Monday, 6 December 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Good morning, Dr Entwistle, can you hear me?

THE WITNESS: Good morning, Sir Brian. Yes, I can.

SIR BRIAN LANGSTAFF: Good. Obviously you can see me?

THE WITNESS: Yes.

SIR BRIAN LANGSTAFF: Good. You are at home, are you?

THE WITNESS: I am indeed, yes.

SIR BRIAN LANGSTAFF: I think it is just your wife who is there in the house with you or ...

THE WITNESS: No. In the house, yes, but I have -- next to me I have my step-daughter, Dr Sara Kundu.

SIR BRIAN LANGSTAFF: Thank you. In a moment or two after you have been sworn you will be asked questions by Ms Scott. You are talking to an audience here, a select audience, which is quite small but there is a much larger audience, well over 100 probably, who will be listening to you online. So bear that in mind, that's who you are talking to, people who want to hear what you have to say.

But first I'm going to ask Oliver to ask you to take the oath. Oliver.

DR COLIN CARRUTHERS ENTWISTLE (sworn)

Questions from MS SCOTT

SIR BRIAN LANGSTAFF: Ms Scott.

MS SCOTT: Dr Entwistle, can you see and hear me?

A. Yes, I can indeed. Thank you.

Q. I'm going to start with a brief overview of your career. So, you qualified in 1958, is that right?

A. Yes, indeed.

Q. You then had various junior doctor roles in Bristol, moving into pathology in 1959?

A. Correct.

Q. By 1963, you had been appointed a lecturer in pathology at the Welsh National School of Medicine, which was a post you held until 1968.

A. Yes.

Q. That post was part time teaching, was it, and part time clinical work?

A. It was mostly laboratory and with some clinical involvement, yes.

Q. Your witness statement tells us that during that period you were -- you ran the routine 24-hour blood transfusion service for the Welsh National School of Medicine?

A. Yes, I did.

Q. Can you tell us what that entailed?

A. The School of Medicine was based at what was then the Cardiff Royal Infirmary. My role was, in fact,

looking after the blood bank of the Royal Infirmary, although I had a dual role, in that it was also part of the Welsh National School of Medicine.

Q. Then in 1968 you were appointed consultant haematologist and deputy director of the Cambridge Regional Transfusion Centre?

A. That is right, yes.

Q. I will come and ask you some more detailed questions about that in due course. Then between 1974 and 1980 you were the deputy director of the National Tissue Typing and Research Laboratory in Bristol?

A. Yes.

Q. Then in May 1980 until September 1995 when you retired, you were the director of the Oxford Blood Transfusion Centre?

A. Yes, indeed.

Q. I'm just going to run through with you some of the committees and working groups and some of the meetings, and so on, that you attended during your career. So from 1980, when you were appointed the director of Oxford, you were a regular attender of regional -- the Regional Transfusion Director meetings, is that right?

A. Yes.

Q. Again, as the director of the Oxford Regional

Transfusion Centre you also attended the regional meetings of the Western division?

A. Yes.

Q. In March 1981, you were elected to serve on the care and selection of donors working party by the Western division of the Regional Transfusion Centres, is that correct?

A. Yes.

Q. In March 1990 you were elected again by the Western division to be the representative on the -- to be their representative on the committee considering the retention of records?

A. Yes.

Q. Then you were elected the chair of the Western division of the regional meetings in July 1991?

A. Yes.

Q. You also sat on the National Blood Transfusion Service and the CBLA liaison committee from 1991 to 1994?

A. Yes, I did.

Q. You were also part of the National Directorate's National Management Committee between 1991 and 1992?

A. Yes.

Q. Then you became a member of the NBA, the National Blood Authority's, executive from its first meeting in October 1993 until around July 1994, is that correct?

A. Yes.
Q. We also have a record of you attending a handful of liaison committee meetings between the Regional Transfusion Centres and BPL in 1993, which was a committee which was badged as an NBA committee, is that right?
A. Yes.
Q. Your CV also tells us that you were a member of the British Society for Immunology, the British Society for Histocompatibility and Immunology *(sic)* and a founder member of the British Blood Transfusion Society?
A. That is correct.
Q. Turning then to your time in Cambridge as deputy director between 1968 and 1974, when you arrived there, was Dr Darnborough the director --
A. Yes.
Q. -- or did he arrive just after you arrived?
A. No, he had been made director of the Cambridge centre two years before I was appointed and in fact because of that he had not had a holiday and I was dropped in it, in my first week in Cambridge, because Dr Darnborough took a holiday and left me there to look after things.
Q. So do we understand from that that the Deputy Director

was a new post?
A. Yes, it was.
Q. Your witness statement tells us that you were primarily responsible for donors and running donor sessions. Is that right?
A. Yes.
Q. If we just look at your witness statement, Paul, please, it is WITN6917001.

If we go, please, to page 4, we can see what you say there in paragraph 8, about a third of the way down that paragraph:

"My main role concerned practical organisation of blood donor sessions, including the training of session directors (including conducting many donor sessions myself), helping the Head Nurse with recruiting and training of donor attendants, dealing with donors who had medical problems (mostly actual or suspected anaemia), and responding as well as possible to any complaints received."

Then you say:

"I also took part in on-call rotas dealing with management of out-of-hours provision of blood and blood products to hospitals in the East Anglian hospitals."

A. That is correct.

Q. In relation to your work on on-call rotas, can you tell us a little bit about what that involved?
A. At that stage, the arrangement was that there would be a night porter on duty for out-of-hours services and he would call whoever was the doctor on call for out of hours consultation and that meant most of the time I did not have to go into the centre but at least authorise the provision of what was needed or what had been requested, provided we had it, which we nearly always did, and authorise, if necessary, the emergency transmission using a blue light.
Q. So, this was requests from hospital blood banks for products or components that the transfusion centre held?
A. Yes.
Q. Is it -- at that stage, did the transfusion centre have regular deliveries to the hospitals that it served?
A. Oh yes, we did.
Q. So this was on top of, if they'd run out of something or they needed something special?
A. If they had run out of -- something special perhaps was required which was not held in stock in the hospital.
Q. If we then look at a document DHSC0101582.

This is a Department of Health document, and it is actually page 7 that is of interest. It is a chart -- table rather, entitled "Hospital blood bank serviced by Regional Blood Transfusion Centres in England and Wales". And if we go down the left-hand column to East Anglia, we can see there it says:

"No. of NHS blood banks serviced: 12

"No. of private hospitals serviced direct: 0"

Then it has a star next to that saying "plus 2 Armed services hospitals".

Now this document is dated May 1982 but does that accord with your recollection of the number of blood banks that the Cambridge RTC was servicing during your time?
A. Would you excuse me a moment, while I do some mental calculations.

(Pause)

Yes, that seems a fair approximation, I think.
Q. Can you describe for us what the facilities were like at the Cambridge Regional Transfusion Centre during the time that you were there, what the Centre itself was actually like and the laboratory services and so on.
A. The building itself was relatively new because the Addenbrooke's -- the new Addenbrooke's Hospital had

only been opened a couple of years beforehand, and the transfusion centre was within the grounds of the new Addenbrooke's.

It was a two-storey building with laboratories on the upstairs section and also the director's room and my own room and secretary's room, and there was also a small lecture theater.

Downstairs there were further laboratories concerned with the processing of blood components and also storage facilities for the mobile blood teams.

Q. What use was put to the lecture theater by the transfusion centre?

A. It was used, when needed, for training purposes mainly.

Q. And training of internal staff or was there training of --

A. Yes, training of internal staff. Yes.

Q. Was any training undertaken of haematologists or other clinicians in transfusion medicine at that stage? From -- by --

A. No, not that I can recall.

Q. Turning then to the donor sessions themselves. Again, probably best way to take this is to look back at your witness statement, WITN6917001.

And if we could turn, please, to page 6 at

paragraph 9. You say this:

"Blood collections by EARTC ..."

And EARTC is East Anglian Regional Transfusion Centre, is it? Was that the proper name for Cambridge Regional Transfusion Centre?

A. Well, originally it was the Blood Transfusion Immunohaematology Centre. That was the title it had been given.

Q. "Blood collection by EARTC were organised on the basis of collection teams. Each team comprised a Team Leader and up to eight Donor attendants, a clerk from the Donor Registry department and two drivers. A doctor attended [the] session independently."

Pausing there, you say in your witness statement that that doctor was sometimes you; is that correct?

A. Correct, yes.

Q. And:

"The teams went out from Mondays to Fridays. Teams would travel to prearranged venues throughout the region where the RTC Donor Organiser had recruited volunteer local donor organisers and had secured suitable premises and publicity. Teams under the control of a senior (more experienced) donor attendant set up usually eight beds for actual blood collection and a comparable number of couches for donors to rest

after donation. The clerk was responsible for implementing questioning of incoming donors and one of the drivers undertook the donors' simple copper sulphate-based finger-prick blood tests for possible anaemia. The doctor performed all venepunctures and managed any medical problems (such as donors fainting, etc). As part of this pattern, donor sessions were usually held in a Cambridge venue on Monday mornings to provide fresh blood to be sent to the Papworth hospital for heart operations."

Is it right to understand from that that there were no donor sessions in the transfusion centre itself? They were all out in the community?

A. As a routine, that is correct. Very occasionally, over long bank holidays, we did have the facilities with a few beds which could -- we could call donors in especially to come into the centre. But that was not a routine procedure.

Q. Was that usually as a response to low stock?

A. No. As I said, particularly for long bank holidays, where we anticipated there would be difficulties in having fresh products over several days without routine collections coming in.

Q. And is it also right to understand that during your time at the East Anglia or Cambridge Transfusion

Centre there was no plasmapheresis programme?

A. No, not at that stage, not as I recall.

Q. Do you recall whether or not there were any sessions in which military donors were bled? So we saw in that chart that there was -- you were providing components and blood to military hospitals. Were there any specific military donor sessions held?

A. There were, yes. We visited two military establishments. And in fact I personally attended one of those sessions, which proved incredibly beneficial to the Service.

Q. And were those sessions undertaken, do you recall, throughout your time at -- in Cambridge?

A. As far as I can recall, yes.

Q. And did you hold any sessions in prisons?

A. No, none at all.

Q. And did you or any of your colleagues at the blood transfusion centre give any consideration to whether or not the military donors may pose a higher risk of transfusion-transmitted infections than the general donor population? Was that part of the thinking at that stage?

A. At that particular time, as far as I can recall, they were not perceived to impose particular extra risks, whatever people might have thought subsequently.

Q. Just one last issue to ask you about in relation to your time in Cambridge, and that's in relation to hepatitis B. You tell us in your statement that while you were there you devised a detection method for hepatitis B antigen which you used personally on donations six months prior to it being adopted for all incoming donations at the Cambridge Centre.

I'm just going to ask you a handful of questions in relation to that. Can you recall whenabouts it was that you developed the detection method for hepatitis B antigen?

A. I can't remember the exact date but I was -- first of all, I was aware that there was a phenomenon which was described then as the Australian antigen, and that was what subsequently was known as the hepatitis B antigen.

And I got in touch with a Japanese gentleman who had made the possibility of providing me with some of this -- the antibody to that antigen.

Now, I won't go into the details how we got round to getting in touch with this Japanese gentleman, but he did actually let me have some serum, which I collected from him when he came into Heathrow Airport, and I used that to try to see whether I could identify any donors who may have

carried the actual virus antigen itself. And for quite a long time in my earlier struggles with this, no, there was nothing. And then, sure enough, inevitably, I did find a serum which did react with this Japanese antibody, and that was my first experience of finding the hepatitis B antigen in a donor.

Q. So is it right to understand from what you have just said that this was at a time before there was screening for hepatitis B within the centre?

A. Yes -- oh, yes, this was long before there was any screening anywhere in this country.

Q. And what kind of test was it that you were using?

A. I used to prepare petri dishes and there would be rows of holes made in agar sitting in the petri dish. In one row of holes would be the antibody from the Japanese gentleman, and in the centre hole of the three would be the donor plasma. There was also a third row which I won't go into. But if there was a positive reaction, there would be a little line developing between the donor plasma and the Japanese plasma when an electric current had been applied across the gel -- I hope this isn't too complicated -- but it would take about 20 to 30 minutes for the electric current to do what it required to do. And

because of the different electrical properties of the virus itself and of the antibody, the two would be encouraged to join and that would produce a line in the agar gel and that would indicate a positive reaction.

Q. And we have heard evidence about different kinds of tests over different periods of time, ELISA tests, RIA tests, PCR tests and so on. Would the test that you are describing be described as one of those kinds of tests or is it a different kind of test?

A. It was different to the others. It was electro -- I can't remember the title now.

SIR BRIAN LANGSTAFF: Electrophoresis --

A. Electrophoresis was the procedure used, as opposed to by radioimmunoassay or ELISA test.

SIR BRIAN LANGSTAFF: Just so that I understand, the acronym for that is IEOP? Am I right?

A. Yes, that is correct.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: And how did that test compare to the later tests that were rolled out throughout -- as we understand it -- the regional transfusion centres for hepatitis B in terms of specificity and sensitivity?

A. In terms of specificity it was totally accurate. In terms of sensitivity I cannot tell you because

I did not do a comparative study. All I do know is that I had developed a test which did indeed pick up some positives. Whether it would pick up all, I do not know. But at least it would pick up some.

Q. And did -- you say in your witness statement that you personally were using it for about six months before it was used on all donations within the centre. Why was that? Were you testing it for yourself during those six months -- that six-month period?

A. Yes, I was doing it out of -- purely as a personal research project.

Q. If you picked up a donation that was positive at that stage, what steps would you take?

A. The immediate thing would be to remove that donation from any possibility of it being issued. And obviously I could have considered sending it away for further tests if further tests were available but of course initially they were not. So all I could do, at that stage, was to remove it from circulation and make sure that nobody got it.

Q. And was anything said to the donor?

A. We had no choice but to say, "Yes, we have a problem here, it appears that you may have picked up an infection", and we had to undertake initial counselling at that stage and refer them on to,

firstly, their general practitioner, and he or she in turn would consider the necessity of referring further to a specialist.
Q. That was the case, was it, even though there were no confirmatory tests?
A. Correct.
Q. So, even in those early days, those were the steps that were taken?
A. All we could say was that this person appeared to have a problem which -- for which there was no treatment at that stage, anyway, and we had no way of doing anything further.
Q. Did you take any steps yourself to share the work that you had done, the research that you had done, and your findings and the test with other centres?
A. Not initially no, I didn't.
Q. You, of course, weren't a director at that stage, so you weren't attending the Regional Transfusion Director meetings but do you know whether Dr Darnborough informed his colleagues, and so on, that this work was being done in the Cambridge centre?
A. I don't think he would do it in the early months when I was doing this purely for myself. Whether he did afterwards, I think he probably must have done because after I had been doing this work for a few months, he

arranged for that same procedure to be extended to become a routine procedure, and it would have been more than sensible to alert his colleagues in other centres.
Q. So you say it would be more than sensible. Do you know whether he did alert his colleagues?
A. I do not know.
Q. So you don't know whether or not it was adopted by other centres?
A. I do not, no.
Q. If it had been adopted by other centres, do you think you would know?
A. Very possibly but, on the other hand, I was also aware that other tests were being developed and came into more routine use in other centres. I'm not sure whether any other centre, actually, adopted the technique that I had used.
Q. Was your test then replaced by a different test in the around about 1972 or was your test used, as far as you recall, for the whole period that you were -- well up until you left the Cambridge centre?
A. Yes, as far as I can recall, that was the only test being used for hepatitis B.
Q. Until you left in 1974?
A. Yes.

SIR BRIAN LANGSTAFF: Could you help me with this, there was something which I have picked up, the acronym CIEOP, counter-immunoelectro-osmophoresis. Can you explain that to me and how that works in comparison with ICOP -- IEOP?
A. Yes, I did refer very briefly to a third row of holes in the agar gel and the idea of that was that in the middle row would be the donor serum, the plasma, in one row would be the Japanese antibody serum, and in the third row, ultimately, when we had a positive, known sample, that could be put into the third row. The reason being then that when you apply the electric current, if there was a positive antibody at all in the donor plasma, that would react with the antigen in the third row, which, if you like, is going in the opposite direction to the little precipitation line that I referred to first of all. So, in that sense, hence, counterelectrophoresis.
SIR BRIAN LANGSTAFF: Thank you very much.
MS SCOTT: I'm going to move on now to ask you some questions about your time in Oxford. So you, as we know, became the director of the Oxford Blood Transfusion Centre in May 1980. You took over from Dr Gunson, is that right?
A. Correct.

Q. You tell us in your witness statement that when you arrived you had a staff of about 120 --
A. As far as I can recall, that is correct.
Q. -- and that you were accountable to the Oxford Regional Health Authority, is that right?
A. Correct.
Q. That remained the case throughout your tenure at Oxford?
A. No. Once the National Blood Authority was formed, they took over -- I was responsible to them, rather than to the Regional Health Authority.
Q. That was right at the end of your time there, wasn't it --
A. Yes.
Q. -- 1993?
A. Correct.
Q. Just to get an idea --
SIR BRIAN LANGSTAFF: I thought it was 1995 you said earlier, retirement?
MS SCOTT: Yes, retirement 1995. Sorry.
SIR BRIAN LANGSTAFF: You mean 1993 for the accountability?
MS SCOTT: Exactly.
SIR BRIAN LANGSTAFF: When the NBA began?
MS SCOTT: Exactly.

Can we look please at NHBT0006265. This is to get a snapshot of the work being done by Oxford Regional Transfusion Centre. If we look at the bottom of that page, we can see it is a document dated 10 May 1990. If we look at the top of that page we can see that it is a Department of Health Medicines Inspector's summary of the Oxford Regional Blood Transfusion Centre.

If we look, then, over the page at page 3, please, under "Introduction":

"Oxford [Regional Transfusion Centre], opened in 1979, is connected to the John Radcliffe Hospital."

Just pausing there. Is it right to understand that, in fact, what happened in 1979 is that the transfusion centre moved to new premises in John Radcliffe Hospital? It had existed before but in the Churchill Hospital?

A. That is correct, yes.

Q. Then it goes on:

"Although the Centre has its own self-contained area on a single floor, there are security problems arising from access to the main hospital on one side and to the engineering/plant rooms to the other.

"The RTC serves a population of 2.69 million, collected around 114,000 donations in 1989 and

employees 202 staff."

Again, just pausing there on the 202 staff, does it sound from -- is it right that there was a significant increase in staff during your time there?

A. No. I said earlier I thought it was about 120, I may be completely wrong. I honestly can't remember.

Q. It is likely that your estimate in your witness statement was a bit too low but the staffing remained about the same during your time there?

A. Yes, as far as I can recall, it was. There certainly was no significant increase or decease.

Q. Then if we go down to paragraph 3, we can see the senior staff list. We can see you there as medical director. Then you have a scientific services manager or deputy director, a quality manager -- what was the responsibility of the quality manager?

A. When I was appointed director there was very little, generally, in the way of quality management in the transfusion service that I was aware of and we certainly did not have a quality department as such within the Oxford Transfusion Centre. However, as time went by -- and this is not a document from the earlier part. I forget what date this document was.

Q. This is May 1990.

A. That's quite a bit later. And there was no quality department, as such, to start with but it felt later on that it became imperative and someone had to run it and, initially, my colleague, Dr David Collins, was involved as quality manager.

Q. Then we see there donor services manager and you tell us in your witness statement that that post was brought into being by you as a result of a restructuring arising out of poor practice.

Can you just tell us a little bit about what you were referring to in terms of poor practices?

A. I suspect what had happened is that, over the course of time, the system in place was possibly not as tight as it should have been and it was necessary to make sure that things were done better for everybody's sake, not only to make sure that the staff knew better what they were doing but also, and more particularly, to make sure that the donors were dealt with in an appropriate manner.

Q. Then running back down the list of senior staff, we can see there is donor organiser, blood collection manager, two laboratory managers and then the heads of the four different laboratories: standard reagents, donor grouping, microbiology and blood products.

Then if we go over the page we can see what the

list of products that were provided by the centre in 1990 --

SIR BRIAN LANGSTAFF: 1989.

MS SCOTT: Sorry, 1989. Thank you, sir. We have got whole blood, plasma reduced red cells, SAG-M red cells. So we can see there that that is the largest most significant number of units issued at that time. Was that something that increased during your time there, the number of SAG-M red cells?

A. Yes, it was. Initially we didn't have any but developments took place that a different additive could be put in with the anticoagulant to make sure the blood doesn't clot and the additive was SAG, which is abbreviation for some chemicals which enable the red cells to last healthily for rather longer in storage, as a consequence of which the expiry time for red cells was extended from three weeks to five weeks.

Q. Was another benefit of SAG-M that you could remove more of the plasma and so you were able to send more plasma or use more plasma, send more plasma for fractionation?

A. That is correct, yes.

Q. Then we have filtered red cells, platelet concentrates from two different methods, and then we have there a number of cryoprecipitate 50 units issued. Just

pausing there, you tell us in your statement that Oxford had stopped making cryoprecipitate when it moved to the new centre in 1979. Was that a decision that was made -- that decision, was it, made before you arrived at the centre?

A. Can I make a correction please? At the time I wrote my statement -- you will realise that this was over 26 years ago, in fact it was over 30 years since I arrived at the centre and I honestly could not remember cryoprecipitate being made during my time at Oxford. That may sound very bizarre but that is the fact and that is the -- I made that statement in true faith. So obviously small amounts, small numbers of cryoprecipitates were being made but, as I said, I have no recollection of that.

Q. It may be obvious, the answer to this question, given what you have just said, but do you recall having any discussions with the clinicians at the Oxford Haemophilia Centre, for example, about provision of cryoprecipitate?

A. I have no recollection of any such discussions at all.

Q. You say that -- and looking at this -- borne out by looking at this, that only small amounts of cryoprecipitate were issued by the Regional Transfusion Centre. Would it have been possible to

increase the issue of cryoprecipitate, had there been a demand for it and had you been asked for it?

A. Obviously, if it had been required and we were the centre producing them, yes, we would naturally have done what we could to meet that requirement.

Q. Would that -- would you have been able to increase cryoprecipitate, the production and issue of cryoprecipitate -- well, how quickly would you have been able to increase the production of cryoprecipitate? If you had been asked, would the time be measured in weeks or in months?

A. Depending on how much of an increase you are talking about, it would be very quick because it could be done literally in a matter of a day or so, if it was required.

I may add, if I may, one further document which I was sent, which I read last week, which showed in 1988 there were 140 units of cryoprecipitate being issued in the course of the whole year. So you can see that it is not a massive charge on the requirements from the laboratory.

Q. Turning back then to the document we were just looking at, the 1990 inspection report, NHBT0006265. If we look then, so we have "Blood Collection and Receipt":

"Standard blood donations are collected at

mobile donor sessions throughout the Region, all teams being based at the Centre."

Sorry, this is 6.1:

"There is also a donor apheresis clinic in the RTC."

Then some detail is given about that in the following paragraphs: equipped with eight machines; 560 donors on the panel; about 105 being bled per week and plans to increase the numbers so that platelet concentrates will be produced by apheresis.

Can you recall how long donors on the apheresis panel were bled?

A. As far as I can recall, it was certainly three monthly, may well have been less than that, because one is only taking plasma off and not taking off the red cells. So they are not at risk of anaemia which an ordinary donor would. Because of that one could actually quite safely take plasma and plated donations off monthly, if that was deemed necessary.

Q. Can you recall how those donors were recruited?

A. I cannot remember the practical details. I would imagine that, because we had donors living within reasonable striking distance of the John Radcliffe Hospital, they may well have been invited through donor sessions to look at documents which would allow

for the possibility of their coming into the transfusion centre for considering apheresis.

Q. Can you recall whether there were any additional checks or steps taken in selecting those donors to ensure that they were healthy and free from infection and -- viral infection?

A. I think there was very little in the way of additional medical supervision. I do know that there were tests of liver function introduced at a later stage and for very good reason but, initially, they were really virtually the same inspection as routine donors. But times did change over the course of my being in Oxford --

Q. Then if we go, we see that in -- if we go back to that document and NHBT0006265. At the bottom of that page there:

"Donor records are now computerised [so we are in 1990] and have been since 1988. The records for the following week's donors are printed out each week and held in the Clinic. When a donor attends and has signed the consent form, the Session Sheet is manually filled in with the name, donation number and group", and so on.

Then if we go over the page, just one more reference I want to pick up, "Mobile Session", 6.1.2:

"Donors at mobile sessions are mainly 'called', the pre-printed computer-generated record sheets being taken to the session. Typically, around 200 donors would be called to a session, with an attendance rate of about 50%. For new donors and 'walk-ins', yellow record sheets are used, the appropriate information being hand-written in."

Does that accord with your recollection that you got about a 50 per cent turn out rate for donors who were pre-called to sessions?

A. That seems a reasonable figure, yes.

Q. How common were walk-ins, can you recall?

A. On average, I would say that the walk-ins, as you call them, would be about 10 per cent of the total attendance at a donor session.

Q. I'm going to come back to this document a little later on today but we can take that down for now, Paul. So, in relation to donor sessions, you say in your statement that there were no donor sessions held in prisons during your time in Oxford, is that right?

A. That is correct, yes.

Q. And --

A. The decision had been taken nationally not to use prisons quite some time before I came to Oxford.

Q. Is it right to understand then that, by the time you

were a director in 1980, were you aware -- sorry, were you aware of any other centres undertaking donor sessions in prisons, by the time you were a director in 1980?

A. No, I was not aware of any. More than that, I was aware that it was a national policy not to use prisons by that time.

Q. Did you have any sessions bleeding military donors while you were at Oxford?

A. Not that I can recall.

Q. I'm going to turn now to the issue of your targets. Is it right to understand that there were, in effect -- your targets, in terms of how you decided how many donations you needed to collect, were made up of three separate elements, the first of which was your target that was provided to you by either BPL or the National Directorate, as to the amount of plasma that you needed to provide to send for fractionation to either BPL or PFL?

A. That was one of the targets, yes.

Q. In relation to that, I will just run through the three and then I will go back and ask you some questions about them. Another part of the target was made up, was it, of your estimation as to the amount of blood you would need to meet the needs of the local

hospitals that you served?

A. That is correct, yes, and that was obviously very much based on past record of the likely requirements and that, by and large, really worked very well.

Q. Again, I will come back and ask you a couple of questions about that. Then was there also -- we heard from Professor Contreras last week that there was a contract between the Oxford centre and her centre in North London to supply them with blood and components.

Did that also form part of your target setting or did you simply provide them with whatever you had spare?

A. I would imagine this was probably happening on the latter basis before I got there but, by the time I arrived, we provided Edgware with -- Dr Contreras's centre, we provided them with blood on a regular basis --

Q. So is it right, then, that that would have also formed -- you would have factored that into your targets for the year?

A. Correct, yes.

Q. So just --

A. And I think -- if I can expand a little on that, it is only fair to say that because we in the Oxford region did have the resource we could easily or relatively

easily find the donations that Dr Contreras wanted, whereas obviously Edgware was having a problem.

Q. Why was that? Why was it that you could find the donations relatively easily?

A. I suspect purely population demographics.

Q. So you never had -- throughout your time there you would have always been able to collect more donations had they been required?

A. Yes, I think we probably could.

Q. Just turning then to the first of your targets, the national target, the target set by BPL and/or the National Directorate. What input did you have into that target? And by "you", I mean the centre.

A. We didn't have an input in deciding how much was required. I think it is fair to say that the BPL was challenged with finding sufficient raw material to provide for products needed, and they devise -- sorry, divided up the total requirement into proportions provided by each of the transfusion centres. So a big centre, for instance, would provide a lot more plasma than a small centre. And consequently we were given a target by BPL: this is what was felt appropriate from -- to be provided by the Oxford centre if possible.

Q. And so was there a check in with you to establish

whether or not that was a target you could meet? Or were you simply just provided it and expected to get on with it?

A. Not really. Not really. We did just that. We got along with it.

Q. Then, turning then to the second target, the target that you set for the -- to meet the local needs. I think you already said that that worked quite well, that it was based on previous years' experience. Was it also based -- or, did you have discussions with your haematological colleagues in the blood banks that you served as to what the needs of their particular hospitals were?

A. Not in specific detail, but I think it is fair to point out that totally outside our normal routines, both us or the haematologists, the haematologists of the whole region used to meet every three months or so in a -- or in a semi-domestic arrangement, maybe talks or discussions, and that gave good opportunity for face-to-face discussions to raise questions, to ask questions, and so on. But apart from that there was no formal review.

Q. I have seen reference to the regional blood club meeting four times a year in the area?

A. That is right.

Q. Is that what you are describing?

A. That is correct. That's correct.

Q. And I will come on to ask you some questions about your interactions with colleagues later on this morning.

Turning then to the contract you had with North London, just to ask you a little bit more detail about that. You have told us that that was an arrangement that started before your time. In your witness statement you link the ability to collect donations from the Slough area with the arrangement to provide blood to the Edgware Centre. Why is that? What's the relevance of the collections in Slough?

A. Well, the Slough area was geographically a part of the Oxford region, and we were, therefore -- the Oxford Centre was therefore bleeding donors from that area and it seems in some senses logical that, if you like, those donations could go back home, as it were, to the Edgware Centre.

In fact, there was a discussion between Dr Contreras and myself on more than one occasion; she asked if there would be any possibility of them taking over the Slough area. But, in fact, we left things as they were.

Q. Can we look then at a document on this issue, which is

NHBT0111632. So this is a record of a meeting of the heads of department, and I understand that to mean the heads of department within the Regional Transfusion Centre, is that right?

A. Correct.

Q. We see some of the names that we just looked at on the senior staff list in the inspection report. If we look at the bottom of that first page, "Rationalisation of Sessions", at 3:

"Dr Entwistle had met with Dr Contreras and a representative from NW Thames BTS to sort out the requirements for Edgware. It had become apparent that although fresh whole blood would be very nice, what they really wanted was platelets. The RHA had agreed that it was not ethical to bleed donors and discard all the red cells.

"As a result, there was now no justification for Oxford to think of increasing red cell collection and Dr Entwistle pointed out that there was no therefore justification for retaining the 5th team. Ideally there should be a 4 full teams, ie 48 DAs on the road."

Then you go on to discuss what the four sessions would look like.

So, is it right to understand that, at that

stage, there was no ability on the part of Oxford to collect platelets by apheresis?

A. That is correct, yes. (Unclear).

Q. So while you had the ability to collect whole blood donations which would have met the needs of Edgware, because that would have required you to get rid of the red blood cells that were needed that was unethical and so you couldn't help out?

A. Correct.

Q. Can we look at another document, please, DHSC0038579_016. This is another document on the issue of feast, if I can put it that way, in one area, yours, and famine in others.

This is an issue which seems to have made its way into the press. So we have here two articles date stamped 12 September 1987. One, on the left, from the Daily Telegraph and, on the right, from The Guardian. It is the one from The Guardian that I'm going to turn to, and it is entitled "Minister denies blood 'shambles'". And these were articles that were written in the wake of then Dr Cash's article in the British Medical Journal in which he described the Blood Transfusion Services as a fragmented and disorganised shambles.

We have looked at this article in previous

hearings so we are not going to turn that up, but you were contacted by and spoke to The Guardian journalist, and we can see what you say on the right-hand column. So if we can pick it up sort of a third of the way down where it starts:

"One of Professor Cash's central criticisms -- that coordination is so bad that one region is cutting blood supplies while another faces shortages -- was confirmed yesterday."

Then:

"Oxford has cut back despite a shortage of more than 100 pints a day in the south London region. Oxford's regional director, Dr Colin Entwistle said: 'There was no way we could justify collecting vast excesses of blood that nobody wanted. That is why we cut back'."

So this article, in 1987, is picking up on a slightly different point to the one we looked at previously, which was that you were cutting back on donor sessions even though you could have collected more donations at a time when there was a shortage, apparently, according to this article, in the south London region.

Were you aware during your tenure, and particularly in 1987 when you were cutting back on

donor sessions, that there were shortages in other regions?

A. You connect two issues there. Two issues there. One was cutting back. We only decided not to move on to a fifth blood collection team. We could have -- if it had been required obviously it would have gone ahead. So we were not actively cutting back in that sense, we maintained our normal collection, which included some going to Edgware. We were not aware that south London was that desperately short and we hadn't been approached by them to see whether we could help them as well.

So even though they may have been short we were not involved in that.

Q. Do you think, looking at it now, that that -- the fact that you weren't even aware that there were shortages in another area -- was a product of the regionalisation of the transfusion service? Had there been a national -- had it been a truly national body, with one body overseeing all of the centres, that that may not have occurred?

A. Certain. And I think this did underline the need for proper rationalisation of the service which ultimately led to the formation of the National Blood Authority.

Q. Moving off the issue of targets then, on to the issue

of what you did with your plasma in Oxford, is it right to understand that Oxford provided plasma to PFL in Oxford, which was a historic arrangement in place when you arrived at the centre?

A. Correct.

Q. And the plasma that was fractionated by PFL was provided directly by the Oxford Haemophilia Centre as Factor VIII or Factor IX or whatever products they were making, that those products did not make their way back to the Regional Transfusion Centre?

A. That is correct. At no time did the transfusion centre hold stocks of Factor VIII.

Q. What about Factor IX?

A. Or any of the coagulation products.

Q. Is this also correct, that Oxford also provided plasma to BPL at Elstree. And again, the products that were made out of that plasma, Factor VIII, Factor IX, went, again, direct to the Oxford Haemophilia Centre and did not come to the transfusion centre?

A. Correct.

Q. And did that remain the case throughout your tenure at the --

A. It did indeed. PFL, so the plasma fractionation branch in Oxford, in fact relinquished its role to the BPL.

Q. So is it the case that in fact the Oxford Transfusion Centre didn't hold any PFL or BPL or commercial products?

A. Correct.

Q. So the only blood products or blood components that their centre held were those made at the centre themselves?

A. Sorry?

Q. The cryoprecipitate -- so --

A. The cryoprecipitate is the only product which the Oxford Transfusion Centre made available to the haemophilia centre.

Q. So all the -- if I can call them -- products, all the products that were held by the transfusion centre were those that were made at the transfusion centre?

A. Yes.

Q. Did the centre have any input or any discussions or have any discussions or any input into the decisions made by the haemophilia centre about purchasing commercial blood products?

A. No, we had no part in that at all.

Q. Moving on then to look at supply of blood and components from the transfusion centre. We are going to go back to the document we looked at earlier, DHSC0101582.

If we look at the table we looked at, which I think was on page 7 -- thank you.

If we look down the left-hand column we can see Oxford, "No. of NHS [hospitals served]: 11", and no private hospitals, but we have got there two RAF and one USAF hospital. Does that accord with your recollection?

A. That is not correct. There were a number of private hospitals in the Oxford region which we also -- to which we also provided small quantities of blood.

Q. So this is a document from 1982. In 1982 do you think this was incorrect?

A. As far as I can remember there were private hospitals. Whether they were there 1982, I'm not sure.

Q. Certainly we have a document --

A. I certainly --

Q. I don't want to --

SIR BRIAN LANGSTAFF: Can you let him finish?

MS SCOTT: Yes, absolutely.

A. Certainly towards the end of my time, I was very well aware of there being private hospitals because we had to negotiate with them for contract purchases. But I was also aware that at least some of them had been there prior to that and I'm very surprised to see this figure 0 in that chart.

Q. Certainly we have a document from 1992 which is from a medical audit visit by Drs Robinson and Hewitt, to the Oxford Centre, which I do not think we need to go to but, for the benefit of the transcript, it is NHBT0009748_001. It is a medical audit from 1992 in which it is said that the centre served ten district general hospitals, two RAF hospitals, one US Air Force hospital and 14 private hospitals. So by 1992 it looks like 14 private hospitals, does that sound more accurate to you?

A. That accords with my recollection, yes.

Q. Can you recall whether there was a period, as you went through your tenure, that you picked up more and more private hospitals or do you recall always having private hospitals?

A. Initially, there was very little in the way of private hospitals and, in any case, even at the end, they did not figure largely in the demands made on our service.

Q. Did you provide any blood or components to any other NHS services, such as dentists?

A. No.

Q. So just hospitals?

A. Yes.

MS SCOTT: Sir, I'm about to move topics and it is going to take me, I think, more than three minutes.

I wonder whether is now a good time to break?

SIR BRIAN LANGSTAFF: Yes. We normally take a break, mid-morning, about now, Dr Entwistle, for about half an hour to allow people to have a cup of coffee, for those who are at home to make some refreshment or indeed just have a break.

We will take a break now. We'll come back at 11.45, if that's okay. Let me tell you what I tell every witness at this stage and it is this, you are giving evidence, what you must not do is discuss the evidence you have given or, for that matter, any evidence which you think you might be asked to give with anyone, whoever that person is, whether family, lawyer, anyone at all, but you can talk about anything else you like. So I look forward to seeing you at 11.45.

(11.14 am)

(A short break)

(11.45 am)

SIR BRIAN LANGSTAFF: Ms Scott, just before we begin again, I think some people may have noticed you have a slight hoarseness of voice and slight cough but I understand, just for their reassurance, you took a PCR test over the weekend and it was entirely -- well, it is either negative or positive -- it was

negative.

MS SCOTT: Indeed, that is correct, yes sir.

SIR BRIAN LANGSTAFF: So you are not suffering from Covid, whatever else you may have seasonally affecting your voice?

MS SCOTT: That is right, sir.

Dr Entwistle, I'm going to start this session asking you about your knowledge of risk of hepatitis and I will come on later to deal with HIV. I think perhaps the best way to start us off is to go back to your witness statement, WITN6917001, and to page 24, please, Paul.

This is what you say at paragraph 87:

"I had been aware since the 1970s after the identification of hepatitis B that there was a condition given the title 'Non-A, Non-B' (for want of a better name). I was also aware that throughout most of my time at Oxford, there was no specific tests for it. It was acknowledged that this condition posed a risk of blood transmission."

Then if we pick it up again at paragraph 90, please. You were asked questions about your understanding of how serious hepatitis C or non-A, non-B could be, and you say:

"My understanding was that hepatitis B was the

most aggressive infection, but that the other forms including hepatitis C could nonetheless lead to chronic liver disease possibly with ultimately fatal consequences in some cases."

I'm just going to show you a document to see if we can nail down the date or thereabouts by which you would have -- which you knew that hepatitis C could lead to chronic liver disease and, ultimately, could be fatal in some cases.

Can we have, please, Paul, PRSE0004766.

This is a document called *Notes on Transfusion*. We can see there it is the revised version of 1984. Sorry, I have got the wrong document up in front of me, which isn't very helpful. Let me find the right document. If we turn please to page 3 of that document -- in fact, can we go back to page 2. It is rather small writing there, if we can enlarge that.

We can see that this is a document issued by the Department of Health and Social Security with the Scottish Home and Health Department and the Welsh Office for the National Blood Transfusion Service and the Scottish National Blood Transfusion Service.

If we go to page 3, we can see on the left-hand side, if we can enlarge that bit:

"This edition of 'Notes on Transfusion', like

its predecessors, has been prepared by a Committee of the Regional Transfusion Directors."

Can you recall whether or not you were on that committee?

A. You say that was 1983?

Q. Yes. It is the revised 1984 version.

A. I can't recall offhand when I was involved in that committee.

Q. So you were, at some point, involved in drafting --

A. At some point but I can't -- unfortunately, I can't remember exactly when.

Q. Can we -- we heard -- we have heard some evidence last week that this document was the definitive publication from the Transfusion Service to be used by those carrying out transfusions, transfusion medicine in hospitals, so for clinicians on the frontline. Is that how you understood it to be used?

A. It could well have been. Obviously, anyone who is involved in transfusion should have pretty good knowledge of what they are doing.

Q. Can we turn to page 19 of this document, please. We have got a section there on the right, "Post Transfusion Hepatitis", and it is the bottom paragraph that I wish to draw your attention to:

"Very similar illnesses can also be caused by

other viruses including the so-called 'non-A non-B' viruses. The latter are also transmissible by transfusion, but as yet no specific laboratory tests have been developed to identify them. The incubation period is also variable extending up to 70 days or more. The clinical course may be acute, or chronic leading to cirrhosis."

Is it fair to assume that, even if you weren't involved in the drafting of this particular document, you would have known what the contents of it were?

A. Yes, certainly.

Q. So if we are trying to pin down a date by which you would have known about the chronic cause of hepatitis C, non-A, non-B in some cases, and the seriousness of it --

A. I was aware of that even before this document came out.

Q. Were you aware of it, do you think, by the time you arrived at the Oxford Blood Transfusion Centre as the director?

A. Yes.

Q. So by 1980 you were aware of the seriousness of non-A, non-B hepatitis?

A. Yes.

Q. Can you recall what -- how you became aware of that

information, what it was that led you to understand that?

A. I don't think there was any specific article or information which I gleaned on that subject but I was certainly aware of it from my general reading and knowledge of the subject.

Q. I'm going to ask you some questions about your view of your role as a director of the Regional Transfusion Centre --

SIR BRIAN LANGSTAFF: Before you do that could I just come back to that document that you had on screen, that is PRSE0004766, and go back to page 2, the page which you passed over reasonably quickly. Can we just highlight that, please, Paul. Thank you.

I just wanted to ask you about this, really, I think, for confirmation, more than for information. *Notes on Transfusion* is:

"Issued by the Department of Health and Social Security with the Scottish Home and Health Department and the Welsh Office for the National Blood Transfusion Service and the [SNBTS]."

The words "for the" could be interpreted in one of two ways. One could mean that it is intended to be given to the National Blood Transfusion Service and those who work in it, the other could be that it is

done on behalf of. I had read this and I want you to know -- I want to know whether I'm right or not, as essentially being issued on behalf, and it may be a reflection of the fact that the NBTS had no direct funding from Regional Health Authorities of its own but had to rely upon central finance, for anything which it was going to publish and send round. Am I right or am I wrong?

A. I don't recall.

SIR BRIAN LANGSTAFF: Thank you.

In that case, it is something which is open for comment in due course by others. It had seemed to me it might be a reflection of the fact that the NBTS was, in name, though not necessarily in control and organisation.

MS SCOTT: I'm going to ask you now about your view about whether or not you considered you had a role in educating your clinical colleagues about the risk of transmission of viruses via blood and blood products.

So did you consider that was part of your role?

A. To be fair, no, I don't think I did.

Q. What about -- did you consider it to be part of your role to educate your clinical colleagues more generally about best practice and transfusion medicine?

A. That is something which hadn't really figured in my thinking.

Q. Can I take you to a few documents and see if that prompts any recollection. The first is DHSC0002221_011.

Now, this is a report from the Central Management Services for the Department of Health, for the DHSS, in 1982, and it is called "Blood: Record keeping and stock control".

It is a review of, unsurprisingly perhaps, record keeping and stock control in the transfusion services and indeed in hospitals. And the report concludes by making a number of recommendations, and if we can turn, please, to page 30, we can have a look at three of those. Recommendation 148:

"It is recommended that Centres ..."

And by that they mean Regional Transfusion Centres.

"... consider as part of their role a formal process to enable the exchange of ideas and good practice at operational level for hospitals to whom they supply substantial quantities of blood and blood products."

149:

"It is recommended that discussion on a formal

basis -- say annual or 6 monthly -- between the medical staff or Director at the Centre and the hospital based haematologist in charge of the blood bank is considered with a view to sharing problems and good practice experienced in blood banking."

Then if we go over the page, please, to 160 and then this is a recommendation for haematologists in charge of blood banks that they are:

"... asked to ensure that they discuss with their medical colleagues economies in blood usage."

That takes the chain through. That is not for Regional Transfusion Centre directors.

So, just pausing there, is this -- in fact I will show you another document before I ask you the question.

So if we could then turn, please, to NHBT0000476, and we can see here this is a DHSS circular from 28 February 1983 to regional administrators, district administrators and so on, and it refers to the "Blood transfusion: record keeping stock control arrangements".

Then if we go over the page. We can see that that's the circular itself. It is entitled "(Draft)" and it is again to Regional Health Authorities. And the summary:

"This Circular asks health authorities to review arrangements for the supply of blood and blood products, and to review concurrently record-keeping and stock control arrangements in Regional Transfusion Centres (RTCs) and hospital blood banks. Its contents have been endorsed by the Advisory Committee on the National Blood Transfusion Service."

Then if we go down to the bottom of that page:

"Regional review of policies:

"2. To facilitate a Regional review of policies, it is suggested that RMOs should convene regular meetings between their Regional Transfusion Directors (RTDs) and the consultants responsible for the hospital blood banks in their Regions to consider matters such as current and future requirements for blood, the scope for economies in blood usage, the proportion of plasma-reduced blood to be supplied, the use of ad hoc deliveries and the amount of stock which becomes time-expired in blood banks. The meetings should also provide the forum for the exchange of ideas as to what constitutes 'good practice' in the Region with regard to blood supplies."

So, first of all, do you recall seeing either the report that we looked at first or this circular? Are those documents that came to your attention, do

you recall?
A. I must be honest, they did not come to my attention.
Q. Do you recall whether or not the Regional Health Authority took any steps to arrange regular meetings between yourself and the consultants responsible for the hospital blood banks?
A. Not that I'm aware of, no.
Q. You are mentioned earlier the meeting of the regional blood club?
A. Yes.
Q. How did that come about? Was that as a response to these recommendations or this circular do you think?
A. I don't know because that system of regular meetings was already in place by the time I came to Oxford.
Q. So it couldn't, just by the dint of the chronology, be a response to what was happening in 1982 and 1983?
A. That's my imagination, yes.
Q. So, in terms of meetings between yourself and your clinical colleagues running the blood banks and indeed carrying out transfusion practice, you have the regional meeting of the Blood Club. Were there any other forums in which best practice or exchange of information took place?
A. Not as such, no. The only other thing I could mention is that we had very informal but regular discussions

over the phone with my haematological colleagues in hospitals as necessary.
Q. Would that arise where you might be rung up for advice, in relation to a difficult case, for example?
A. That is one possibility, yes, or if there was some new development or some new recommendation that I was aware of and needed to pass on.
Q. Might that have included information about viral infections in blood and blood products?
A. I am sure that must have been discussed. I can't say more than that.
Q. In terms of the regional Blood Club, what was the purpose of those meetings and what actually occurred during those meetings?
A. It was a forum for discussion primarily but sometimes with a specific topic being discussed in more detail.
Q. Can you recall whether transfusion-transmitted infections were discussed at those meetings?
A. Offhand, I can't recall.
Q. I'm going to move now to ask you some questions about your work on the Working Party on the Care and Selection of Donors which reported to the Regional Transfusion Directors meetings.

It is right, isn't it, that that working party was responsible for drafting the guidance document

entitled "Care and Selection of Donors"?
A. Correct.
Q. If we just turn the 1984 version up, we find that at NHBT0053225. Is it right to understand that this 1984 version was a revision of the previous 1977 version?
A. As I understand it, yes, it was.
Q. So, again, by dint of the chronology, you wouldn't have been involved in the drafting of the 1977 version because --
A. No.
Q. -- you were not in the Blood Transfusion Service at that time. Just looking then at the title of this document and we can see it is "Guidance for the Selection Medical Examination and Care of Blood Donors". Given the autonomy that each Regional Transfusion Centre had, do you know the extent to which this document was followed by other Regional Transfusion Centres?
A. No, I don't. I have no reason to know what they were doing.
Q. In terms of your own centre, so in terms of the centre at Oxford, would you expect those working at donor sessions -- so both the administrative clerk and the medical officer -- to have followed the guidance in this document?

A. Yes.
Q. Would they have received training on and received a copy of this document?
A. I can't recall whether they would have had that document, they might well have done but, certainly, there was some training at the start of their undertaking sessional work for us.
Q. So if we look then at the detail of the document and then I'll ask you some questions about how -- what your understanding of the donor sessions and how they ran and how donors were selected.

We can see in the first page that there is, under paragraph 1, there is some general guidance about the age of donors, the weight of donors, and so on. Then at paragraph 2, again, general guidance about intervals between donations, and then paragraph 4 looks at hazardous occupations, and general guidance and more specific guidance in relation to that.

If we then turn over the page, we get to "Section II -- Medical Examination of Donors", and it says under "Medical History":

"A donor is the best judge of his or her fitness, and truthful answers to simple questions about his or her medical history and general health

form a large part of the assessment.

"The donor session clerk should specifically question the donor about the conditions listed on form NBTS 110A and request the donor's signature on form NBTS 110. Any conditions declared should be recorded by the Clerk or preferably by the Medical Officer, most conveniently in the 'medical history box' on the NBTS 101 donor record card or other equivalent document."

So, just pausing there then. Is it right to understand that the first -- well, that the system relied on the donor disclosing whether or not they had suffered from the conditions listed in the form mentioned there?

A. Yes, that is correct, and it was inevitable that if they failed to disclose, for whatever reason, there is no way that we could pre-judge.

Q. So, was any training given or was there any expectation that either the donor session clerk or, indeed, the medical officer would carry out some kind of assessment themselves of the donor and whether or not they were a suitable candidate for donation? So setting to one side what had or hadn't been disclosed by the donor, was there any other kind of check by those individuals?

A. No, not really.

Q. So, if a donor discloses a relevant condition on the form, then is it right to understand that that would trigger a referral to the medical officer for consideration?

A. Yes.

Q. Of whether or not that donor should be deferred or whether or not that donor could donate?

A. That is correct, yes.

Q. And the medical officer would then turn to this document for guidance as to how to deal with that particular donor?

A. Yes.

Q. And is it also right to understand that the medical officer would ask questions -- would effectively interview a donor who had been referred to him or her, in order to get more information about the condition?

A. I think it would be fair to say they would ask further questions. They wouldn't necessarily interrogate them but I think have sufficient information to say, "Yes, okay, we can forget that for today", or, "Perhaps we had better not give blood today", or even take the matter further.

Q. So you would expect there to be some exchange of information once something had been disclosed?

A. Some exchange of information, yes.

Q. Was there an opportunity for that discussion to take place in private during a session in the community or would there have been sessions, at least some sessions, where that discussion would have had to take place in the large room that was where all the other donors and staff were?

A. It would almost inevitably be in what you might call open forum, yes. But obviously one would try to -- shall we say, try and take the patient slightly to one side so they are not sort of right next to somebody.

Q. Was that a concern, that given how reliant the system was on donors being honest about what might be rather embarrassing or difficult matters to talk about, that that was being done without much privacy?

A. It is a consideration which perhaps should have been dealt with differently, but it wasn't.

Q. So let's look then at what was available by 1984 in relation to those who may be considered to be high-risk donors for Aids. So, in 1984, the donor would have been provided with the NBTS 110A. Is that right? We just looked at the guidance and it said the donor session clerk should specifically question the donor about the conditions listed on form NBTS 110A and request the donor's signature on form NBTS 110.

Would the donor have been given the form NBTS 110A or is that something that the donor clerk would have had?

A. The donor clerk would have had it but other copies of that leaflet would be available for them to have read prior to seeing the clerk.

Q. So if we look at NBTS 110A, which is at page 18 of the document we were just looking at, the guidance, NHBT0053225, we can see that this is appended to the 1984 guidelines. And if we see right at the top there, I think it says "NBTS" -- or the bottom of -- "NBTS 110A (Rev 1983)". So we understand that that form was revised in 1983. Does that accord with your recollection?

A. Mm.

Q. Then you say:

"This is very important -- please read carefully each time you attend."

That would suggest, would it, that this was a leaflet provided for the donor?

A. Yes.

Q. We know from the guidance that the donor session clerk must ask specifically whether or not the donor has suffered from any of the matters set out there, which includes:

"Hepatitis (jaundice), or been in contact with a case in the last 6 months."

Doesn't include AIDS, which seems to have been handwritten in there with a question mark. Is that, again, how you remember it in 1984?

A. Well, this looks to me like a possible draft rather than the official document.

Q. And by 1984 there was the separate Aids leaflet which had been produced by the Department of Health, and that would have been available at donor sessions, would it?

A. Yes, there would be separate leaflets which specifically listed risk of Aids.

Q. And I will come on to ask you some questions about that in due course. So just sticking then with this and the point in the session at which the donor clerk is asking the donor questions. Again, that would be an open session, would it? Those questions would be being asked orally and they were being asked orally in open session?

A. That is correct.

Q. Then turning back then to page 2 of this document, we see there, it says -- the last paragraph there:

"A more detailed list follows of conditions which may affect actions taken with a particular

donor, whether to accept a donation, to refer the donor to the Medical Officer or to decline their offer permanently. Any donor not accepted because one of the conditions listed will, if they ask, be referred to the Medical Officer."

Then there is set out a list of conditions. These are conditions that both the donor clerk and the medical officer will be taking into account, is that right?

A. Yes, I mean if any -- if the donor admitted to any of those, he or she could be referred to the doctor for consideration.

Q. Then we see there "AIDS, Disqualify, See appendix 1". We can see appendix 1 is at page 10:

"Notes on Certain Diseases.

"Acquired Immune Deficiency Syndrome ...

"Practising homosexual and bisexual men, drug abusers both men and women, persons from Haiti and Central Africa, particularly Zaire and Chad, haemophiliacs and the sexual contacts of all those mentioned must not be accepted as donors."

So that wording comes from, does it not, the first leaflet on AIDS?

A. Yes.

Q. We can look at that in due course, if necessary.

Then, if we go back then, please, to page 3 of this document, and down to "Hepatitis". We know that the donor clerk will have asked specifically about hepatitis or jaundice, "refer" -- and if that's disclosed we can see here that it is referred to the MO and, again, it says "See appendix 1".

So if we turn back to appendix 1 and to page 11, please, we can see there the guidance that's given to the medical officer:

"Individuals who give a history of jaundice or hepatitis or in whose blood anti-HBs is present may be accepted as donors providing that they have not suffered from jaundice or hepatitis in the previous twelve months, have not been in close contact with hepatitis or received a transfusion of blood or blood products in the previous six months, and providing their blood gives a negative reaction for the presence of HBsAG when tested by an accepted sensitive method (eg RIA). An approved test for hepatitis B surface antigen should be performed each time a donor is bled; donors whose blood is shown to carry [hepatitis B surface antigen] shall be excluded from the ordinary donor panel. They may only be considered for reinstatement under special circumstances and if they have been subsequently demonstrated by appropriately

sensitive tests to be persistently negative for known viral markers, (HBc, HBe) for at least twelve months and have an adequate level ... of anti-HBs antibody."

A. May I comment on that if I may?

Q. Yes.

A. Quite honestly, if a donor presented with a history as presented there, whatever the subsequent microbiological tests were, as specified there, the odds are that donor would not be accepted anyway.

Q. Are you talking there about somebody who has a positive test for hepatitis B surface antigen? Because there are two different categories here, aren't there? One is somebody who gives a history of jaundice and then those that are shown to carry the antigen?

A. Those who have a history of jaundice we would not have accepted anyway, and those who certainly have tested positive, they would be excluded without question.

Q. So, am I right in understanding that what you are saying is that, despite what this says in terms of accepting those with a history of hepatitis or jaundice, as long as it was more than 12 months ago, in practice, in Oxford, that's not what happened. In practice, in Oxford, if one disclosed that had history you would not be accepted as a donor.

A. Yes, we would not accept them.
Q. So is it right to understand that, in fact, you departed, Oxford departed from these guidelines?
A. Perhaps we were overly restrictive.
Q. Do you recall whether or not you discussed that with any of your fellow Regional Transfusion Directors and explained that that was your practice?
A. No.
Q. Why not?
A. Well, I would personally have thought that reinstatement of those donors was questionable. And if they had got hepatitis B, who knows whether they might have something else as well, which we have not tested for. So I was personally less happy to accept those sort of donors in the future.
Q. And were you also concerned that if you accepted somebody with a history of jaundice, then, in fact, it may be somebody who was infected with non-A, non-B hepatitis and, applying this guidance, you may be letting such a person onto the panel to donate?
A. Well, that's precisely what I was thinking. I was unhappy with that particular recommendation.

I am also aware, of course, that long before the discovery of hepatitis B, the Service was aware of jaundice being a possible marker for trouble. What we

have subsequently found out was, of course, most of those were not hepatitis A or B or hepatitis C but might well have been so-called infectious jaundice, which is a different disease altogether. And it wasn't until specific tests became available that we could define exactly what was what.
Q. How is it that these guidelines came out in the terms that they did in relation to hepatitis, given that you, as I understand it, were the chair of the working committee that was drawing up these guidelines and didn't, in fact, agree with one of the key recommendations within it?
A. I felt it was over-generous, shall we say. But nonetheless there were others on that committee whose advice was respected and I think one has to be cautious in trying to draw up a common agreed policy which everyone can agree to even though some people might feel slightly different within that.
Q. And so is it right to understand that you would have trained your staff to take a rather more cautious approach than that set out in the guidelines?
A. In general terms, yes.
Q. And do you think there was a danger that because this was the written guidelines that in fact some of your staff would have applied the guidelines and not

applied the more cautious test that you thought was appropriate?
A. I honestly can't say.
Q. Can I then -- picking up on a slightly different issue, on the issue of consent which you seemed to have raised in a meeting of July 1984, can we turn, please, to DHSC0002245_002.

This is a meeting of the Regional Transfusion Directors in July 1984 at which you were present. And if we can turn, please, to page 3, there is an entry at the top there, "Care and selection of donors", and it is the second paragraph:

"Discussion took place on the format of the blue form signed by donors and whether this can be regarded as consent. Dr Entwistle is pursuing this with the protection society and will inform RTDs of his findings."

I'm just going to take you to one more document before I ask you about this. It is NHBT0090316. This, we can see, has a compliment slip on page 1 from you. If we go then, please, over to page 2, we can see a memorandum to the Medical Protection Society dated 1 August 1984 from a firm of solicitors, Le Brasseur & Bury.

It says:

"Dr CC Entwistle
"Re: Consent and Blood Donors"

It sets out some advice and at the bottom there is a signature.

Is it right to understand that this memorandum was provided by you to the Regional Transfusion Directors meeting -- if we go back over the page, the previous page -- for the meeting on 10 October 1984?
A. I can't imagine that that was not referred back -- in fact, I think it was referred back to the directors meeting. I was also aware that there had been some difficulties, not in our region but elsewhere, with regard to consent being acceptable or not. But the Medical Protection Society felt that the consent was actually implied, yes.
Q. So is this right, you raised it as a concern at the meeting we just looked at because you were concerned -- it had been raised with you and you wanted to understand what the position was. You then --
A. Yes.
Q. -- went off and got some advice from the Medical Protection Society, and they appear to have provided you with the advice that they themselves received --
A. Yes.

Q. -- and you provided that advice back to the Regional Transfusion Directors meeting?
A. I am sure I would have done but I cannot recall today whether I did or not. I am sure I must have.
Q. All I'm inviting you to consider is that that's what it looks like, because you have got a compliment slip suggesting that --
A. Yes.
Q. -- attached to the memorandum from the Medical Protection Society.
A. It is likely that I would have referred it back.
Q. Then if we look at the detail, then, if we go back to page 2, please, Paul, if we look at the detail of what the Medical Protection Society were told, the second paragraph:

"Your member refers at the end of this letter ..."

I think that's you.

"... to 'the apparent loophole in our present arrangements', but we do not think there is in fact any loophole. Have Dr Entwistle or his fellow directors in other centres ever experienced any complaint by a donor alleging lack of consent? It is difficult to conceive how any such complaint could be sustained.

"As we understand it, the prospective donor takes the initiative in contacting the Blood Transfusion Service and expressing a willingness to give blood, and is then sent an appointment to attend a session. Before any blood is taken the donor is asked to read and sign a form ... which is addressed to 'Blood Donors'. In our view all the circumstances point clearly and unequivocally to implied consent. The consent is implied not only by the signing of the document ... but from all the circumstances, ie the initial volunteering, the attendance at the session, the signing of the form, and the permitting of blood to be taken without raising any objection."

Did that put to bed, as it were, the concerns that had been raised with you about whether or not there was sufficient consent by the blood donors?
A. Yes, it did, because there had been a case referred to the medical directors meeting from another region where a donor queried whether consent was valid. But, obviously, you will see from what the Medical Protection Society have just quoted there, they thought it was perfectly valid.
Q. Then for the sake of completeness, which I probably should have taken you to before looking at the issue of consent but I will take you to now, just have

a look at the forms that we do have that the donor would have been provided with to sign during the session. If we can look, please, first of all, at NHBT0010861_004.

So this is, we can see halfway down, the form NBTS 110. If we look on the left-hand side under "Birthplace" it says NBTS 1011 revised 1965, in very small --

SIR BRIAN LANGSTAFF: I think it is "101/P".
MS SCOTT: Yes, I think that must be right. It suggests there "Rev 1965". I haven't found, not to say it doesn't exist, a form between then and 1985. Is that a form that you recognise? It is from significantly before your time, 1965, but is that a form that you recognise or do you think there would have been revisions subsequent to that?
A. I suspect -- I'm pretty certain there would have been revisions to that.
Q. So the next one that I have been able to find is at DHSC0002277_068.

So this is the 1985 version and -- revised 1985 and then it says "To blood donors", so this seems to be a later version than the one we looked at, at the back of the guidance, the 1983 version. Again, it doesn't appear in the 1985 version to have any

reference to AIDS but it does -- in the list of conditions, but it does say:

"Please read the leaflet ... about AIDS."

So the donor is directed to the AIDS leaflet and then tells the donor that all donations will be tested for the AIDS antibody. Then the donor is asked to sign below on this form to show that they have read the notice and they agree to their blood being tested.

Then, lastly, the 1990 version, which is at NHBT0006682_008. It is in a slightly different form here and it is entitled "Declaration by Donors", and they are asked to declare various different matters, including that they haven't had an infectious disease in the last two years or been in contact with an infectious disease, haven't lived abroad other than in Europe, one about inoculations or vaccinations, and then they haven't had any of a list of the following, which includes jaundice, doesn't include AIDS, but then again directed to the AIDS leaflet and say "I am not at risk", and then agree lastly that the donation can be tested for AIDS antibody and other infections.

Certainly from 1985 to 1990 were those the forms in use at the Oxford Centre --
A. Yes, they are.
Q. Moving on then to deal specifically with AIDS. You

have told us in your statement that you first became aware AIDS was a medical problem in 1982. Can you recall the circumstances in which you first became aware of AIDS?

A. From general press and medical press.

Q. When did you first become aware that AIDS or HTLV-III was caused or could be caused by blood or blood products?

SIR BRIAN LANGSTAFF: Which is it, could be or is?

MS SCOTT: Is.

SIR BRIAN LANGSTAFF: Was caused as opposed to might be caused?

MS SCOTT: Well, let's start with might be caused.

A. I was aware right from the start that the question of infection with the AIDS virus was associated with transmission via blood in some form, whether it was through transfusion, which is only one form, but through other unusual practices, and through cuts and whatever, but blood seemed to be required for transmission to occur by whatever means.

Q. So is it right then that from 1982 that was your understanding?

A. Yes.

Q. Given that fact, were you concerned at the length of time it took for the Department of Health to produce

the first AIDS leaflet? We know from other evidence that we have heard that that was produced for distribution by the Department of Health on 1 September 1983. Do you recall whether or not that period of time, between you knowing about AIDS and understanding that it required blood for transmission, and having available to you a leaflet to provide to your donors, whether that caused you any concern?

A. I think one has to remember that 1982 was a very different social situation to what we have today. We are looking back with hindsight which is a different matter altogether. The public conception of AIDS, as, it came to be known as AIDS, was that it was a condition which was primarily linked to persons with certain practices, which we needn't go into details, and was not a matter involving the general public and, although blood was necessarily involved, yes, that's -- the transmission seemed to be within restricted groups.

And it was only as time went by that it realised that there were other possibilities to be considered, that in fact AIDS was transmissible, as was evidenced particularly from the populations in Africa, and it was realised that AIDS was becoming a more serious problem and that the general public, which included

blood donors, would have to take this on board.

But we could not do that -- bearing in mind the public fear of AIDS, which there was at that time, we could not do that until we knew exactly what we were up against, which of course in those days we didn't, and we had to draw up guidelines for donors which would not scare them rigid.

So this is one of the reasons why it took a long time for an approved document to be produced which would address this situation and would give the opportunity for those people in the dangerous activities to withdraw themselves as potential donors, while, at the same time, giving donors the opportunity of disclosing those risks.

Q. So is it right to understand from what you have just said that, in fact, that length of time between when you knew about AIDS and the association with blood, or it being caused by blood, and the leaflet in September '83 didn't at the time cause you any concern?

A. What, the long time between the two you mean?

Q. Yes.

A. I think initially, 1982 onwards, people used to think: oh, it is only going to be happening in these at-risk groups, which isn't going to be the general

public, it's not going to be donors. But that's an attitude which obviously had to be challenged in due course.

Q. And so was that your view then, in those -- in that period '82 to September '83?

A. I think it is fair to say yes because, initially, not an awful lot was known as to who actually could be involved, apart from the so-called at-risk groups.

Q. So is it also right to understand then from what you have said that before the leaflet became available in September 1983, Oxford was not taking any steps to screen out high-risk donors from donating?

A. The Oxford Centre was following the recommendations agreed by the directors that we would all -- all the transfusion centres would follow the same system in terms of dealing with the advice requesting information about at-risk activities. It was felt very strongly that we should all go by the same rules.

Q. We have heard evidence that it was left to the discretion of the Regional Transfusion Directors as to how to distribute the first leaflet to donors. So there were three choices: the choice of sending out with the call-out card, handing to donors in sessions or having them available in sessions. I'm just going to turn to a document, NHBT0020746, and just ask you

about the practice in Oxford.

So this is a letter from you, if we go over to the second page, to Dr Wagstaff, dated 14 June 1983. If I turn, first of all, to paragraph 6:

"The leaflet being prepared should be made freely available at donor sessions along with other BTS literature. We consider it should not be handed to each and every donor at the clerking desk for the reasons given in 3 above."

So there we can see, is this right, that you took, as it were, the least invasive, if I can put it that way, option of leaving it available at donor sessions. Is that right?

A. That is correct. And the reason why we chose that route is that bearing in mind public attitudes at that time, we felt that if each and every donor was given the AIDS leaflet, there would be some at least who would take exception to being, as they might see it, threatened, and it was felt more acceptable to adopt what we did.

Q. Would you also accept that, by taking the course that you did, that there may be some high-risk donors who never read the leaflet?

A. Quite possible.

Q. And --

A. But, on the other hand, you are never going to stop some high-risk donors failing to declare what they've done.

Q. But equally, there may be some high-risk donors who ended up donating simply because they didn't realise that they were, in fact, high-risk donors who should be deferred, would you accept that?

A. If they didn't risk it, they are not going to disclose that, are they?

Q. Can we look back at that letter then, because you also give some -- you set out your views about a question you were being asked -- you were being asked a question about whether donors should be questioned about matters that might identify AIDS at sessions.

So you say there:

"In response to your letter of 7th June, we have reconsidered our approach to blood donor questioning with AIDS in mind. We do not consider the aggressive approach is justified ..."

Are you there referring to the aggressive approach as oral questioning of donors? Is that what you were referring to?

A. Yes. Indeed, yes, because it was felt -- not only me but others too, felt that what we might call aggressive questioning in an open session like that

would cause far more trouble than was warranted.

Q. Why was it thought that questions about, for example, sexual practices or lifestyle, would be necessarily aggressive? Is there not a way of doing that that isn't aggressive, that is neutral and for information purposes only?

A. Well, we could not see how that could practicably be done in an open-donor session.

Q. Do you think it would have made a difference if there had been the ability at donor sessions for there to be privacy? Would that have made a difference, do you think, to your view?

A. No, I don't think it would, on balance.

Q. Then you set out your reasons in that letter, so if we can just have a quick look at that:

"There are no specific medical questions, the answers to which indicate presence of, or liability to develop AIDS. Answers to non-specific questions about loss of weight, enlarged glands, night sweats, etc. Are thought to be too vague, misleading and possibly frankly unhelpful."

Paragraph 2:

"Even if specific questions were available, it is likely that the correct answers may not be offered where necessary, indeed the truth may be positively

concealed."

Just pausing there, that is something you referred to in your earlier answer. What was your view about the extent to which donors were, in fact, positively concealing risk factors when being asked questions generally about their medical condition and specifically in relation to AIDS?

A. I'm not saying in any way that that was the norm, I'm just saying it is possible.

Q. Had you come across instances where that had occurred?

A. Me personally, no, but nonetheless the possibility remained.

Q. Then you carry on at 3:

"The evidence to date suggests that those would-be UK donors most likely to develop AIDS come into the category of two of the 'Hs' namely homosexuals (especially the more promiscuous ones) and heroin or other drug abusers. The other Hs probably do not apply for practical purposes. Routine questioning of donors in the open forum of a clerking desk to seek information on their personal habits of this sort is considered to lead to:

"a) rare disclosure of the truth, or

"b) deliberate withholding of information, or

"C) a very large number of

annoyed/irritated/puzzled/upset donors to whom the questions do not apply. The resulting loss of donors as well as the aggro, could be awful."

I think that's what you have just told us. Then you say in 4:

"A sense of perspective should be maintained. The infections known to be associated with AIDS are far more prevalent in the USA even in their so-called normal healthy donor populations. The incidence of donors with past hepatitis B, Herpes simplex, CMV, Syphilis etc in the UK population is so much at variance with the USA experience that the ill-defined questionnaire designed for American donors is considered inappropriate for the UK, at least on present evidence and at the present time."

I think you told us that you considered that the incidence of AIDS in the donor population was thought to be low but here you are saying something slightly different, that, actually, in the population in the UK as a whole was also much lower than in America. Was that your understanding and belief in June 1983?

A. That was the belief at the time and most of the information coming in about AIDS was arising at that time from the States and it was not seen as a massive problem in this country, at that time. Obviously,

things changed quite drastically over the next few years.

Q. Then if we can go over the page, please, just to pick up on the last penultimate paragraph, and then you say:

"If an inordinate fuss were made about AIDS, then possibly important other donor information may be at risk of being overlooked, ignored, not disclosed etc. There are already very many conditions about which information is already sought. It seems most reasonable and appropriate that at least as far as this country is concerned, AIDS should be dealt with by so many other disorders, and be covered by the blanket ruling that should there be ANY MEDICAL DOUBTS about the fitness to donate, then that donor should discuss the matter with the Medical Officer in charge of the session."

So what was your concern there, that if one elevated the question of AIDS by particular questions about lifestyle and practices, and so on, one might be at risk of losing the other important information about other infections?

A. That was one of the concerns, yes. And I felt -- as I said there, we felt try to keep things in a reasonable perspective, bearing in mind what was

known at the time.

Q. And so those matters that you have just set out at paragraphs 1 to 5 go, really, primarily, don't they, to the question of whether or not donors should be orally questioned in a donation session.

What was your rationale for taking the approach you did in terms of the handing out and dissemination of the leaflets? Why was it that you took the view that they should only be available at sessions rather than either being provided in call-up cards or individually to donors as they arrived at the session?

A. We felt that call-up cards was not the most appropriate way, not least because that would not cater for the walk-in donors.

Secondly, we felt that if the leaflets were available on display for donors to read before coming to the clerk, that was probably the most private or discreet way that could be addressed without causing too much anxiety, and they would give the donor the opportunity of disclosing or not as appropriate when they finally got to the clerk.

Q. So if we then look at another document to see what was happening in 1984. Can we go, please, to DHSC0002241_002.

So we have here a letter to the DHSS dated

28 March 1984, from you, entitled "AIDS LEAFLET". You are replying to a request for information from the DHSS about how the leaflet is going in the region. You say you have stock of approximately 13,000 and you have issued approximately 1,000.

What does that mean? What does "issued" mean?

A. 1,000 leaflets were used at donor sessions.

Q. Right. And then you say the rate of usage per month is now negligible. Then you set out:

"Method of distribution ... leaflets are displayed with other BTS leaflets at sessions at the clerking-in table and at the tea table."

And then you say:

"5. The effect on donor attendance: none as far as we can see.

"6. Feedback ... none for practical purposes."

Picking up a couple of those points. Is it right to understand that by March 1984, donors were not picking up and removing from the tea table, the clerking table, the leaflet. Is that what "now negligible" means?

A. Yes. I think one has to remember, again going back to the fact that this is now March 1984, which is a very different situation already from the situation in 1982 when there was so much public worry. By 1984 things

were beginning to settle down somewhat and most of -- the vast majority of the donors did not perceive that AIDS was quite as bad a problem as was first thought.

Q. But of course at this time there is no screening in place so the only, sort of, line of defence against high-risk donors is via the leaflet.

A. Correct.

Q. Was it a concern to you that actually having them available didn't seem to mean that they were being read?

A. That's the one. That could be argued, but I don't know whether that was the truth or not.

Q. And then moving on then to the effect on donors of the leaflet, it is right to understand that your concerns about the impact of the leaflet, in terms of putting donors off and the consequence that would have for the blood supply, hadn't, in fact, been borne out in your area and the donors didn't seem to be bothered one way or the other about the presence of the leaflet?

A. I think that is a very fair assessment, yes.

Q. Moving on then to the second AIDS leaflet, and then that will bring us to lunchtime I think, can I take you first of all to a meeting of the Western division of the region -- of the Blood Transfusion Service, of 7 December 1984, which we find at NHBT0113565.

We can see there you in attendance, and if we turn over, please, to the second page of that document, we can see at "AIDS":

"The general problems of Regional Transfusion Centres relating to AIDS was discussed. It appears that Centres will not be able to test for HTLV III antibodies for at least six months. The promised DHSS AIDS leaflet was not yet available. Four Centres have produced their own version for the time being. Concern was expressed at the lack of information from the DHSS, particularly in relation to heat treatment of Factor VIII."

Two matters arising from this, were you, can you recall, concerned about the fact that the promised AIDS -- second version of the AIDS leaflet was not yet available?

A. I do not recall exactly what the situation was at that time. I don't think we produced our leaflet independently. Because I felt the -- and I think I was not alone in feeling, that we should go by whatever was agreed nationally. And so --

Q. So you don't -- I'm sorry.

A. So I don't think we would have set out to produce an independent leaflet of our own, which might --

Q. So you don't think -- sorry --

A. So it varied. Sorry.

Q. I spoke over you, sorry. I interrupted you. You said: it might ...

A. I don't think it would be right -- didn't think it would be right for us to produce a leaflet which might be at variance with what was ultimately thought as being correct elsewhere or might conflict, perhaps, with the Department of Health document when it finally came.

Q. So is it right then that you think it is unlikely or you weren't one of the four centres to have produced their own versions -- second versions of the AIDS leaflet?

A. I don't recall our -- I don't recall the Oxford Centre producing a leaflet independently, no.

Q. Then if we turn then to two more documents before we break for lunch, DHSC0002159. This is a Department of Health circular issued in January 1985 and it is to Regional Health Authorities, and if we go down, please, to paragraph 4 revised distribution arrangements. We can see there:

"Ministers have decided that it is essential that the revised leaflet be brought to the attention of each donor on an *individual basis*. This would normally be achieved by sending each donor a copy of

the leaflet with his next call-up notification. It is realised that this may not be practicable for industrial sessions (or for new donors presenting at sessions) -- in these cases alternative arrangements should be made to ensure that each donor is individually given the leaflet before any blood is taken. Displays of leaflets, while continuing to be useful, will not meet these new distribution requirements. Because the advice has changed significantly, the revised leaflet should be sent even to those who received the 1983 version."

Just pausing there. Do you recall whether or not that circular made its way to you and you were aware that there was an instruction from the Department of Health as to how leaflets -- how the second version of the leaflet should be distributed?

A. I must be honest, I don't recall that document. If I did see it, I presumably would have been required to act upon it but I don't recall it, I'm sorry.

Q. Then last document then, which -- before we break for lunch -- is NHBT0000745. This is a letter dated 20 October 1989 to Dr Gunson from the deputy director at the Oxford Centre. It says:

"Colin [that's you] has left to attend [a] meeting in New Orleans. In his absence I have

obtained a copy of his reply to Bill Wagstaff's letter of 7th June. He does not appear to have replied to the second letter dated 6th July."

He says this:

"I can find no evidence that the AIDS leaflet made available to Blood Transfusion Centres in 1984 was formally issued to donors. Indeed the first time the AIDS leaflet was sent to donors individually with their call up card or as a hand-out at sessions was in March 1985."

So there seems to be a gap, Dr Entwistle between the instruction coming from the Department of Health in January 1985, that the leaflet should be provided individually to donors, and that being put in place at Oxford in March 1985. Do you know why that was?

A. No, I'm sorry, I don't.

MS SCOTT: Sir, I'm slightly over time. I'm going to move on now to a slightly different topic in relation to HIV and AIDS. Now might be a good time for a break.

SIR BRIAN LANGSTAFF: Yes, the only thing which arises possibly out of that last exchange is the health circular was addressed to Regional Health Authorities, I think. It was not addressed to Regional Transfusion Centres, as such.

MS SCOTT: Yes, that is correct.

SIR BRIAN LANGSTAFF: So, presumably, the route would be that it goes to the Regional Health Authority and if they think that it is of sufficient importance, as they ought to, in the case of a circular, they would pass on the information to whoever needed to know. Would that be the way that it came to you?

A. That's the way it should have come to me but, as I said just now, I do not recall seeing that document.

SIR BRIAN LANGSTAFF: But obviously that might take a short while but that's something which I shall have to consider.

At the moment, I'm considering when we should come back after lunch, and we will make it 2.00, I think.

So 2.00, if you please. 2.00.

(1.03 pm)

(The short adjournment)

(2.00 pm)

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: Good afternoon, Dr Entwistle.

A. Hello.

Q. Just a couple of points to pick up from this morning's session. First of all, just to make a correction. I was showing you the forms before lunch and suggested that I hadn't found a form between 1965 and 1985. It

has been pointed out to me that we do have a form from 1977. I don't think we need to go to it but just to correct the transcript, the URN for that is DHSC0003734_066, and it was pointed out to me that Dr Napier was taken to that form.

The other, second point I wanted to pick up, before I ask you about arrangements in Oxford for HIV testing, was a follow-up question from the question Sir Brian put to you before we broke for lunch and that was to just ask you what your relationship was like with the Regional Health Authority, what the communications were like and how often you met, and so on?

A. Well, not so much with the RMO, Regional Medical Officer, but with others in the Health Authority communication was pretty regular and very good relation with HR and with the gentleman who was overseeing the Blood Transfusion Service.

Q. We were looking earlier at a circular and you thought that that hadn't made its way to you. You certainly couldn't recall seeing it. Was the health authority fairly good at disseminating information to you that they had you ought to see or were they not so reliable?

A. I don't think I'm in a position to comment on that.

I think one of the big problems one might be up against, as I am sure you must have found too, is sometimes when you get a massive document it is awfully easy to overlook a paragraph.

Q. So turning then to the arrangements in Oxford for HIV testing. Can we turn first to NHBT0004521. So, this is -- so NHBT0004251.

SIR BRIAN LANGSTAFF: I think we may be drawing a blank on that one.

MS SCOTT: Perhaps I can deal with this without going to the documents. We will see how we do. Maybe we can come back to it if we don't get very far. Is this right, that initially when you were being asked -- when planning for HTLV-III testing was being undertaken, the initial view from your centre -- from you and your centre, was that you would need to do some building work before you would be able to start screening donations for HTLV-III, is that right?

A. That was our original thought. However, because it was apparent, very readily apparent that the rest of the centres were going to start screening as from -- I think it was the middle of October '85, we had a duty of obligation to get going by that date so we had a radical re-think of the arrangements in our microbiology section of the laboratory, and we were

actually able to start HIV screening on time.
Q. The reason you were able to do that is because, as you say, you had a radical rethink and you reorganised the space, did you?
A. Yes.
Q. Did you ever get your building work?
A. No, we didn't do that. Our original thought was we would possibly take over part of the store which was next door but, in the end, that was not necessary, thank goodness.
Q. Then, let's try this document, DHSC0000177. So this is "AIDS, Booklet 2, Information for Doctors Concerning the Introduction of the HTLV-III Antibody Test", dated October 1985.
If we turn over the page we can see that this is a letter to "All Doctors in England", from -- and if we turn over to page 3, we can see that it is from Dr Acheson, the Chief Medical Officer.
If you turn back please to page 2., I want to ask you about what arrangements were in place in Oxford when HTLV-III screening was brought in.
So we can see that it says, at the beginning of this letter, that:
"From a date in mid October [second paragraph] to be announced, all blood donations will be

screened ..."
And:
"At the same time, alternative facilities for providing antibody tests on a confidential basis will become available --
"a. at [GUM] clinics.
"b. by arrangement with the patients' general practitioner at certain other clinics as arranged and publicised by the District Health Authority."
We have heard and seen evidence that there was a concern on the part of the Regional Transfusion Directors that there should be alternative venues for screening, so as to avoid high-risk donors coming to donate in order to get a HTLV-III screening test; is that right?
A. Certainly, we did not want high-risk donors coming in just to have the benefit of the test.
Q. So can you recall whether, when you started screening in Oxford, there were these alternative arrangements for those that wanted to get an HTLV-III test to go and have one?
A. I understood that they were actually in place, yes.
Q. Then we go down to the bottom of that second page:
"It is essential that all individuals who are found to have positive antibody tests receive

counselling both in order that they may understand the meaning of the results and to advise them how to avoid transmitting the infection to others."
Then, if we go over to page 11, we see under "Counselling", it says:
"Within [GUM]/Sexually Transmitted Disease clinics multidisciplinary collaboration involving social workers, clinical psychologists and health advisers is usually available to assist the proper counselling and support of AIDS sufferers and their contacts. Support is also available from some community based groups ..."
And some details are provided.
On the question of counselling, what counselling arrangements were in place and were the donors who tested positive able to access?
A. Well, I personally was only involved in one (inaudible) came, and in fact I was the person who initiated counselling. I arranged to meet the lady, who lived in Reading. I met her at the Royal Barts Hospital and explained the situation as best I could. I had had the benefit of going to a meeting in St Mary's, Paddington, on how to counsel patients who might have HIV, and I was able to sort out a probable mode of acquisition of infection and point her in the

direction of her GP, who might then point her further for appropriate further management and possible treatment, bearing in mind that at that stage there was no specific treatment available for HIV.
Q. So it wasn't -- and I appreciate you are talking about the practice of counselling one individual, but as far as you -- there wasn't a practice of trying to access these multidisciplinary-type team approaches of counselling for donors?
A. No, we were not involved in that at all.
Q. Then if we can just go to page 8 of this document to look at the confidentiality provisions:
"The strictest confidentiality must be maintained when an HTLV III antibody positive individual is identified. Where a person is tested for HTLV III infection or for its complications and it is thought to have been sexually transmitted, health authorities have an obligation to maintain confidentiality of information under the terms of the National Health Service (Venereal Diseases) Regulations ... Unless the patient has given his consent, personal health data relating to him must not be disclosed to anyone for any purpose other than the health care of that patient, except where the disclosure is necessary to prevent the spread of

infection. Disclosure of this information for purposes other than medical or public health reasons could lead to serious consequences for the informant. Adequate safeguards to protect individuals against unauthorised disclosure must be adopted."

One could read that there are two different levels of confidentiality in relation to the results of HTLV-III tests depending on how the person became infected, but is that the way that it was read by you and your colleagues at Oxford or were all donors treated in the same way in terms of confidentiality?

A. As far as I'm aware, they were all treated the same way. Confidentiality was maintained in that no information was passed on to anybody except with the specific consent of the individual concerned.

Q. And that would include, would it, passing on test results to GPs or to other clinicians for further treatment?

A. Indeed.

Q. And would that also include passing on information to family members or partners of the donor, infected donor?

A. We would not do that, but obviously we would stress to the individual concerned that they would be the ones to pass on the information as appropriate. But

certainly we did not feel that it was either other obligation to pass it on nor should we pass it on.

Q. Moving on then to a slightly different HIV-related topic, if I can put it that way. If we could have, please, NHBT0092851.

If we could go, please, to page 2 of this document, you can see that this is the minutes of a Western division of the NBTS consultants meeting of 4 October 1985, and we can see a third down that you were present at that meeting.

If we could go to the bottom, please, of this page. We see at paragraph (c):

"It was agreed that absolute confidentiality should apply to donors found to be HTLVIII antibody positive. A proposal from Dr Moss, Consultant in GUM that GUM specialists be notified was not accepted."

So that bears out the evidence you just gave us. Then it is (e) that I wanted to ask you questions about:

"Aids update. It was accepted that there would be substantial amounts of untested long life frozen components in circulation (mainly in hospitals) at the time of the general announcement on testing. Centres were operating different policies for the use of this material. The [over the page] testing of frozen

stored red cells was also considered. It might have to be accepted that current stocks cannot be tested -- many donations were in fact collected before the prevailing epidemic. The washing and reconstitution might also reduce the risk of virus transmission. New donations obtained from past contributors could be tested and when found negative their preceding donations be certified as being safe."

Now, just with that prompt, if I can put it that way, can you recall what the practice was in the Oxford Centre for any stocks that the centre had themselves that had been harvested prior to testing that might perhaps be frozen, whether or not those were released post the testing date as untested components and products?

A. Well, we had no frozen red cells at all. So that can be forgotten about and I wasn't -- I can't recall offhand what other products you might be thinking of.

Q. Well, would you have, for example -- what long life products, products with a long shelf life was the centre -- would the centre or could the centre have been holding in October 1985?

A. There could have been fresh frozen plasma, which would have been in store, yes. And that's all I think we would have held.

Q. So can you recall whether you tested that fresh frozen plasma and then released it or whether you would have released it post-7 October 1985, despite the fact that it was untested, because it had been collected before that date.

A. I see what you are getting at and I can't recall exactly what did happen. It would have been nice to have withdrawn it before testing it, which we couldn't do anyway.

But I suspect -- I may be proved wrong, but I suspect it would have been issued. Even though it had not been tested, it would have been collected for introduction of testing.

Q. When you say you couldn't have tested it anyway, why was that?

A. Because we would not have had separate samples from that frozen plasma.

Q. So you would have had to test the whole batch?

A. Indeed.

Q. Would that not have been possible?

A. Not really. I think we would probably have to have abandoned any frozen stocks.

Q. Then, turning to the stocks that were in hospital, which was given specific regard in the meeting minute we just looked at. So the expectation of the Western

division was that there would be, at the time that testing came in, substantial amounts of untested long life frozen components in circulation. Can you recall what the practice was at Oxford in terms of that material? Do you think Oxford recalled those products and tested them and then released them or do you think they were left in circulation to be used post-testing but as untested products?

A. I can't recall but I suspect they would have been issued in the normal way, even though they had not been tested prior to screening.

Q. So you can't recall but you think it is likely that there would have been some products both issued by the Blood Transfusion Centre and issued by the hospital blood banks, after the date on which testing for HTLV-III came in and those products would have been untested. Is that a fair summary of your evidence.

A. Would be untested, yes.

Q. Can we then turn, please, to NHBT0019630_003. Now, I wonder if you can, first of all, help us to understand what this document is and how it came into being. We can see it is a witness statement from you and it goes over several pages and then, if we go, please, to page 7, we can see the date of it, 4 January 1990. Can you remember what this witness

statement was produced for, why it was produced?

A. I have no recollection what that was for.

Q. The paragraph I wanted to take you to starts at page 6. You talk there about testing and then, in the second and third paragraph, you talk about counselling, and then it is at the end of the last paragraph I want to pick up. It starts about halfway down there:

"Should a donor become HIV infected, the corresponding antibody does not develop and become detectable until after a timelag which varies from a few weeks to perhaps several months. The risk of a donor giving blood during such a timelag or 'window' of infection has been calculated to be in the order of about 1 in a million, that risk being less in the UK than some other countries who accept donations more than twice a year from the average donor. Consequently, if a donor were to become infected there is a good chance of there being only one previous possibly virus-containing plasma donation which would be most probably still held in quarantine anyway before being pooled and fractionated."

We will go on to look at the situation in relation to plasmapheresis donors.

Just pausing there, was it the practice of

Oxford -- at Oxford to keep back donations of new donors until a second HTLV-III test had been carried out, to guard against the risk of them donating during that window period?

A. Not as I recall, and I don't recall any recommendation coming that we should have done either.

Q. So that presumably would be both in relation to new donors and in relation to established donors, there was no policy?

A. Indeed.

Q. Then if we pick up then where we left off in that document and look at the situation in relation to plasmapheresis donors:

"The situation could potentially be slightly different in respect to donations given by pheresis, in view of the much greater frequency of donation, and also in view of the rapidly expanding role of pheresis in meeting plasma demand."

So then you go on to say what the new code of practice says in relation to frequency of donation.

You say there:

"In Oxford, most of our approximately 400 pheresis panel donors arrange to come monthly. Although this frequency of donations could be a possible problem if a donor were to become infected,

safeguards are provided by our knowing the donors concerned very well, by undertaking rather more rigorous health checks on them before embarking on pheresis and at regular intervals thereafter, by routinely screening every donation, and by keeping their donations in quarantine, frozen both at the Centre prior to shipping to BPL, and for several months at BPL before fractionation. Although we have no proof for our impression, we believe that pheresis donations may possible if anything, constitute a lesser risk from HIV 'window' infection of plasma for fractionation than conventional donations."

Looking at that, does that accord with your recollection that there was a different system for pheresis donations?

A. Yes.

Q. And you kept donations in quarantine until another test, effectively, had been taken to guard against the risk of a donation being taken during the window period?

A. Yes, that is a fair comment. The risk we felt would be significantly less.

Q. What was the position in Oxford in relation to products such as platelets, which needed to be used within a few hours of the donation being taken?

Was it possible to always test the platelets for HTLV-III?

A. Yes, because the platelets would be collected on day 0. The test would be done first thing next morning, or even that same afternoon of day 0, then they would be available for issue after testing had been completed. There is a window of using platelets for up to three days, possibly more.

Q. Was there any practice of putting warning labels or providing any kind of warning on products that, for example, the blood or the product may still contain viruses because of this risk of donations being made in the window period? Because clinicians would be expecting, wouldn't they, post-HTLV-III testing coming in, that the product would be free from HTLV-III, but in fact there remained a risk, didn't there, that the product may still contain HTLV-III?

A. There remained an exquisitely small risk, yes, but I don't think any such warning was ever put onto a product itself.

Q. Can we turn to a document just to get your evidence as to whether or not you were aware of this document and, if so, what you understood it to mean. It is SHPL0000163_033.

It is a WHO Expert Committee on Biological

Standardisation, 29th report, and the date at the bottom is not very clear -- 1978, I think it says.

Then if we turn over to the second page. We get the more detailed title of the report which is "Requirements for the Collection, Processing and Quality Control of Human Blood and Blood Products".

If we can turn over, please, to page 18, the particular that I wanted to ask you about is on the right-hand side, B.3.6.

Can we go over to the next page. Perhaps we will come back to that, we seem to be having a little difficulty with getting that page up.

I can ask you the general question: was that a publication that you were aware of and that was something that you were familiar with?

A. No, I can't recall having ever seen that before until a copy was sent to me recently.

Q. Can we try this document then, PRSE0001355. We have an original Transfusion Directors meeting with you in attendance on 20 January 1988. If we can turn, please, to page 6 of that document.

We can see halfway down a title "Package insert from Platelets":

"Dr Entwistle questioned the need to provide a package insert for platelet preparations.

Discussions on this centred on the need for up-to-date Notes on Transfusion (to which general package insert might refer) and appropriate training of staff. It was recalled that at the Product Liability Meeting, Mr Evans, (Solicitor) had pointed out that it was also necessary to anticipate what people may do wrong. The Chairman asked Dr Moore to approach the DHSS Solicitors for further advice."

Can you recall what this was about and why you were questioning the need to provide a package insert?

A. At this time, I can't recall what that was about, sorry.

Q. Do you think it was -- could it have been in order to warn of contra -- in trajections or risks of platelets, in relation to platelets?

SIR BRIAN LANGSTAFF: There are two questions which emerge. I thought you were asking about could he recall why he was questioning the need for the insert. Your question now seems to be what an insert might have been there to do.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: I think we may take it that a package insert will say whatever a package insert says. If Dr Entwistle can't remember then I don't think he can probably help us further on this.

MS SCOTT: Okay, Thank you, sir.

I have a handful more questions to ask you in relation to HIV.

Can we turn now to BPLL0010773. So this is a letter from you to Dr Snape, dated 13 January 1986, and you are answering various questions that have been put to you. Paragraph 1, you explain that donations at Oxford were tested from 7 October 1985. Then you say this at paragraph 3:

"Retrospective investigation of any positives that turn up will obviously be pursued up to six years if possible."

I just wanted to ask you about the systems in place in Oxford for, effectively, look back. So when a donor tested positive, what action was taken by Oxford to investigate whether any previous donations had been used by patients?

So was there a system in place for carrying out those investigations?

A. There was what I could best describe as an ad hoc system, insofar as this was not a regular routine activity. On the other hand, obviously, when a positive case turned up, it would be necessary to go back and see what we can find by way of further information about that same donor.

Q. And do you know what the reference to six years -- why you were limiting it to going back six years?
A. I was puzzled when I saw that this last few weeks. And I can only imagine it is because it was a general feeling that there was no risk of HIV in this country prior to about six years before the testing had started. In other words, the late 70s.
Q. And do you recall whether, as part of the retrospective investigations you would have taken steps to try to ensure that the eventual recipient of a donation was informed that they may have HTLV-III?
A. That is an obvious corollary why there was a positive, but I don't recall there ever being one.
Q. And equally, would the retrospective investigations have included informing BPL or PFL that they had received infected or potentially infected donations?
A. I think it was something they would need to know about in case they still had material in the system.
Q. So that is something they should have known about. Can you recall whether or not that was something they were told about?
A. No, I can't offhand, I'm sorry.
Q. And were there any circumstances or do you have any recollection of whether or not information would have been provided to the haemophilia centre about the fate

of any infected donations?
A. No, I don't recall any such information being passed on.
Q. And then, just a further document on HIV look-back. NHBT0015108.

It is a letter from Dr Gunson to all RTDs saying:

"[He has] been asked by the Department of Health to contact you with respect to the identification of any possible blood donations which may be implicated of transmitting HIV to patients as a result of blood transfusion.

"Could you please identify the blood donors that you have found to be confirmed HIV antibody positive since the commencement of testing and send a list of the donation numbers of the previous donations (if any) from these donors, together with the dates of delivery, to the Consultant Haematologist at the hospital concerned. Some of you may already have this information available from 'look-back' programmes.

"The Department of Health are anxious that no potential beneficiaries are over-looked ..."

This is some six years later than the letter we saw from you to Terry Snape, and you are being asked by Dr Gunson to carry out look-back. Can you recall

what action was taken as a result of this letter?
A. Frankly, no, I can't.
Q. Then last issue in relation to HIV, can we look, please, at NHBT0019630_003.

So this is the witness statement that we looked at earlier, and if we can turn, please, to page 3 of that document. The second and third paragraphs you are talking about the stockpile of plasma that had built up at BPL as a result of the rebuilding of BPL, and the reduction in their ability to fractionate.

It is at the third paragraph I want to pick it up. You say at the beginning of that paragraph that the problem with having the stockpile was that the HTLV-III testing came in and the stockpile was untested, and you say that the stockpile was affectionately referred to as the "iceberg". You go on to say this:

"All Centres had to examine the records of all donations sequestered in the iceberg to see whether their corresponding donors had donated blood more recently, had been screened and had perhaps had proved positive for HIV 1. In Oxford we traced about two thirds of the many thousands of donors concerned and were able to confirm that they had subsequently been bled, tested and were found clear. We understand

that the remaining donations, from donors for whom no further information was available, could not be used, and have not been processed."

So is it right to understand that the two-thirds of the donors that you did find, that was because they had subsequently come back to the centre to donate and had been -- their donations had been tested because HTLV-III screening had been introduced by that stage?
A. That was my understanding, yes.
Q. And then the third that you couldn't identify, that was because they hadn't returned to the centre to donate and so there were no tested donations for that third --
A. That is correct.
Q. Were any steps taken to try to get in touch with that cohort of donors, to see whether or not they would be willing to come back to the centre and have their --
A. Not that I'm aware of.
Q. I'm going to pick up now then with HCV and hepatitis C and look first at a document from October 1990. NHBT009472_050.

We looked at some documents last week with the witnesses who gave oral evidence last week, and I don't intend to put you to the same documents that they looked at but I just want to show you a handful

of documents to get your evidence on what you can recall about your thinking at the time.

It is NHBT009472_050.

No? Okay. Let me come back to that if we have better luck with the system in relation to that one.

Can we try this document, NHBT0000074_030.

This is a letter you wrote to Dr Lloyd from the northern -- Newcastle transfusion centre. We have heard evidence that Dr Lloyd began testing at his centre prior to the date that had been set for all Regional Transfusion Centres to begin their HCV testing.

It is a response to a letter to Dr Lloyd informing Regional Transfusion Directors of this plan. We have looked at it before so I don't propose to go to it now, but for the transcript it is NHBT0000073_014 and this is your response to that letter. We can see here that you say:

"I am utterly dismayed at your proposal to break ranks from the rest of the BTS of England and Wales by embarking on HCV testing in the way you have described.

"I know you already realise that we have a National Directorate who have striven hard to try and generate so cohesion into our Service and your

proposal can be viewed as nothing less than destructive, when other Centres are aiming to introduce their testing not so long afterwards. I would have thought commonsense would have indicated that we should all introduce testing for this reagent from the same agreed date.

"I would fervently ask you to reconsider."

If I could ask you some questions about your thinking in the light up to writing this letter. We have heard evidence that the UK was -- introduced testing rather later than a lot of other developed countries. Was that something that you were aware of at this time?

A. I know other countries were introducing it at different rates but, on the other hand, that is not surprising because we all have different resources available at our disposal, but I was very firmly of the opinion, as you will have gathered from this letter, that, having got a National Directorate with its own policy for the service as a whole, that we should follow the directorate's policy and not break ranks in this way. It could be argued that Dr Lloyd was providing the additional benefit of having some extra donations screened before, whereas others not, but on the other hand I still think that the tone of

that letter was right, that it should have been done as from the agreed date.

Q. Would you accept that, by introducing screening for HCV earlier, Dr Lloyd was producing a safer product for the patient?

A. That was not the issue. I would not disagree with that in principle but that was not the issue which I was referring to.

Q. But it was an issue, wasn't it? Wasn't that an issue that needed to be weighed in the balance against the issue that you have just spoken about, the issue of cohesion and all centres beginning testing together, would you agree with that?

A. I would agree it is another view but, on the other hand, I felt then, and I still feel, that we had an approximation to a national service, in this case a National Directorate, and that we should have followed the Directorate's guidelines. Potentially that could lead to chaos if we all did things differently.

Q. What was the concern about that? What chaos would ensue if different -- testing was brought in at different times at different centres?

A. Would it mean that some centres who were not testing would have donors who might say this is unfair because

those people up the road have got blood which has been tested and yet you can't do that for me. That is an argument that could be put forward. I quite agree with that. But I was concerned to establish the screening in the approved manner in accordance with the directorate view.

Q. So for you it was more important, was it, that there should be cohesion amongst the Regional Transfusion Centres than that the blood donations should be tested for hepatitis C in some areas several months early?

A. I have already answered that question.

SIR BRIAN LANGSTAFF: I wonder if I may ask a question arising out of this. Could we just have the letter back up, please?

MS SCOTT: NHBT0000074_014.

SIR BRIAN LANGSTAFF: If we have got it, it is the last sentence of the second paragraph:

"I would have thought commonsense would have indicated we should all introduce testing for this reagent from the same agreed date."

What were the particular aspects that make it commonsense? "Commonsense" is a very misused word, it often means "thinking as I do as opposed to you do". So what were the particular aspects of commonsense that you thought led to the same conclusion as you

were reaching?
A. Well, this is another example of what had been amiss with the Blood Transfusion Service over the years. That people were doing things differently in different places. There wasn't commonality, and there were efforts being made, and the National Directorate was a first step in that direction, to try to get some commonality and uniformity throughout the system, so we all had the benefit of doing things in a cohesive manner.
SIR BRIAN LANGSTAFF: So, in effect, the commonsense is the same point as the cohesion point?
A. Yes.
SIR BRIAN LANGSTAFF: Thank you.
MS SCOTT: Is it right to understand that in relation to -- I think I will come back to that point. We will see if we can get the other document up that we were unable to see earlier.
I'm going to turn now to the question of the arrangements in Oxford for counselling for hepatitis C. I think the best way to do that is through looking at the documents. Can we look at OXUH0001862_004.
This is a letter, "Dear [blank]". Then if we go over the page we can see that it is from Dr Dike, the

associate specialist at the Regional Blood Transfusion Service. Dr Dike was leading, was she, I believe it is -- it is a female doctor, is that right? Was leading on the issue of donor counselling for hepatitis C, is that right?
A. Correct.
Q. And this letter appears to be to a blood donor who has tested positive for hepatitis C as a result of screening of the donation, and so -- the first paragraph just sets out some background and picking it up at the second paragraph:
"I am writing to let you know that our newly introduced routine test for hepatitis C antibody has given positive results on your recent blood donation. This indicates that you have had an infection with the hepatitis C virus at some time, and therefore might be able to transmit this infection to a patient being transfused with your blood. I am sure you will appreciate that we cannot accept blood donations which might cause illness, and therefore I regret that we shall now have to remove your name permanently from the donor panel."
Then it sets out some information about hepatitis C and the risk to the liver.
And you say it usually causes a mild

inflammation of the liver -- or Dr Dike does, but a small proportion can become quite ill and have long-term effects. Then this:
"I think we should inform your own doctor of the results as he may wish to discuss with you the possible need for other tests. I would be grateful if you could complete the enclosed form and return it to me. Your answers will be treated confidentially, and the information you give may be helpful in tracing cases of hepatitis and sources of infection. After I have received your reply I will send your doctor the results of our tests on your blood. I suggest you arrange to see your doctor about a week after you write back to me."
Then over the page:
"Your doctor should be able to answer any questions you may have in mind after reading this letter, but if you need further assistance please contact me."
Then, again, making the point that they should never donate blood again.
So is it right to understand that your practice for those donors that were HCV positive was not to make an appointment at the centre but to inform them of their infection by letter and seek permission to

share the diagnosis with the GP and for the GP to pick up the baton in terms of counselling and decisions about further treatment?
A. Yes, that's fair.
Q. And were you aware that other centres were carrying out different practice, that they were counselling donors themselves?
A. I was not aware what other centres were doing. I had no occasion to ask.
Q. And why was it that you took that route rather than having -- calling the donors in yourself? When I say "yourself", I mean calling the donor into the centre and the centre counselling the donors, at least initially?
A. I can't recall what the thinking was behind that but that was the thinking that we adopted at that time.
Q. And do you know -- there was an offer made by Dr Dike in this letter to the infected donor to call for a further information should the donor want to. Do you know whether or not such phone calls were received by the centre from donors for further information?
A. I don't know offhand.
Q. Then if we look, to complete the picture, at the letter then sent to the clinician, the GP rather, if we look at NHBT0053158.

Again, we have another letter here, "Dear [blank]", from Dr Dike. This appears to be the letter sent to the GP:

"Your patient is a new blood donor, and routine testing of a blood donation taken on [blank] is positive for hepatitis C antibody ... The donor has been informed of this and has been given this information to bring to you. We have further tested [blank] blood for Hepatitis B, Syphilis and HIV 1 and 2 antibody and I enclose those results."

Then the letter goes on to give some information about hepatitis C and encloses some information about hepatitis C which the doctor may use to counsel the patient with. And then some information about sending samples to a virologist at Public Health Laboratory Service.

So presumably this is the letter, is it, that was sent to the GP if the infected donor gave consent to the transfusion centre to get in contact with their GP?

A. Indeed.

Q. I'm going to just ask you a couple of questions about surrogate testing for what was then non-A, non-B. I understand from your statement that surrogate testing wasn't implemented at Oxford on whole blood

donations but it was implemented on -- or at least ALT testing was implemented on plasmapheresis donations; is that right?

A. Correct.

Q. What was the reason for that?

A. Well, for -- the main reason was that we were going to see the plasmapheresis donors much more regularly, much more frequently than we felt it was appropriate, that we ought to try and take a closer look at them for that reason. Even though we were well aware the ALT test by itself is deeply flawed in terms of its relevance to hepatitis C.

Q. But the thinking was, was it, that for a donor that donated, and we saw in a previous document, once a month, more stringent testing should -- or some testing to -- even though imperfect, it was better to have ALT testing than nothing at all?

A. It might help.

Q. How in practice did it actually work? If there was a raised ALT reading on a plasmapheresis donation, what would happen? Would the donor be deferred? Would it be kept in quarantine? What would happen?

A. That donation would be quarantined, but -- and the donor would be re-tested shortly afterwards -- well, within the next month, and very frequently the ALT

test might be back down, normal, or whatever. The ALT was a very unreliable test.

Q. So if the reading was then back to normal, would the assumption be that this wasn't a non-A, non-B, this was -- the ALT was raised for some other reason and the donor could continue to donate and the donations could continue be used?

A. That was our thinking at the time, bearing in mind that there was no actual specific test for hepatitis C at that time.

Q. And if the ALT reading continued to be elevated, what would happen? If it was elevated in the second test what would happen then?

A. We would seriously have to consider removing that donor from the pheresis panel.

Q. And what would the donor be told?

A. They would be told that there appeared to be something which was not quite normal but we did not know what it meant. It is unlikely to be serious but we did not know any more details at that time and subsequently other tests might be able to confirm a different story but that's all we could do at that time.

Q. And what impact did the introduction of ALT testing on plasmapheresis donations have on the amount of donations available from plasmapheresis donations,

were many quarantined?

A. No, they were not. There were very few.

Q. Did that tell you anything about the concerns that had been raised about introducing ALT testing, the whole blood donations?

A. It just raised another unknown, which didn't really help in some respects. It helped only in the respect that, well, perhaps this donor would be put to one side for the time being, and then reviewed maybe a few months down the line. But as I say, it was not a reliable test, and most elevations of ALT are due to other causes.

Q. Given the experience of plasmapheresis donations, ie that the introduction of ALT testing had not had an impact on the amount of donations available, was there any re-thinking about the position, about the decision to introduce ALT testing and surrogate testing for whole blood donations?

A. Not really, for two reasons. One is that it was a practical consideration of getting the test actually done. And secondly, once again we had this question of: what was the national policy? What was the directorate thinking? Should we not be following in the agreed pattern of behaviour?

Q. Is this right, even if you had been a supporter of ALT

testing, because of your views on the national policy, you wouldn't have introduced it in any event?
A. I think that is true. What would have been the obvious thing to do, if one has sufficient evidence to be really dogmatic about it, is to go back to the Directorate and say, "Look, this is the situation we found, how about re-thinking your national policy?"
Q. I'm just going to ask you a handful of questions on hepatitis B.
SIR BRIAN LANGSTAFF: Before you do that, this question of whether to introduce surrogate testing is one which arose before the National Directorate. So presumably you were taking the same approach, before the National Directorate itself was formed, to the way in which the National Blood Service -- Transfusion Service was actually operating?
A. Indeed. We were trying to do our best to treat people much the same way if we possibly could, even though it was sometimes very difficult.
SIR BRIAN LANGSTAFF: Part of the reasoning for introducing a greater degree of cohesion was that people were doing different things, to an extent?
A. To an extent they were, yes.
SIR BRIAN LANGSTAFF: Yes.
A. I don't think any other centre had seriously

introduced surrogate testing.
SIR BRIAN LANGSTAFF: Do you know how many other centres were ALT testing their plasma?
A. I just said, I don't know whether anyone else was doing surrogate testing.
MS SCOTT: In fact, before we leave the question of ALT testing plasma, can we just look at BPLL0010787. Sorry, I have given you the wrong reference, NHBT0000077_092. It is just the first paragraph of that letter from your administrator to Dr Gunson, 13 March 1990:

"Dr Entwistle has advised me that we are going to receive an increased sum for fresh frozen plasma collected by plasma pheresis, which has been ALT tested."

Do you know why that was?
A. Well, this follows on from what I was saying just now about doing surrogate testing, such as it was, for pheresis donors and the fresh frozen plasma collected that way was part of that procedure.
Q. So --
A. So we were aiming to do ALT testing on -- to procure fresh frozen plasma.
Q. Do you know why -- my question wasn't perhaps very clear -- do you know why a higher price was paid for

that plasma?
A. I don't, except that some people may have thought it was potentially safer. I don't know. But we were getting a better price for it, that is true.
Q. I'm just going to ask you a handful of questions about hepatitis B, NHBT0081007. This is a letter from Dr Dike to Dr Barbara, enclosing the annual returns for Oxford's HBsAg positive donors "as requested by you".

Do you know why that information was being provided to Dr Barbara by Oxford, other than obviously he had asked for it?
A. I think, at that stage, which was relatively early, it was only three years after screening was introduced, Dr Barbara was very much involved in a programme of collecting national data to try to determine what was the exact national prevalence of HBsAg.
Q. I think it is three years after HTLV-III or HIV testing has been introduced but I don't think it is -- it's quite a few years after HBsAg testing had been introduced?
A. He was keeping the system going.
Q. Then the second paragraph there:

"On our computer system the donor number is more permanent than the donation number. The latter gets

lost in the archives once we have clocked up the donation number '999,999FN'. I have now made sure that all our HBsAg positive donors can be referred to on our computer by their donor numbers ..."

What was the consequence of the problem with the donation numbers? Did that make it difficult for you to trace through donation numbers when you were doing -- carrying out tasks like look-back?
A. It could make a difference in time for when the donation numbers have exceeded that magic figure of all the 9s. Hence that is why my colleague had to devise a modification to the computer system to make sure that those suspect donors would be picked up if they came again.
Q. So, are you describing there a problem with the computer system but that Dr Dike actually established a workaround which meant that you could in fact trace donors and their donation numbers, despite the problem with the computer?
A. Yes, it was obviously imperative that we had to be able to trace them if they turned up again.
Q. I'm just looking through my notes to see how much longer I have got. I have probably got another 20 or 30 minutes, depending on whether or not we can get those documents back up on the system. I don't know

whether now would be a good time for a break?
SIR BRIAN LANGSTAFF: It depends whether it is 20 or 30. If you think it is more likely to be 20, let's go ahead and allow Dr Entwistle his tea break at 3.30 pm or thereabouts and come back with the questions which Core Participants may have.

If it is going to be half an hour, well, let's do it in two stages, have a break now and there will have to be a further break later on, doctor, to allow Core Participants to field -- to send their questions into counsel and for counsel to then ask you what others think would be helpful.

MS SCOTT: I think 20 minutes but I'm conscious that some of my -- I haven't asked some of my questions because the documents haven't come up on the screen.
SIR BRIAN LANGSTAFF: Let's try it. Shall we go ahead.
MS SCOTT: Yes, I think that's -- because I'm just going to ask you Dr Entwistle now some questions about records.

We have looked at *Notes on Transfusion*. We can come back to that document if necessary but there is a clear recommendation within that document for reports of transfusion-transmitted infections to be made by clinicians in hospitals to Regional Transfusion Centres. Was that something that the

clinicians in your area complied with? Did you get regular and timely information about transfusion-transmitted infections from the blood coming from your centre?
A. Frankly no. I had very few reports of any sort like that.
Q. Why do you think that was?
A. I don't know.
Q. Did you take any steps to try and improve that situation?
A. No, I don't think I did. I wasn't even aware that that was a problem, otherwise I would have taken steps.
Q. How is it you are aware of that now?
A. You are asking the questions about it.
Q. So it may be that, in fact, there wasn't a problem because there weren't any transfusion transmitted infections you just simply don't know?
A. There were very few that I ever heard of. There was one that I put in my witness statement, in fact, which may have been a transfusion-transmitted infection, although it was never finally proved, and that was the only one that I can recall.
Q. Again, we can go to the document if necessary but we looked earlier at the report on record keeping and

stock control, the report made to the Department of Health and Social -- the DHSS. I think you said you hadn't seen that report before but, in there, there is a recommendation for blood banks, hospital blood banks to make monthly returns to the Regional Transfusion Centre for reasons of stock control. So is that a system that was in place in Oxford when you were there?
A. Yes, it was.
Q. So how did that work? Was it a monthly return from each hospital blood bank, is that what you would expect?
A. I think it was nominally once a year, let's put it that way.
Q. So it was supposed to be monthly but it may be rather less frequently? What information was supposed to be and was, in fact, as a matter of generality, provided to the centre in those returns?
A. I'm sorry what was the question?
Q. What information was supposed to be provided in those returns and was, as a matter of general practice, provided?
A. Blood received and blood returned in date, if necessary. In other words, could not be used in time and that was an obvious thing which had to be done.

Q. So you would have a record of any unused blood?
A. Yes.
Q. So then you would assume, would you, that anything that had not been returned to you as unused had been given to a patient?
A. Yes, it is a fair comment.
Q. Did that system work quite well? As a matter of generality, was that complied with?
A. As far as I was aware, yes, it was but, as I say, I didn't personally look into the details of that so I can't answer any further questions than that.
Q. You were the Western division of the Blood Transfusion Service's representative on the retention of records working party, reporting to the National Directorate, is that right?
A. As far as I was aware, yes.
Q. You -- there was a piece of work done, is this right, by the working party about the number of years the Blood Transfusion Service should retain their records?
A. There was discussion about that but no firm conclusions were ever reached.
Q. So there is discussion about there being a 30 year retention period being appropriate, is that right?
A. There were discussions about different lengths of period for it to be retained and there was also

a suggestion that perhaps we should follow the pharmaceutical industry, but then the question was raised, "well, why, is it essential?" And I don't recall there being a definitive decision taken as to what the period of retention of records should actually be or even which records. Different periods could perhaps be kept for different records.

Q. Do you recall what the retention period for records in the pharmaceutical industry was?

A. I think the figure of 30 years had been suggested.

Q. Just in relation to your practice in Oxford, you tell us in your witness statement that the paper donor record cards were kept indefinitely, as far as you were aware; is that right?

A. Yes.

Q. Did you, at any time during your tenure in Oxford, order the destruction of any records?

A. No.

Q. So is it right to say then that, during the period of 1980 to 1985, any records that were created in Oxford would have been in Oxford until you left?

A. They should have been there, yes, either in the written form on donor cards or on the computer records and that was still ongoing.

Q. In relation to donors who were found positive for any

viral infection, what was the position in relation to their records? Were they held indefinitely to ensure that they didn't come back and donate again?

A. Correct.

Q. Were there any arrangements for sharing information between Regional Transfusion Centres about such donors to ensure that they didn't, for example, go and donate in a different area?

A. Not that I was aware of, neither had we been asked to do so.

Q. Can I just ask you to look at a document we looked at this morning which is NHBT0006265, which is the 1990 Medicines Inspectorate Report.

If we turn, please, to page 9 of that document, I just want to draw your attention to some of the problems with the recordkeeping that were identified in that 1990 visit. It says, second paragraph down:

"The procedure for dealing with donations which test microbiologically positive is inadequate."

It goes on to give details, and then skipping the next paragraph down to:

"The records kept in Microbiology of the withdrawal and disposal of positive products are totally inadequate. There is no list of the products made, just the donation number. There is no record of

the final fate of the packs concerned, eg autoclaving or held in the laboratory. The records, such as they are, are incompletely maintained. There is no procedure for follow-up if packs are not delivered to Microbiology. There is no signed 'receipt' given to Blood Products staff when packs are delivered to Microbiology."

Then the next paragraph:

"The flaws in the procedure were highlighted with case of the SAG-M red cell pack in the Grouping Laboratory fridge ... It transpired that the donation had been identified as TPHA positive but instead of withdrawal and disposal, it had been put into Grouping fridge. In order that a Group label could be issued for it, the donation was entered as 'clear' on the computer record. However, although the red cells were held (albeit in the wrong fridge and the wrong laboratory), the effect of altering the computer entry was to enable the plasma to be cleared for issue. Investigations during the inspection revealed that the plasma had, in fact, been dispatched to Elstree some 3 weeks previously. (Steps were taken at the time of inspection to have the pack recalled from Elstree.)"

So there in 1990 there are some quite serious concerns raised about recordkeeping, and so on. I see

you shaking your head, what do you say about that?

A. It was a damning indictment of a totally inadequate situation and, obviously, things had to be done to put things right.

Q. And --

A. We could not go on that way.

Q. How long would you say that that inadequate situation had been in place?

A. I have no idea. It is obviously something which was recorded at the time but there is no evidence as to how long that had been going on or why. But, plainly, lack of supervision was very evident. And I plead humble pie for that.

Q. Were steps taken by the centre to remedy the inadequate system that was revealed in that report, in that inspection?

A. Yes, we revised the system of the supervision laboratories and my deputy, Dr Marlene Fisher, became overall manager of the laboratory side of things. She was a very bright girl and very efficient and things looked up considerably after that.

Q. Turning then to hepatitis C look-back. Again, I'm going to do this via reference to the documents. So NHBT0087333. So this is a letter from 21 October 1986 to somebody from Dr Dike, and it says:

"We have been told by the Public Health Department that you have had hepatitis recently. I am sorry to hear this and do hope you are feeling better now.

"If you are or have been a blood donor please will you let me know when and where you last gave blood. I should be most grateful if you could also let me have details of any close contacts of yours if they are blood donors."

Is it right to understand that, certainly in 1986, you were being informed by the Public Health Department of cases of viral hepatitis in your area, so that you could do investigations to see whether or not they were blood donors?

A. This was not a regular feature and this is an odd one.

Q. So it is not, as far as you can recall -- it wasn't a common occurrence that every time there was a case of viral hepatitis you were informed and you did investigations?

A. Yes, something like this was an odd occurrence.

Q. If we turn over the page to page 3, you can see that that letter is dated 21 October. We can see on page 3 -- it is a handwritten date the day before, "Searched -- no trace as donor". So it looks like you are notified, you do a search, there is no trace of

the person being a blood donor but, nevertheless, you write to them to ask whether or not they have been a blood donor. Does that sound -- I think you said this was an odd one. It wasn't something that you think happened regularly?

A. -- (Overspeaking) --

Q. Can we turn then to NHBT0057093_002. So this is Standard Operating Procedure in relation to transfusion-transmitted hepatitis. It says there, we can see it under "Edition", date effective 6 July 1992. It replaces a previous one from -- is that from 1991? Is that what we understand that number there, 1003/02 91 01?

A. I believe so, yes.

Q. Can you recall whether or not you had standing operating procedures in relation to transfusion-transmitted hepatitis from -- well, it certainly looks like from 2001. Do you think there could have been such procedures earlier than 2001 -- sorry, 1991?

A. I would think if it wasn't -- I couldn't tell you the precise date when they were introduced but by the time -- 1991/1992, I would think that is likely. I can't think of a precise date.

Q. So then is this fair, there may have been earlier

versions but you are not sure, but 1991 --

A. I'm not sure.

Q. -- certainly there were?

This seems to deal with the situation whereby you are informed by a clinician that there has been an infection of transfusion-transmitted hepatitis in a patient. So if we look over at page 2, you can see what's supposed to happen on receipt of paragraph 1 -- well, the aim is to trace donors who may have transmitted hepatitis in order to prevent a recurrence and, if possible, to prevent any other components of the current blood donation from being used, and it sets out there what you have to do on receipt of a verbal or written report that a patient is suspected of having TTH, a full inquiry is to be made.

Then paragraph 3:

"All the blood donations involved must be retested ..."

Just pausing there. Can you recall when the centre started keeping serum samples of blood donations? How far back would you have been able to test?

A. I can't tell you offhand, I don't recall.

Q. Do you think that was something that was introduced during your tenure or something that you inherited?

A. It probably was, but it's a practical detail that I wasn't involved in and I can't recall when it was introduced.

Q. Then:

"All the blood donors involved must be suspended from the donor panel. Each one is sent a standard letter and questionnaire ... together with an addressed box and sample tubes ..."

For further tests to be able to be undertaken, or they are asked to visit the doctor.

Then if we go over the page to paragraph 6:

"When all the results of the donors' questionnaires and blood tests and the patient's clinical details are known, an assessment is made ... to resolve the questions:

"a) Did the patients have the TTH?

"and if so

"b) Which donor transmitted the infection?

"Letters are written to all the donors involved, telling them whether or not they are thought to have transmitted infection, and explaining that they have now been either reinstated or withdrawn."

If we then turn on to the position in 1994, the national look-back programme, if we look at NHBT0055409_001.

Just before I do ask you questions about the national look-back, in relation to the standard operating procedure in 1991 and 1992, have you -- do you know how common it was for look-back to be undertaken under those standing operating procedures at Oxford?

A. I honestly don't know because I personally wasn't involved in that part of the centre's activities. And I can't answer the question I'm sorry.

Q. If we look then on 20 September 1994, there's a handwritten letter from you to Dr Ala, "Re: HCV look-back". You say in the first paragraph:

"We agree in principle that look-back to recipients of blood from donors now found HCV positive is something which should be pursued. Those recipients who have survived so far could be identified and counselled and some will need further investigation and treatment. The scale of clinical involvement here needs to be assessed, and costs of treatment determined, and money found! Not easy. Hepatologists should be on board."

If you carry on down:

"We think around 150 patients may exist on our patch. We don't have the resources at this stage to undertake this extra work."

Do you know how you came to an estimate of 150 patients who may exist on your patch?

A. Yes. Well, we were aware by that stage that the likely incidence of hepatitis C in the population as a whole was going to be a lot less than the number of screen test positives. We knew that the screen test positive rate was in the order of one in every 200, which means the number of genuine positives is perhaps 1 in every 2,000. And on that basis we would see somewhere in the order of one every week during the first year of screening.

So there would be -- we had something like 120,000 donors a year, which would mean something like -- sorry, donations a year, which would mean there would be about six -- about 50,000 coming twice a year, on average, and about 10,000 new donors in a given year.

At the rate of 0.1% we would see somewhere in the order of possibly 300 or so cases a year, not 150, which is our first guess.

SIR BRIAN LANGSTAFF: Can you just help me with the figures there. One in 200 is a figure of 0.5 of a percent, I think, and the rate that you have just quoted is 0.1 of a per cent. Can you help with what I'm comparing there?

A. I'm sorry, Sir Brian, can I correct myself, please?

SIR BRIAN LANGSTAFF: Yes, of course.

A. I think the figures should read 0.1% screen positive and 0.01 genuine positive.

SIR BRIAN LANGSTAFF: Very well. Thank you.

MS SCOTT: Now, the instructions on the national look-back from Dr Robinson were promulgated in January 1995 with further guidance provided in April 1995, and we can look at those documents if necessary. You had an opportunity to look at those prior to giving your evidence. But conscious as I am that you retired in September 1995, and given that the evidence you have given so far is that Dr Dike was leading, as I understand it, on look-back and donor counselling, are you able to help us with the steps that were taken at Oxford in order to comply with the national HCV look-back programme in 1995 before your retirement?

A. I hate to have to say this but I think I must be perfectly honest. The National Blood Authority had instituted independent assessors to look at all transfusion centres and the Service as a whole, and this took place during 1994.

The message was coming across loud and clear in Oxford that the Oxford Centre was vulnerable to the possibility of being closed. No decision was taken

until during 1995.

Now, in the June of 1995, beginning of June, I was summoned to the National Blood Authority premises in Watford and I was told point blank that the Oxford Centre was indeed going to be, and I quote, "closed". So you can imagine that over the course of the preceding months our attention was not exactly focused where it should have been. And indeed I was told, as I said, that the centre was going to effectively close, my own personal position was going to disappear, and that is why I opted to take early retirement. And I must be quite honest, I almost lost interest.

Q. And so I think -- am I right in understanding that the answer to my question, in terms of can you help us with what steps, if any, given your answer, were taken at Oxford in order to put into place the HCV look-back, you are not able to help us with that?

A. Well, I can tell you something, if I may be allowed to advise you on something which happened after I retired. Is that allowed?

Q. Absolutely, yes.

A. Dr Dike in fact, who was looking after the HCV situation, did look at the number of people who were positive, identified them, and indeed -- but didn't

have enough staffing resources to be able to do the appropriate chasing up for look-back, going into the hospitals and looking up the patients. She did do that after I retired, when she got some additional help, and in fact I think she looked at some 350 donors who had been positive. And if I recall correctly, about two-thirds of those were still available and still alive.

MS SCOTT: Sir, that, subject to working on whether I need to ask anything arising from the documents we couldn't get on the system beforehand -- I will just have a think about that -- concludes my questioning.

SIR BRIAN LANGSTAFF: Well, it was certainly a lot nearer to 20 than 30 minutes, so thank you.

We will take a break now. You are going to field questions from Core Participants?

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Shall we give you until 4.00 to do that?

MS SCOTT: Yes, Thank you, sir.

SIR BRIAN LANGSTAFF: 4.00, if you don't mind, doctor. What happens now, as I have described earlier, is that a number of questions are suggested to counsel to ask, I don't know how many that will be, maybe a lot, maybe a few, but if you would come back at 4.00, then

counsel will ask those questions.

It won't then take very much longer, I suspect, but I can't be absolutely certain before your testimony is finished.

A. Thank you, Sir Brian.

SIR BRIAN LANGSTAFF: 4.00.

(3.37 pm)

(A short break)

(4.00 pm)

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: Dr Entwistle, I have a handful of questions to ask you on topics from Core Participants and their legal representatives.

You gave some evidence about having informal discussions with clinical colleagues in local hospitals and the question is whether during those discussions or otherwise you discussed the need to minimise the use of blood or blood products, given your awareness of the unavoidable risk that they carry?

A. I don't think we specifically discussed that but I think one of the take-home messages, which I will try to convey, is that transfusion, just like any other medical intervention, is a form of treatment which may have risks, maybe small, maybe big, whatever

those risks are the clinician using transfusion should do so bearing in mind the need and the possible alternatives that could be used.

The need, bearing in mind the risks.

Q. We looked at a document which referred to making a visit to New Orleans. Did you visit any blood banks when you were in America?

A. No, I didn't, because I was privileged to have a very brief visit to go to the American Association of Blood Banks meeting but it didn't allow me time to divert on to local blood banks, which would have been very interesting, yes, I have no doubt, but I just didn't have the time to do that, I'm afraid.

Q. Now, I have been asked to ask you a question about the arrangements with BPL for pro rata or whether you got back a pro rata amount for the plasma that you provided. I have got a couple of documents I can take you to to prompt your memory about that unless you are able to answer it without going to documents.

A. Well, I think I can. At one stage in the early '80s, we were a bit behind in terms of what we were required to produce, but from about mid-'80s onwards we had no problem, we were well on track.

Q. Can I -- I will, in fact, I think, take you to a couple of documents just to make sure we have got

the full picture.

The first one is CBLA0001380.

So this is a letter from -- if we go over to the second page, it is from Dr Lane to you, dated 12 June 1981, and if we go back to the first page, Dr Lane says:

"As you know, Oxford and Wessex are the only regions that do not appear on the pro rata league table for factor VIII supply, the reason being that all Oxford plasma and half Wessex plasma is fractionated at PFL and the system of fractionation vis a vis data collection does not appear to correspond with that at BPL."

Then if we go down to the big paragraph starting:

"I have requested that Oxford plasma and Wessex plasma be brought into line with other regions ..."

Then he sets out the advantages and disadvantages of that and the arguments.

Then if we go over the page he concludes by saying -- the arguments either way, sorry -- "Removing this final irregularity", I think he means there Oxford and Wessex not being involved in the pro rata system:

"... will not create difficulties but in the

long run is a much better guarantee of improved service and supply of factor VIII to Oxford and Wessex than at present. I hope to obtain your agreement with the points set out in this letter, and would ask you to obtain mutual agreement on these matters with Dr Rizza at the Oxford Haemophilia Centre."

Then if we look then at CBLA0001389, we can see your reply, which is 23 June 1981, and you say:

"Thank you for your letter of 12th June ...

"I set up a meeting yesterday with Ethel Bidwell, Jim Smith, Terry Snape, Dr Rizza and myself to discuss this whole matter. We all agree that the proposed new arrangements are probably not a great deal more than a paper exercise in terms of accounting for what goes where. It appears that the practices relating to distribution will remain unchanged, and that any Factor VIII produced either at PFL or Elstree from Oxford material will continue to be issued direct to the Oxford Haemophilia Centre. We are satisfied that it would be proper for the Oxford Centre to come in line with the others, and it is right that we should contribute to the Lord Mayor Treloar School. We also appreciate the advantages of Oxford production being buffered in the event of unforeseen hiccups with their batches."

Then you say at the next paragraph:

"One point which I think should not be forgotten is that about half of the patients that come to the Oxford Haemophilia Centre are referred from outside the Region, and this very often is because they are the more difficult cases to deal with. This point will not be lost when I put my next submission to the RHA for funds to increase our plasma collection."

Is it right to understand that, prior to this exchange of correspondence, you weren't in the pro rata system but following this exchange of correspondence Oxford was brought into line with the other Regional Transfusion Centres?

A. Yes, that was my understanding, and I think this was largely a historical phenomenon, in that, of course, the Churchill Hospital is also the location of where the Oxford Haemophilia Centre is and that's how PFL got involved with that in the first place. As time went by and the demand for products went up, and up, and up PFL could no longer cope anyway and BPL had to assume the fractionation for everybody.

So, in fact, the redistribution was actually simplified.

Q. Were you aware that Dr Contreras in the Edgware Centre had a leaflet that was supplemental to the nationally

agreed material provided to donors? A supplemental questionnaire which donors could fill in confidentially to identify whether or not they were in high-risk groups. Was that something that was brought to your attention?

A. Not that I can recall, no. And was she the only one to have that?

Q. The evidence that she gave last week was that that was something that she and Dr Barbara came up with after visiting America, and that was something that they instituted in the Edgware Centre. I do not think she gave evidence about whether or not that was put in place in other centres. That is not something you were aware of?

A. No.

Q. You were asked questions this morning about donations sessions undertaken with military personnel, and you said they were extremely beneficial. I have been asked to ask you what you mean by that.

A. Well, normally we reckoned to have about 100 to 120 donors at a session. One particular one at a military establishment, they rang up during the course of the morning, "Could we keep going over lunchtime?"

"All right. If you must."

We finished up with 240-odd donations that day. Which was -- well, all I can say is that the staff concerned were brilliant.

MS SCOTT: Those are all the questions I'm going to ask from the Core Participants and the legal representatives.

SIR BRIAN LANGSTAFF: I have none of my own.

MS SCOTT: Dr Entwistle, is there anything that you would like to say at this stage?

A. Yes, if I may.

Firstly, can I say what a tremendous amount of work, Ms Scott, that you and your colleagues must have done to sort out these documents. You have done a tremendous job. And coming from a non-transfusion background, I think you are to be congratulated. And I think that all I have to say. But thank you all very much for your attention and I wish you well with whatever the outcome may be.

SIR BRIAN LANGSTAFF: Thank you, from my perspective, and my congratulations to you, if I may, for the careful way you have given your evidence. You have given, clearly, evidence which, when you have been asked a question, you have actually thought about the answer in order to try to get it right. And that gives one confidence that you are telling us what you know and

what you don't know as best you now recollect it, and given us the insight you have into the position that the Oxford Centre took, that is the transfusion centre, and its slight remove from the Oxford Haemophilia Centre, which got its supplies elsewhere.

But thank you for that and also for giving us another view on when a director of a Regional Transfusion Centre first knew of the various particular challenges to blood. It was a fascinating account, in particular to listen to how you had, in effect, been the first person in our blood transfusion system to start a test for hepatitis B. It is a pity that you didn't have -- of it is perhaps a credit to you that you had the humility not to claim rather more forcefully than you did the credit for that but thank you.

A. Thank you, sir.

MS SCOTT: Tomorrow, sir, we have the evidence of Dr Galea.

SIR BRIAN LANGSTAFF: Yes, so tomorrow, 10.00, Dr Galea.

(4.12 pm)

(Adjourned until 10.00 am on Tuesday, 7 December 2021)

INDEX

F:

F:

F:

F:

F:

F:

F:

F: