a document you exhibited to your statement, WITN6935018.

Some notes, I think authored by you, headed "Transfusion - Do We Have Any Choice?" I'm going to come back to what you say elsewhere in this document tomorrow, but if we just turn to page 4, halfway down the page it says:

"This leaves two more areas:

"Predeposit and something that I have not mentioned before - Directed donations."

Then you say:

"Directed donations are those made by family or friends for a patient. This sounds like a good idea. My 'brother', 'sister', 'aunt', 'uncle', 'best

friend', 'neighbour' cannot possibly be at risk of HIV/Hepatitis/Venereal Disease etc, hence much safer than the blood donor."

Then if we look in the next -- sorry, at the bottom of the page. You say:

"... Voluntary donors are safer."

This is the last three lines:

"Family members who are not volunteer donors are therefore ordinary members of the population with a higher risk of HIV infection and other infections."

We haven't, I think, with other witnesses, discussed this particular category of potential donors, the directed donation. What was your thinking here?

A. I mean, these were just notes I made for myself ready to give a talk at a hospital -- at a hospital I-- anyway. Um, my thought process, as you see there, it can't -- you know, "Someone in my family can't possibly be at risk". You sort of have this innate feeling that your family and friends must be, you know, very good, very clean living or whatever. And so if you -- and this was very much about directed donations not going to an ordinary voluntary session.

Q. Yes.

A. So it would be nice to -- you know: let's get our

family to donate for another family member or for a friend in hospital, so we direct the donations because they must be safer. And I was saying: well, no, there's not really any evidence that they're safer. And in fact they may be less safe because they are under social pressure, as you've alluded to in other cases, they're under social pressure to donate. So I -- perhaps around that time directed donations was something being talked about, so I thought it would be a good thing to bring up in a talk.

Q. I want to then pick up the issue of AIDS. How and when, as far as you can recall, did you first become aware of AIDS and it's potential transformation through blood or blood products?

A. It's hard to remember when. I mean, you know, during training, you know, you read a lot so you know that there's a problem. And, you know, I recall reading the -- the earliest journal articles talking about this new disease, that something was happening. So, you know, we're going back to the very early days of this, because I recall these articles and they're saying, "Well, we don't know what's causing it". There were even people saying with haemophiliacs it might be due to some odd change in the constitution of Factor VIII by fractionation which is impairing their

immune system.

So I've been aware of transmission certainly since, you know, some of those early articles started to confirm out in the States.

Q. Again, putting it back in the context of your own career, you were in that period, 1982 through to say 1984, that was your I think senior registrar training when you were doing the rotation between the different hospitals?

A. Mm-hm.

Q. So do you recall any sense in the haematology community at that time any particular sense of urgency or concern about the potential threat that AIDS posed?

A. Goodness. Um ... I don't recall that terrific sense of urgency. I mean, I recall seeing some of the first haemophiliacs who were exhibiting signs and symptoms associated with AIDS when I was at the RVI. So, you know, people -- we knew there was -- this was going on, this was happening, but did we know it was happening amongst non-haemophiliacs? People receiving regular transfusions? No, I don't think we did.

It would have been unusual, because the number of people we -- donors we picked up once we started testing for HIV, the numbers were very, very small. So the likelihood of this being an issue that was

being brought to people's attention on a regular basis, with people getting it from transfusion in the Northern Region was low. We knew about it from other regions, and certainly I don't think there was a terrific -- I don't feel a terrific sense of urgency amongst the general transfusion population -- you know, haematologists. But you should ask them.

Q. And just in terms of seeing haemophiliac patients with early signs at the Royal Victoria Infirmary, again, just trying to put that in a chronological context, you told us earlier that you thought your RVI placement was the third of the three.

A. Mm-hm.

Q. So would that have been around 1986, then, that you were there?

A. Um ...[frozen screen]... '86, I'm trying to -- I honestly, you know, my -- one of the things I found about this whole business is that I have difficulty putting things into sort of chronological order, and I do find at times that I am not quite sure. So I wouldn't like to be sure but I, you know, as you said, I believe my RVI placement was the third of four in that block so it would have been in the latter part. So you're probably about right.

Q. Then perhaps just one more document before we finish

for today, WITN6935027. These are handwritten notes. Are they your handwritten notes?

A. They are indeed.

Q. They're remarkably legible, in that case:

"The Acquired Immunodeficiency Syndrome and the Human T-Lymphotrophic Leukaemia Viruses.

"Notes made at a symposium held at the London School of Hygiene and Tropical Medicine on 3rd April 1985. With some additional material from a Brief review published in Blood, February 1985, and the Interim guidelines from the Advisory Committee on Dangerous Pathogens."

So it looks, Dr Lloyd, as though you attended this symposium in April 1985. Can you recall what prompted you to attend?

A. This was a major issue -- I mean, AIDS -- and so, yes, I wanted to go to this. It wasn't just a, sort of, a routine one of the conferences coming up. I certainly wanted to go to this. It was -- and as you can see -- I mean, what you see here, I only reproduced a couple of pages, the first and last, and perhaps the one in the middle. It was a longer document and I took a lot of notes.

Q. If we go to the second page, there's a heading, nearly halfway down, "Mode of Transmission", and then the

second paragraph under that records:

"The transmission by blood or blood products is now well documented, and this includes 'needle stick' injuries in staff handling infected materials, intravenous drug abusers sharing needles and patients receiving blood or certain blood products. It appears that Human Albumin Solutions (PPF) do not transmit the virus, nor do intramuscular preparations of immunoglobulin. Factor VIII concentrate is known to transmit HTLVIII, and one case is documented of a patient who had received only UK produced [Factor VIII] concentrate developing AIDS."

Then if we just go to the next page, it's the last long paragraph --

A. You can see there's a lot of pages -- a lot of pages missing. I think that has "Page 12" at the top.

Q. It does.

A. I didn't attempt to reproduce the whole thing.

Q. It says:

"Prospects for limiting the spread of the disease including encouraging homosexual men to limit the number of partners they have, to use condoms, and presumably once known to be HTLVIII antibody positive, to refrain from sexual contact."

Then you go on to talk about the implications

for transfusion:

"For blood transfusion, all donations should be screened for HTLVIII antibody -- as tests are now available, although not yet as commercial kits. Potential donors from risk groups must be excluded as far as possible. Effective literature and advertising campaigns should be used. All plasma for processing should be tested and treatment of finished products should be carried out to render the product non-infective. Heat treatment of [Factor VIII] concentrate may render the product non-infective, but at the cost of a 50% reduction in potency and a resultant increase in [cost]."

So do you recall anything more in relation to that symposium, any further discussions about the implications for blood transfusion and the measures that should be implemented in the Transfusion Service?

A. No, I don't. I mean, I have the document, and if you want to see my whole document, I'm quite happy to scan it and let you read it. But now, off the top of my head, I can't remember all the other things that were -- that I wrote. But, obviously, this sort of colours your -- informs your view of the issues, certainly. I mean, we can see that we've got a problem.

SIR BRIAN LANGSTAFF: Well, a slightly different tack, can we just go back to the page before?
MS RICHARDS: Yes, it's page 2. WITN6935027, page 2.
SIR BRIAN LANGSTAFF: It's not this page, maybe the next page, maybe the page before that.

Yes, I think this is it, thank you.

Just something that caught my eye as we flicked through this, it's the third sentence under "Introduction":

"The number of cases of AIDS reported to the Communicable Disease Surveillance Centre at Colindale was 140 as at March 1985."

So the context of this is, as you have set out from the seminar earlier, that 140 had been reported, it's a figure which doubles every six months or so. So that gives some idea of the background, against which you were considering screening and safety of donations.

A. Mm-hm. Oh yes.
SIR BRIAN LANGSTAFF: Those were the cases of AIDS, so that's the manifestation of an infection, which, if the cases of AIDS are doubling, the infection must have been doubling before that, so it all depends how long people have actually been infected, and --
A. Yes.

SIR BRIAN LANGSTAFF: -- been able to pass it on.
A. Yes.
SIR BRIAN LANGSTAFF: So if one traces it back, there could be actually quite a lot of people in society who might unwittingly wish to donate blood who would be coming forward.
A. Yes, the number -- you know, you go -- well, as I'm sure you know, I'm sorry, you start off by getting infected and you don't -- there's virtually no indication that you're infected. Then there's a period of -- whether it was, you know, depending on the person, one, two, three, four, five years while they're infectious but haven't got any overt symptoms. So that's significant, particularly in the period before HIV testing.

After HIV testing was introduced, the really significant period is that bit between being infected and becoming antibody positive and presumably a small number of people going on who were infectious but weren't seroconverting, weren't becoming HIV positive. But, you know, this meeting, you know, does -- it really opened your eyes.
SIR BRIAN LANGSTAFF: Yes.
A. This was a significant issue we're going to face.
SIR BRIAN LANGSTAFF: And it goes on to say that that's

the English experience in -- as at March '85 in the States, it's recording over a thousand cases by the end of '86, or suggesting. Yes, thank you very much.
MS RICHARDS: Sir, I'm going to pick up next with Dr Lloyd's -- some of the measures that he referred to on the page we looked at a few minutes ago, how they were implemented in Newcastle in terms of leaflets and so on, but given the time, perhaps we should pick that up tomorrow morning.
SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: Tomorrow afternoon, Dr Lloyd's tomorrow morning.
SIR BRIAN LANGSTAFF: Dr Lloyd, your 8 o'clock again, if you're kind enough to be with us in your early morning, we should be very grateful.

For us --

A. That's absolutely no problem.
SIR BRIAN LANGSTAFF: For us, it's 10.00 in the morning for our next presentation.
MS RICHARDS: Yes, and then we'll pick matters up with Dr Lloyd at 1.00 tomorrow, our time.
SIR BRIAN LANGSTAFF: So until 10.00. Thank you very much.
(5.32 pm)
(The hearing adjourned until 10.00 am the following day)

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