Thursday, 2 December 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Professor, I'm going to ask Kamila to ask you to take the oath.

PROFESSOR DAME CARMEN MARCELA CONTRERAS (affirmed)

Questions from MS RICHARDS

MS RICHARDS: Professor Contreras, I'm just going to ask you to tell us very briefly an overview of your career. You qualified as a doctor in Chile, I think, and then you came to the UK and you took up a post at the North London Blood Transfusion Centre in 1974 as a senior scientific officer?

Would you mind answering yes or no, rather than nodding because the transcript doesn't pick it up.

A. Yes.

Q. Briefly, what did that role entail?

A. After having been at the Medical Research Counsel and the Royal Postgraduate Medical School, I trained in red cell immunohaematology, so I was in charge of a small reference laboratory, and also of education in red -- in blood grouping, I would say, blood grouping and antibody screening for patients, advising the staff of the centre on those issues and doing research.

Q. You stayed in that role until May 1976. Then you

A. Yes.

Q. You were in that post until February 1984, and then in February 1984 you became the medical director at the North London Regional Transfusion Centre?

A. Yes, I did.

Q. Had your predecessor, your immediate predecessor, been Dr Tom Davies?

A. Yes.

Q. You stayed in that post until November 1995, is that right?

A. No, as --

Q. As medical director of the Regional Transfusion Centre?

A. Yes, until 1995.

Q. Then you became executive director of the London and South East zone, which gave you a degree of responsibility not just for the North London Regional Transfusion Centre, which I think by then had moved to Colindale, but also for the Cambridge, Brentwood and Tooting centres; is that right?

A. Yes.

Q. You were working at that point then for the relatively newly established National Blood Authority?

A. Yes.

Q. You stayed in that post until August 1999, I think,

became a medical assistant in blood transfusion, again at the in North London Transfusion Centre. What was the nature of that role?

A. It was very similar to the previous one but I had revalidated as a doctor in the UK and I had taken all my memberships and my exams, so I could be paid as a doctor. I had come as a British Council scholar and then I could enter the rat race, as you would say, and become a medical doctor.

Q. You were in that role until the middle of 1978 and then from July 1978 to February 1980 you were a senior registrar in haematology at St Mary's Hospital and at Northwick Park Hospital. Broadly, what did that role entail?

A. It was mostly to do with haematological patients, but I think I was appointed because of my interest in immunohaematology and haemolytic disease of the newborn, so I spent a large time of my time doing clinical and research work on what they call rhesus haemolytic disease of the newborn, Rh negative mothers who have Rh positive children and are incompatible, so doing exchange transfusions for babies, et cetera.

Q. Then in March 1980 you returned to the North London Regional Transfusion Centre as deputy director and consultant in blood transfusion, is that right?

and then from August 1999 to February 2007 you were the national director of diagnostics, development and research at NHSBT?

A. Yes.

Q. You also took up a position as professor in transfusion of medicine at The Royal Free and UCH between 1988 and 2008?

A. Yes.

Q. We'll obviously come back to some of those positions of responsibility in more detail. You've sat on multiple committees and working groups during your career, I'm not going to ask you to go through them, you've listed them in your statement, and we'll look at some of those of most direct relevance to the Inquiry in due course, but at you're also the author of multiple papers and the co-author of the textbook *Blood Transfusion in Clinical Medicine*.

A. Yes.

Q. I understand from your statement, Professor Contreras, that you've not previously been asked to give evidence to any public inquiry looking into matters relating to infected blood?

A. Yes, that's right.

Q. You also say in your statement you haven't been involved in any litigation relating to transmission of

infections through blood and blood products but you did give evidence in criminal proceedings against the Chief MLSO who was charged with offences relating to the theft of plasma, alongside Dr Mark Patterson of the National Heart Hospital in the 1980s?

A. Yes.

Q. So that's your only involvement in litigation?

A. Yes.

Q. I'm going to ask you now to tell us a bit about the Regional Transfusion Centre itself, the North London Centre. When you took up your post there in 1980, it was located in Edgware; is that right?

A. Yes.

Q. You've said in your statement that it wasn't fit for purpose. Ultimately, there was a move to a new centre in Colindale but that wasn't until the end of the 1980s. In what sense was it not fit for purpose?

A. Well, it was -- it wasn't built for purpose so it was really a collection of rooms, with not really clean rooms, as are necessary in a blood centre. We were very cramped, very crowded and, you know, it was leaking, the pipes weren't working very well. It was a real disaster zone.

Q. If we look at your witness statement, please, at WITN5711001, and if we can go to page 18, please,

Soumik, you describe here the staffing and structure of the centre during your period as director, and I'm going to just take this from your statement because it's a useful summary.

So you tell us in paragraph 71 that, by the mid-'90s, the staffing was around 350 people. That comprised medical and scientific doctors, MLSOs -- can you just tell us what the role of the MLSO was?

A. The Medical Laboratory Scientific Officers, who train in the service, as compared with Scientific Officers who have a university degree, but then they become proper scientists. But they train from when they leave school and they are trained mostly in the National Health Service and, in our case, we trained our -- and they have to pass exams from Junior MLSO to proper MLSO, Chief MLSO and Senior MLSO, Medical Laboratory Scientific Officer.

Q. Then going back to paragraph 71, you described:

"... scientific officers, nurses, technicians, laboratory aides, admin and clerical staff, drivers, team leaders, donor attendants, cleaners and porters."

I'll come back to some of the staffing issues in relation to donor sessions at a later stage.

If we then go down to the bottom of the page and we just see the departments, so you tell us there:

"The structure [of the centre] comprised of departments, as follows:

"a) Donor Services ..."

And if we go to the top of the next page, the donor services department had responsibility for:

"- Donor records;

"- Donor organisation;

"- Donor recruitment and publicity;

"- Call-up and donor communications."

Again, we'll come on to a number of those areas in the course of the morning.

"b) Mop teams: doctors, nurses, donor attendants and drivers."

And you say that section had the majority of staff members.

Is it right to understand those are the teams that are going out to various different locations to undertake the donor sessions?

A. Yes, and also at the static clinics.

Q. And then you refer to the:

"Static clinics for routine and apheresis donations ..."

And again we'll come on to some of those issues. They had:

"... doctors, nurses, donor attendants and

receptionists."

Then we had the:

"d) Components Laboratory or Processing of Blood."

So that's the laboratory where the mechanics of the processing of the blood that has been collected at the donor sessions is then processed into its various components?

A. Yes.

Q. Then we have the biochemistry lab, and then the microbiology lab. That's where, amongst other things, the testing for screening for viral infections would be undertaken; is that right?

A. Yes.

Q. Was that very much the responsibility of Dr John Barbara at the North London centre?

A. Yes, it was -- well, Dr John Barbara's responsibility and the consultant in charge of that microbiology, the medical consultant. Dr John Barbara was a senior scientific officer and there was also a medical consultant. Usually -- most times was Dr Hewitt.

Q. And we anticipate hearing from both Dr Hewitt and Dr Barbara over the coming hearings.

Then we have, bottom of the page, the:

"g) Blood Group Serology or Red Cell

Immunohaematology ..."
Department.
Then if we go over the page, we can see a range of other departments set out there. (j) refers to the:
"Teaching and Training Department, planned training for all grades of staff at the Centre as well as for Senior Registrars, nurses and MLSOs on rotation. The training and teaching were performed by consultants, scientists, nurses and MLSOs."
I'll come back to some aspects of training in due course.
And then we can see the remaining departments there set out, including the quality department.
So your statement gives the impression of a large centre. Was the North London Centre one of the largest Regional Transfusion Centres in the country?
A. Physically we weren't, but in complexity we were, because our client hospitals -- because of the more graphics of -- and because we had the most demanding hospitals. So yes, insofar as the complexity of the work that we did, we were the most complex.
Q. And yours was one of two transfusion centres in London, the other being the South London Centre in

Tooting; is that right?
A. Three. There was Brentwood as well.
Q. Okay, so if we count Brentwood as part of London.
And we'll look at some documents which give a flavour of the range of hospitals that were supplied by the centre in due course, but you were responsible, effectively, or the centre was responsible for supplies to the whole North Thames region; is that correct?
A. Yes, North West Thames.
Q. North West Thames region and that would encompass a number of the big teaching hospitals in London?
A. Yes.
Q. Was there any particular relationship or liaison between your centre and the South London Centre or the Brentwood centre other than through the divisional meetings?
A. Well, at the Regional Transfusion Directors meetings as well, and the divisional meetings, and sometimes we might talk on issues -- on professional issues, but ...
Q. Can I just ask you a little more, first of all, about your role and responsibilities in that period of time in the early eighties when you were the deputy director and consultant in blood transfusion. So from

1980 until early 1984, when you took over from Dr Davies.
What particular areas of the centre's work did you have responsibility for as deputy director?
A. Mostly the scientific areas. Well, I was interested in red cell immunohaematology, blood grouping, and antibody screening, and transfusion reactions in hospitals. Teaching. I've always been passionate about teaching, so teaching not only of the centre staff but of the hospital staff, and HLA typing -- quality as well. And yes, and I started becoming interested in transfusion microbiology.
Q. And then once you took over as director in February 1984, you were ultimately responsible for all aspects of functioning of the Centre; is that right?
A. Yes. Ultimately, yes, but I had the Regional Health Authority managing me, but I was answerable to them.
Q. Again, if we just go back to your statement, just to get an overview of the kinds of areas of responsibility you had.
If we put the statement back on screen, please, Soumik. Thank you. And we go to page 14, bottom of the page.
You tell us at paragraph 52 at the bottom of the page that:

"[You were] responsible for budget control, collection, processing, testing, storage and distribution of blood, plasma and blood components."
Over the next page:
"[You were] responsible for the provision of reference services in Transfusion Medicine and for the provision of advice and training in transfusion medicine."
I'm going to be asking you quite a lot about that later, Professor Contreras.
"... responsible for regulatory compliance and research and development into blood transfusion."
You were responsible for the design -- ultimately responsible for the design and technical requirements of the new centre in the move from Edgware to Colindale.
Then, paragraph 57, you talk about how, when you took over your directorship, you established firm relationships with the hospitals which the Centre served and, again, I'm going to come back to that.
Paragraph 58 you refer to:
"... training and research in [relation to] transfusion medicine and transfusion transmitted infections ..."
So that's a broad overview, is it, of your

responsibilities as director?
A. Yes.
Q. You mentioned a few minutes ago the Regional Health Authority. You were ultimately accountable to the Regional Health Authority and that was the North West Thames Regional Health Authority?
A. Yes.
Q. You told us in your statement that you would have monthly meetings with the regional medical officer. What was the purpose of having such regular contact?
A. It was to update them on the progress or any problem -- progress of the Centre, any problems we might have, so that -- they were the holders of the purse, so -- and any advice I could have about any developments that might be happening in the hospitals we served. Because the regional medical officer always knew in advance if there was going to be more cardiac surgery in a hospital or if they were going to introduce bone marrow transplantation in a hospital. So it was a two-way communication, and -- yes.
Q. And you described in your statement in terms of funding that, broadly speaking, the Centre was adequately funded. Is that right?
A. Yes.
Q. We can take the statement down, thank you, Soumik.

Now I just want you to help us understand a little about the organisation of what was notionally called the National Blood Transfusion Service in the 1970s and 1980s, but was something that you described in your statement as "a feudal system where we had autonomy over our own regions".

In your own words, Professor Contreras, how did the National Blood Transfusion Service operate and the individual Regional Transfusion Centres operate?
A. Well, as I said, we were quite autonomous in the way we dealt with our donors, in the way we dealt will with our hospitals and in the way we dealt with our regions. I was very lucky to have this constant contact with my Regional Health Authority. And the -- we met at Regional Transfusion Directors meetings but it was in a very loose way and, yes, we agreed on some national policies like donor selection criteria, and later on with management information system, but we were really managing our own centres, and that could be seen by the collection rates of different centres per thousand population, you know, the number of collections, the -- I mean, the number of activities that we did. Not every centre had tissue typing developed, and not every centre had a tissue bank or a cord blood bank. So we were very dependent on the

interest of Regional Health Authorities to develop the services, and on having the adequate senior staff to relate to our hospitals.
Q. And you have described in your statement -- can we go back to the statement, Soumik, page 56 and 57 -- strengths and weaknesses of the National Blood Transfusion Service.

We'll look just briefly first of all at what you say were the strengths, so voluntary, altruistic repeat donation, a truly public service. Public saw it as a national rather than regional service. Pride in staff.

You talk about an improved information exchange between centres. Is that at the point in time at which it became a genuinely national service rather than the feudal system of the seventies and eighties?
A. No, I think that we had some information, but of course the -- with the creation of the MBA -- well, there were no more centres or centre management teams, but gradually we became -- we became -- we exchanged more information with -- yeah, with the creation of divisions as well, you know, we tried to exchange more information between us.
Q. Indeed I think that's probably the point picked up at subparagraph (h) at the bottom of the screen:

"There was increased exchange of information at the RTD meetings."

You then refer to:

"The creation of the management information system (MIS)."

I'll come back to that at a later stage, Professor Contreras.

If we go over the page to paragraph 227, you've then identified a number of weaknesses of the way in which the service was structured, prior to the creation of the National Blood Authority. So just so we understand it, when you say "It [in paragraph 227(a)] was a non-executive body with no real powers other than the power of persuasion", are you talking about there the period of time where there was the National Directorate --
A. Yes.
Q. -- and its relationship with all the individual --
A. Yes.
Q. -- Regional Transfusion Centres. Then you point out:

"The regional transfusion centres had different levels of funding and involvement by their respective regional health authorities.

"There were different IT systems in place, idiosyncratic to each centre ..."

You then observe that, in terms of Dr Gunson's role as national director, once the National Directorate was established, he had no executive power, he could only advise and persuade.

"Some [Regional Transfusion Centres] had severe structural deficits."

What did you mean by that?

A. That they were not adequately funded.

Q. "RTCs were very different administratively and managerially.

"There was duplication of research and development and little collaboration between centres.

"Productivity was different at different centres.

"Innovation was different at different centres.

"Efficiency was different at different centres."

You refer to the comparison of collections of blood and plasma per million of population, and:

"Liaison with hospitals was different at different centres, as consultants and scientists at some centres had little or no relationship with clinicians at the hospitals they served."

So that is a description of the downside, as it were, of having a system of a number of Regional Transfusion Centres, each autonomous, accountable only

to their Regional Health Authority; is that right?

A. Yes.

Q. In terms of the system of Regional Transfusion Director meetings, I think those took place roughly four times a year, you were a regular attender at those meetings once you became director?

A. Yes.

Q. What did you see as the main purpose or benefit of those meetings?

A. Exchange of information between centres and agreeing some national issues, like donor selection or introduction of testing or screening, progress in -- mostly in production, and also exchanging information about plasma procurement, and all those issues. We hardly ever discussed what I call transfusion -- well, what's called transfusion medicine.

Q. I'll want to come at a later stage to your own views about the importance of transfusion medicine and the attempts that were made by you and your colleagues at the centre to shape policy and practice in that regard, but what why do you think that wasn't a significant feature of the discussions amongst Regional Transfusion Directors?

A. I think that -- I'm speculating for them -- it was because they were mostly concerned about collecting

enough blood and collecting enough plasma for BPL, and issuing the different components. So I would say that some centres were so concentrated on the collection that they had very little contact with the hospitals.

Q. Now we know that the last Regional Transfusion Directors meeting took place in January 1989. If we just look at the formal minutes, first of all, of that meeting.

Soumik, it's NHBT0018188, please. We can see the date there, 18 January 1989 and we can see, Professor Contreras, that you were in attendance. If we go to the second half of the second page, you'll see, Professor Contreras, there's a heading "National Director's Report", "Communications with the Directorate", and there's a report from Dr Gunson, I don't need to ask you to look at the detail of it, but if we look at the bottom paragraph, we can see Dr Gunson reporting that, since the last RTD meeting, a National Management Committee had been established and he proposed meetings between the Committee and Divisions. Then it says, towards the bottom of the page:

"If this role for the National Management Committee and the Divisions was agreed he asked Directors to consider the future of the RTD Meeting

and suggested that the [go to the top of the next page] business part of the Meeting should be shorter ..."

Then there's a discussion reported, I'm not going to go through all of it Professor Contreras. I think you've seen this document and were asked about it in your statement. That long paragraph talks about how contact would be maintained between Dr Gunson and Professor Cash.

Then the second paragraph records:

"Dr Wagstaff [summarising] the discussion which led him to ask if it was the wish of those present that the RTD Meetings should be discontinued and be replaced by an Annual Meeting open to all NBTS Consultants with a Scientific Agenda. This was agreed unanimously."

Now, there's no record there to any particular contribution from you but I think you've seen very recently, and it was referred to in the course of Dr Napier's evidence, a different account of this meeting which suggests that the idea of ceasing to hold RTD meetings regularly was your idea. We'll just have a look at that and then I'll ask you about it.

So that alternative record of the meeting is SBTS0000628_011. So you'll see at the top of the page

it says "210th English Regional Transfusion Directors Meeting, Wednesday 18 January 1989".

I'm afraid I don't know who the author of this document is, Professor Contreras, but it's somebody's account of attendance at the meeting. If we go to page 3, we can see, halfway down the page, a handwritten heading "Future of RTD meetings", and what this says is:

"At this point, Dr Wagstaff and Dr Contreras joined the meeting. Dr Wagstaff took the Chair and Dr Contreras was invited to give her views on the future of RTD meetings as this had been discussed in her Division."

Then at the next sentence it says:

"She proposed that the RTD meetings be abolished."

There's then various points set out, I'm not going to go through the detail of them all. If we go to the bottom of the page, thank you, the bottom of the page, the last sentence asserts:

"There was no discussion of the advantages and disadvantages of dissolving the RTD meetings."

Then, over the page, we have the author's comment or reflection on this decision, with the last paragraph under that heading, which has been

underlined, saying:

"... none of this discussion took place, these are my personal views and in the midst of a slightly non-plussed silence, Dr Wagstaff concluded that the 210th was to be the last RTD meeting in its present form."

So a slightly different account there of the discussions that took place. Can you recall whether this was something that was your idea, to stop holding these regular RTD meetings?

A. Well, as it's stated in the RTD minutes in the proper -- I think this was written by one of my Scottish colleagues, because they had an interest, of course, in the English and Wales Blood Transfusion Service. If you look at the minute -- the original meeting minutes, Dr Gunson, it was he who suggested, this was a *fait accompli*.

Nobody consulted us about the existence of the National Management Committee. This came -- Dr Gunson came to the meeting to inform us that it had been formed, and he was the one who suggested that this -- that we should continue meeting as divisions. So if I said something, I must have agreed with him, there was no point in having a National Management Committee, divisional meetings and regional meetings.

We were very busy and transfusion directors meetings took two days. We had to travel around the world -- around the country, sorry, and stay overnight because usually they took half an afternoon, an afternoon and a morning. So it was to decide very little, it could have been done by letter or by fax, and we had the divisional meetings and the National Management Committee meetings so I didn't see any point of having this -- I called it sometimes a club, continuing to meet.

Q. In terms of the divisional meetings, the North London Regional Transfusion Centre fell within, I think, what was called the Eastern Division, and your meetings were, is this right, with your colleagues in Brentwood, Tooting and Cambridge?

A. Yes.

Q. Is it right to understand that you would essentially at least until the Regional Transfusion Directors meetings were abolished, you would essentially pick up at a divisional level the kind of topics that were being discussed at the Regional Transfusion Director meetings but approaching them from your divisional perspective?

A. Yes.

Q. Now, obviously, as the 1990s moved on, the National

Blood Authority was established and I just want to ask you about the views you expressed about that at the time, which you set out in a letter to Dr Gunson. So that's NHBT0001875, please, Soumik?

So this is a letter, 19 July 1990, from you to Dr Gunson, headed "Proposal to the Department of Health for a Nationally Managed Blood Transfusion Service in England and Wales", and you say this in the second paragraph:

"Although in principle I am in favour of the concept of a National Blood Transfusion Service that should include Regional Transfusion Centres and the CBLA, in the current NHS climate, I am against a nationally managed Blood Transfusion Service. I have discussed your paper with my colleagues at NLBTC [that's the North London Blood Transfusion Centre] and they all, except for Branko, agree with this reply."

Then you say, in the next paragraph, if I pick it up in the fourth line:

"However, the paper [Dr Gunson's paper] does not provide any concrete evidence that national management would improve local management in the BTS. In some Regions like our own, there would simply be another tier of management -- since we effectively are managing the centre ourselves and are not

dictatorially 'managed' by the [Regional Health Authority]. A National Management would increase costs, reduce local accountability and be contrary to the current climate of dispensing with large 'national' organisations."

You then talk about the co-ordination work undertaken by the National Directorate since its inception. Then, if we go over the page, you then set out a number of numbered reasons for being against a nationally managed Blood Transfusion Service. I'm not going to go through all of them but I just wanted to pick up a couple with you. The first is what you say at paragraph 2. You say in the third line at paragraph 2:

"National management would not 'supplement and support' local management ... but would remove a level of responsibility we currently hold and also, very importantly, the local pride of staff ... It would no longer be our Centre working for our hospitals. We would be directed nationally and it is difficult to maintain staff loyalty and pride ... We cannot see how a centrally managed service would ... make this service more efficient, and ... more accountable."

We've previously discussed, a few minutes ago, Professor Contreras, some of the disadvantages of the

autonomous Regional Transfusion Centres so that people were dependent on their relationships with their Regional Health Authority, there were different systems, different levels of funding and different standards, and so on.

Given that you had those views about the disadvantages of the feudal system, why was it that you were concerned about the establishment now, in the 1990s, of a National Blood Transfusion Service?

A. I think that I believed that it hadn't gone far enough. This was a middle-of-the-road solution with no funding, with a large number of additional management staff with high -- quite costly, but with nothing -- not talking about reduction in the number of centres, performance indicators, costing, and he didn't say whether funding would come.

We were all short of cash to run the services. So it was -- I have always been of the idea of a truly national blood service and a truly well-managed National Blood Service as was proven later on, but this was a middle-of-the-road idea, very badly conceived and with some staff that I don't know where he would have got it from, because he had asked for something similar a couple of years earlier after I think it was an Ernst & Young report, and the

Department of Health did not give him the funding.

And now, he didn't have any funding and wanted to start this national management without -- he didn't give us a good basis for it.

Q. If we just go to the next page, there was one other of the numbered reasons I wanted to highlight, which is paragraph 10. You expressed the concern that uniformity would drag you down to the lowest common denominator rather than raise standards generally. So it would just be an extra tier of national management rather than -- is this right, rather than a fundamental reorganisation of the service?

A. Yes.

Q. Now, obviously, the National Blood Authority was, in due course, established and, indeed, you took on a role in the mid-'90s with the National Blood Authority and subsequently with NHSBT. Looking back now, do you consider the establishment of a national service in the 1990s was the right course?

A. Yes, I do consider that, and I was really the chairperson of the National Blood Service Committee that, together with Bain & Company, the management consultants, proposed the National Blood Authority but that meant pain because we had to close some centres or some activities at some centres. We had to abolish

Regional Transfusion Directors, all those management teams, so we had to be cost effective.

And I really believe that was the way to go. I think that nowadays there are two or three testing centres for the whole country; we had 15 before. And so there wasn't a need for 15 -- to repeat 15 times all the things we did.

Q. If we just look at your statement, Professor Contreras.

Soumik, if we could have back WITN5711001 and go to page 32. You'll see towards the bottom of the page, in this part of your statement you were commenting upon your letter to Dr Gunson, the letter we've just looked at.

If we can just to the next page, please, and look at paragraph 131. You said there that:

"[You] felt that there was a lot of inequality between the different blood centres at the time with respect to performance, how and to what extent they were funded and managed and their relationship with their hospitals and patients."

Then you observe that the proposal being put forward by Dr Gunson didn't address properly, in your view, how that inequality would be addressed.

Could I ask you just to elaborate upon the

particular respects in which you felt there was inequality between the different centres? How did that inequality manifest itself in the 1980s and early 1990s?

A. In funding. Mostly it was, really, money. Some Regional Transfusion Centres never met with the Regional Health Authority. They were devolved to the district and the district had other priorities. So many were very short of cash. There is an example amongst the documents that I've been given, for example, of Dr Martlew asking for a plasmapheresis clinic. You know, we had three plasmapheresis clinics.

So I saw that there was inequality. We had more consultants, some of them had one or two consultants in the transfusion centres. We had more scientific officers. I could see that there was evidence of inequality. And there is a report that you provided me with from the Department of Health showing the inequalities amongst transfusion centres.

Q. Just to pick up on that issue of funding, can we just look at a letter that you wrote to your divisional colleagues in August 1991, it's DHSC0004369_014. I'm not going to go through it in particular detail and you're talking, amongst other things, about the

relationships with BPL and issues in relation to that but, if we just look at the last few lines on this page, you say:

"... in my opinion the problem of the NBTS was one of under-funding and of subsidy of BPL. I stated that if we wanted a properly organised National Blood Transfusion Service, the Department of Health would have to pay for it."

Then, if we go over the page, you say at the end of the first line:

"I insisted that many RTCs were under-funded and that a great deal of capital was needed for premises and equipment."

There's then a discussion about a number of specific points, I don't need to trouble you with. Then, if we look at the last paragraph of the letter, you say:

"My personal opinion is that the idea of an NBA was sold to the [Department of Health] on the basis of savings and cost-improvement. The present government and new NHS are not in favour of centralisation, hence the only incentive for advocating an NBA is cost savings. It is sad to see that the Department will allow such a short time for consultation about the future of the NBTS."

So I think it's right to understand that, at the time, you were expressing, I think on a number of occasions quite vociferously, your concerns about the underfunding of the service.

A. Yes.

Q. Did that change or improve once the National Blood Authority was established? Did it become a better funded service in your view?

A. Well, at least in my zone we broke even and were able to improve, for example we were able to establish two additional mobile teams in Ipswich -- and I can't remember the other place -- and we reduced -- we didn't have management team, Regional Transfusion Directors management -- we had only one management team. So we could -- yes, the service improved.

Q. Looking at it now, with the benefit of having worked both in the previous system for a number of years, as a Regional Transfusion Service Director, and then having worked for the National Blood Authority and for NHSBT, is it your view that there should have been an establishment of a properly funded National Blood Transfusion Service much earlier than there was?

A. Yes.

Q. Can I then just ask you broadly about relationships with the Department of Health. We'll come on to some

specific interactions with the Department of Health as we look at particular issues. But, as director in the 1980s through into the mid-1990s, and the establishment of the NBA, to what extent did you have regular dealings with the Department of Health?

A. Well, there was always a representative of the Department of Health at our Regional Transfusion Directors meetings. And, you know, in some of the other committees that I took part in, they were all -- many of them were established by the Department of Health, so there was always a deputy medical officer or a medic from the Department.

So those were the relationships that we had, but it was -- as regional centres, we had much closer relationship with our Regional Health Authority and the chairman, the medical officer, the treasurer.

Q. In terms of the individuals at the Department of Health with whom you had dealings, again, I'm thinking very much of the 1980s through to about around 1995, through attendance at Regional Transfusion Directors meetings and the like, who were the main individuals at the Department of Health who would attend meetings or with whom you might have dealings?

A. Well, for a time, we had dealings with Dr Diana Walford, Dr Hilary Pickles, Dr Alison Smithies. Very

occasionally we would -- I had Ken Calman visiting the centre because he wanted to know what -- but it was mostly those, as far as I can remember, and also Roger Moore who then became Dr Gunson's deputy but, at the time, he was at the Department of Health, Tom Kelly, who did a study, the management study, and I can't remember who else.

Q. In terms of, then, of the Chief Medical Officer or Deputy Chief Medical Officers, you've referred to Ken Calman and he became Chief Medical Officer -- I can't remember off the top of my head the date --

A. Yes.

Q. -- but in the 1990s, I think the early 1990s. Prior to that, do you recall having any interactions directly with his predecessor, who would have been Donald Acheson?

A. Very little.

Q. In terms of Deputy Chief Medical Officers, can you recall any particular dealings between Regional Transfusion Centres or the National Blood Transfusion Service and any Deputy Chief Medical Officers, Dr Harris or Dr Metters --

A. With Dr Harris, I remember writing to Dr Harris, I can't remember what about, but I remember writing -- yes, with Dr Harris and Dr Jeremy Metters.

Q. If we then move on to some of the work of the North London Regional Transfusion Centre, I'm going to start by asking you to look at a document authored by Dr Gunson. It's at DHSC0001677. If we go to the second page, you'll see there's a letter from Dr Gunson to Dr Smithies at the Department of Health, July 1984, enclosing some documents for discussion.

If we go to page 5, one of the discussion documents is headed "Organisation of the Blood Transfusion Service". Then Dr Gunson describes the functions of Regional Transfusion Centres and he divided into functions performed by all RTCs and then functions performed to a greater or lesser degree. I just want to get a sense of what functions were performed by the North London Regional Transfusion Centre?

So would it be right to understand that the North London Centre performed all the functions we see listed on this page: recruitment of blood donors, collection of units of whole blood; preparation of blood labile products; harvesting of plasma for fractionation at BPL; collection of hyperimmune specific antibody plasma for the preparation of specific immunoglobulins.

Those are all functions carried out by the North

London centre?

A. Yes.

Q. Then if we go over the page, the top of the page, we see three further functions:

"Collection of high-titre blood group antibody plasma for the preparation of blood grouping reagents at BGRL.

"Blood grouping, antibody testing and disease screening ... on collected blood.

"Storage under appropriate conditions and issuing of blood and blood products to District Hospitals within the region."

Again, are those all functions that the North London centre undertook?

A. Yes.

Q. Then if we look at Dr Gunson's description of functions performed to a greater or lesser degree in Regional Transfusion Centres and if we bear in mind this is as at 1984, and it's the point in time at which you became director, so if we think of 1984, antenatal blood group serology, was that done at North London?

A. Yes.

Q. "Quantitation of blood group antibodies by automated techniques"?

A. Yes.

Q. Cross-matching?

A. Yes.

Q. Acting as a regional reference centre for hospitals in case of transfusion problems?

A. Yes.

Q. "Preparation of blood grouping and antiglobulin reagents"?

A. Not antiglobulin reagents but blood grouping reagents, yes.

Q. Histocompatibility testing for the purposes there set out?

A. Yes.

Q. Next page, screening of donor blood for antibodies to specific diseases?

A. Yes.

Q. Provision of an immunology service for the diagnosis of conditions such as immunoglobulin abnormalities and complement abnormalities?

A. No.

Q. Therapeutic plasmapheresis?

A. Yes, but at hospitals.

Q. And then cytopheresis for platelets and granular sites?

A. Yes.

Q. And screening of donor bloods for rare cell antigens?
A. Yes.
Q. So consistent with the impression you gave us in your evidence earlier, the North London Centre carried out a wide range of functions, more than some of the other centres might have done?
A. Yes, and I must say that there is something missing here, and I forgot to say it when we were talking about my response to Dr Gunson -- I'm sorry to interfere -- but it is that never was transfusion medicine included in these documents. You know that, for me, the relationship with the blood centre and the physicians and surgeons and patients, is a great deal of the work of the blood centre, it should be.
Q. We'll look at some of the documents and some of the evidence in that regard probably later on today.

If we just go to the bottom of this page -- well, actually no, if we just look at paragraph 3, first of all, I just want to ask for your observations on that.

Dr Gunson said:

"The regional organisation of the Service, and in particular, with regional financing, means that the primary aim is to provide a service for the region only. This means that difficulties can be experienced

in one region because of the special conditions applying, eg platelet supplies to the London Teaching hospitals whilst other regional centres could, with planning, provide an excess over their regional needs. Whilst in emergencies RTCs will help each other out, there is little long-term co-operation in the rationalisation of blood collection and preparation of labile products between regions, although this occurs sporadically."

Would you agree with his observations --
A. Totally.
Q. Then we can see at paragraph 4 he refers to some RTCs having assumed responsibilities for the major production of certain products, and an example for North West Thames is anti-tetanus specific plasma. Were there any other particular products that the North London Centre specialised in?
A. Oh, yes. Eventually, we were involved in the collection of all specific plasmas, anti-hepatitis B, anti-tetanus, and we were one of the major producers of anti-D immunoglobulin, anti-herpes zoster, yeah.
Q. I might come back to the issue about hepatitis B immunoglobulin later, Professor Contreras. Again, just sticking with an overview of the centre, if we go to NHBT0001997, please. This is an annual report for

1993/1994 for the North London Blood Transfusion Centre. We don't, I think, appear to have any earlier reports. Would it be right to understand that the premises we see pictured here, these are the new premises, the purpose-built premises in Colindale?
A. Yes, when I was appointed, they told me, "You have one wish, Dr Contreras", and I said, "I would like a new centre."
Q. And that was 1989, I think, in which you -- *(unclear: overspeaking)*
A. Yes.
Q. -- new centre?
A. Yes.
Q. If we go to page 5 of this report, we can just get a sense of the objectives that were being set by the centre in its '93/'94 business plan, and the report describes eight objectives set for the year. I'm not going to go through all of them, but one is collection, so to collect 225,000 -- sorry, Soumik, can we go -- there, thanks.

"To collect 225,000 whole blood donations."

And it describes the centre having the highest collection rate in the country. And the second paragraph under that heading says:

"A further increase in whole blood donations

above the previously high level demanded a number of strategies. Basic to this was the recognition that the service must be more geared towards the needs of donors."

I'll come back later, Professor Contreras, to some of the strategies that might have been deployed. But one of the main objectives, therefore, is to meet and identify target in terms of collection of donations and, although this is '93, '94, would it be right to understand that every year there would have been a target that you were aiming to reach?
A. Yes, this was our own target, after discussion with the hospitals to see what advances or improvements they were making that would need more blood, like liver transplantation, for example.
Q. I'm going to skip over objectives 2 and 3. If we can go to the right-hand column, objective 4:

"Promote good transfusion practice at hospitals."

And you've made reference there to "Hospital Transfusion Committees". Again, we'll come back to those in much more detail, but this is something you're identifying in '93, '94, the importance of promoting good transfusion practice in the hospitals.

Had that been something that was a feature of

work of the centre at an earlier stage?
A. Since 1984.
Q. Then fifth objective is improve cost effectiveness and efficiency. I don't think we probably need to look further at that.

And then if we go to page 7, we've got a heading "Interactions with donors", and a number of subheadings. I just wanted to ask you about the heading "Donor Association", and it says under that heading:

"The donor association continues to be a vital part of our recruitment strategy."

And then further description of the work of the donor association is given. And then the next paragraph talks about telephone recruitment campaign and telephone retention of donors and telephoning lapsed donors and so on.

What was -- sorry, how long had there been a donor association at the centre? Can you recall?
A. Before my time. I think it was started by Dr Cleg -- he encouraged donors to participate, and it was started with -- I believe it started with plasmapheresis donors.
Q. And so one of the means of trying to meet your targets and ensure you had enough donations, was to have this

good relationship with donors; is that right?
A. Yes.
Q. And to use donors to try to help you increase the number of donations?
A. Yes. We had every year -- every six months, we had donor award ceremonies as well for donors who had given 50 or 100 donations. So there were many donors who have given 100 donations in their life.
Q. If we go over to the next page we've got a heading: "Donor Recruitment - the personal touch!"

Reference to call-up letters, posters, telephone calls, work of a public relations teams and so on. So would it be right to understand there might be a number of ways in which, as a centre, you could seek to try to increase the amount of blood that you collected?
A. Yes. And I believe that the best one was giving good customer service to the donors, giving -- feeling them -- feel wanted and important, and that brought more donors in.
Q. If we just go to page 19, please, we've got some statistics in terms of donation targets and number of donations.

So this tells us about '89 onwards. I'm afraid we don't have similar statistics for the period prior

to 1989. But we can see, can we, in that table or chart on the left, that for the year '89 to '90 you had a target of 210,000 donations. It wasn't met in that year, but you collected 194,423, and then we can see increases in the number of donations collected over the following years, so that in 1991/1992 you exceeded the target, and you continued to exceed the target over the following two years. Is that the right way to understand this?
A. Yes.
Q. Then if we can just go to page 24, this is to get a sense of the geographical area and the number of hospitals served by the North London Centre. Obviously, again, this is at 1993/94, so the position may have been a little different in earlier years. But we can see, I think, from this list that there are a large number of NHS hospitals to which the centre supplied blood and blood products, including a number of leading hospitals in London such as Charing Cross, Chelsea and Westminster, Great Ormond Street. We've got Harefield, Northwick Park, Royal Brompton, Royal Free, and so on. So a number of the leading teaching hospitals in London as well as a range of other hospitals.

And then you also supplied private hospitals.

A. Yes.
Q. Had that always been a feature of the centre's responsibilities?
A. Yes. Private hospitals are -- were always dependent on the blood service. And still are.
Q. And then for the -- during the 1980s and first half of the 1990s, can you remember which haemophilia centres the centre supplied with factor concentrates?
A. We never supplied factor concentrates, because it went directly to the haemophilia centres.
Q. So let's start with commercial concentrates. Would it be right to understand then that the centre never held commercial concentrates?
A. Never held commercial concentrates.
Q. So if, for example, the haemophilia centre at the Royal Free Hospital, which fell within your area, wanted to purchase concentrates from Immuno, that would be a relationship directly between the Royal Free and the pharmaceutical company and it never had anything to do with the centre?
A. Nothing to do with it.
Q. And you didn't store the concentrates for any of the centres?
A. No. Our allocation went directly to the hospitals that needed it, to the haemophilia centres.

Q. I want to deal with commercial concentrates and then BPL completely separately.
A. Yeah, yeah.
Q. So in terms of commercial concentrates, did you have any allocation to was that absolutely nothing whatsoever to do --
A. Nothing whatsoever.
Q. Then in relation to concentrates manufactured by BPL, so BPL Factor VIII, Factor IX concentrates, you're supplying the plasma to BPL over the years. Am I right to understand, then, that the concentrates that you are then allocated under the pro rata system didn't physically come back to you but would go directly from BPL to the individual Haemophilia Centres?
A. Yes.
Q. So you had no role in distributing factor concentrates at all?
A. No.
Q. And, do you recall, was there any system of regular meetings or discussions with the Haemophilia Centre Directors within the North West Thames area?
A. We -- Peter Kernoff was -- Peter Kernoff was the director of the Royal Free Haemophilia Centre and he was part of some of the meetings that we -- was it the

National Management Committee or the liaison with the -- with Elstree, with BPL. And of course, we -- since we all had hospitals allocated to us, for example, I had the Royal Free. So the Haemophilia Centre director would attend our hospital transfusion committee. So, with every haemophilia centre that there was in the region, there was a consultant and they would attend our ...
Q. But of the hospital transfusion committees, I think, were a creation of the early 1990s or thereabouts, or do you --
A. No, we started them a little bit earlier. A little bit earlier. But -- yeah.
Q. If we leave aside, then, haemophilia centres and supply of factor concentrates, what was the system for hospitals, hospital blood banks, to obtain products from you? So if a hospital want to get a quantity of whole bloods or red cell concentrates or some other blood product or component that was processed at the centre, how would that be done?
A. They -- according to the historical demand, we would be providing -- we always believed that most of the blood needed to be in the hospitals and not with us. We didn't want to hold it. So we gave them what they needed and we gave them the very -- the big users had

deliveries once or twice or even three times a day, and that was according to their plans, and they would send us their demands on the week before or sometimes the day before. So we supplied them with their needs, whenever we could, but sometimes we couldn't meet all the needs for their stocks.
Q. So were there hospitals where you would know that on a daily basis they were bound to need a certain amount of something --
A. **(Witness nodded)**.
Q. -- so there would be a regular system?
A. Yes.
Q. Then the hospital blood banks would then also be contacting the centre to say, "We need X, Y and Z today, tomorrow, this week"?
A. Yes.
Q. Can I just come on to questions of regulation of the work of Regional Transfusion Centres, and systems of inspectional auditing.

If we go back to your witness statement, Professor Contreras -- so, Soumik, WITN5711001 -- and we go to page 29. Yes.

You say in paragraphs 113 and 114 of your statement, that the centre was regularly inspected, and you refer to inspections by the Medicines

Inspectorate with power to close a centre for non-compliance, and then a range of other forms of regulation including external audits from other Regional Transfusion Centres.

Then if we go to the bottom of the page, paragraph 114, you say:

"Regulation of the blood services and BPL really started formally after the removal of Crown Immunity in April 1991 and the appointment of the MCA (Medicines Control Agency) under the Medicines Act ... as the licensing authority, ie blood centres needed a licence from then on and inspections of Transfusion Centres were mandatory every 2 years for holding a manufacturer's licence."

Then over the page, you describe in paragraph 115 the system prior to that, where you could have inspections by the Medicines Inspectorate, but these were "advisory, rather than enforceable".

And I think we saw with Dr Napier yesterday or the day before some documents from the late seventies which talked about informal inspections by the Medicines Inspectorate.

Professor, is it right to understand that, looking at the time you were so centre, so from 1980 through to 1991, where we had the formal system set

up, you were inspected by the Medicines Inspectorate but they didn't have any power to, for example, close the centre or order or require you to take particular steps?

A. Yes, well, they would require us to -- they made a report, and then we had to reply to them -- we had a time limit to respond to them, making all the improvements that he was requiring or all -- or complying with the Orange Guide, and we had to reply to him.

And I even asked Mr Cavanagh, when we were at Edgware, to try to close the centre so that we would get a new centre quickly. But he said, "I don't have the power to do that."

Q. And so in relation to these advisory inspections prior to the system changing in 1991, would that involve, for example, inspection of the centres' systems and processes for record-keeping?

A. Yes.

Q. And the donor selection/donor screening systems, would those be inspected?

A. Yes.

Q. And the processes of testing, so microbiological testing, for example, would that also be part and parcel of the inspection process?

A. Yes.

Q. And recommendations might then be made?

A. Yes.

Q. And is it right to understand they couldn't be enforced but the expectation was that you would comply with the recommendations?

A. Yes.

Q. And I think we've got an example of an inspection report at NHBT0006240.

So this is an inspection report of the North London Centre, we can see it's now at Colindale, and the date of the inspection is May 1989. So this is prior to the new regime from 1991 onwards.

"Date of previous inspection:

"Purpose of visit ..."

This records this is the:

"First inspection of new centre."

So it's the first inspection at Colindale. But there had been, had there, similar inspections carried out at Edgware?

A. Edgware.

Q. Then we can see:

"Recommendations/Action:

"1. A copy of this report to be sent to the Regional Health Authority for comment and proposed

action.

"2. Follow-up inspection when clean room facilities and procedures corrected.

"3. Full re-inspection within 2 years."

So although there wasn't the power to close the centre, is it right to understand that the ways of trying to ensure that centres complied with recommendations would be: the Regional Health Authority would be sent a copy, the inspectors could come back --

A. Yes.

Q. -- to see what you'd been doing, and then the inspectors would come back for a full reinspection on a biannual basis?

A. Yes, and we would invite -- we usually would invite -- once we had corrected everything, we would invite them to come and have evidence.

Q. Then if we just go back to your witness statement at page 29. So WITN5711001, page 29. At paragraph 113. The third bullet point refers to external audits from other Regional Transfusion Centres.

So did that happen in the course of the 1980s, that other centres would undertake audits of your centre?

A. Yes. Yes. In the late eighties, I think it was.

I can't remember very well, but --

Q. And likewise did you undertake audits of other centres?

A. Yes.

Q. Can you recall which other centres you yourself personally audited?

A. I really can't remember, but I remember going to centres with a couple of members of my management team, with my quality manager and another member of my management team. But I can't remember which centres they were.

MS RICHARDS: Sir, I note the time, I'm going to move on to another topic so probably a good moment for having a break.

SIR BRIAN LANGSTAFF: Yes.

Well, we'll take a break now until 11.45. It allows all those who are watching at home -- that will probably be about hundred people or so doing that -- to have a break, have a coffee, and the same for us here.

Let me tell you what I say to all witnesses when we come to any break, and it's this: you're giving evidence. One of the rules which you must adhere to is you may not discuss the evidence you have given, or anything which you think you may yet be asked about in

evidence with anyone, whoever that person is -- a friend, family, lawyer, anyone -- but you can talk about anything else you like. So I look forward to seeing you at 11.45.

A. Thank you.

(11.15 am)

(A short break)

(11.45 am)

MS RICHARDS: Professor Contreras, I'm going to ask you in a moment about your understanding of the risks and seriousness of different forms of hepatitis but, before we look at hepatitis B and then non-A, non-B hepatitis, you've described in your witness statement how, as part of your teaching work, you would seek to educate students about the risks of blood by writing on the chalkboard the words "Blood can kill".

Now, obviously blood can kill not just because of transfusion-transmitted infections but for other reasons, but it can certainly kill because of transfusion-transmitted infections. Can you give us an idea of when you would be providing your students with such a stark warning? Is that a feature of your teaching in the 1980s?

A. Yes.

Q. What was it that you were tying to get your students

to understand?

A. That you have to balance the risks between transfusion and no transfusion, and between transfusion and alternatives, and that there are several risks in transfusion and the worst one was errors. So I want them to understand that they have to think before transfusion.

Q. If we turn to hepatitis B, first of all, as a transfusion-transmitted infection, in your witness statement, if we have that back on screen, please, Soumik WITN57 -- thank you, you're ahead of me, and go to page 72, please. You've said, under the heading "Hepatitis B" that hepatitis B was something you were aware of both as a virus and in terms of its significance, its seriousness, from the 1960s onwards; is that right?

A. Yes.

Q. And it was something which you understood could potentially be fatal?

A. Yes.

Q. Now, we know that some form of screening of blood for hepatitis B was introduced in England and Wales in 1972. So, by the time you started working at the North London Regional Transfusion Centre, there would have been testing for hepatitis B. Can you recall

what your understanding was of the sensitivity of those tests in the 1970s and early 1980s?

A. Well, we later learned that they were not as sensitive, you know, the initial tests were not as sensitive as time evolved and we were getting better tests, so we realised that the sensitivity wasn't as good as it could have been, but that was a problem with the technology that we had, the techniques we had at the time.

Q. When you took over as deputy director in 1980, can you recall which type of test the centre was using at that point.

A. Not exactly, but I think that it was either the RIA, the radioimmunoassay that had some risks because it used a radioisotope, iodine-125, or we had already moved to reverse passive haemagglutination that was safer for staff and Dr Barbara made it more sensitive by diluting the -- and using the technology from -- that was using haematology in microbiology and make it -- making it quite a sensitive technique.

Q. So in terms of the changes in the testing techniques used, Dr Barbara may be the person who may be able to assist in relation to that?

A. He is an expert in that.

Q. But would it be right to understand that there would

have been an awareness in the centre amongst you and your colleagues that, notwithstanding the fact that testing had been in operation since the early 1970s, there could still be cases of hepatitis B being transmitted through transfusion?

A. Yes. We learnt that from Dr Dane, as well, that -- and even now, perhaps, there are a few cases.

Q. Just so those following understand, Dr Dane was based where?

A. At the Middlesex Hospital.

Q. His area of expertise was?

A. Hepatitis and he was the discoverer of the surface antigen of the Dane particles, yeah.

Q. Now, if we then turn to non-A, non-B hepatitis, and if I ask you to go back in time, as it were, to say 1980, when you became deputy director at the centre, is it right to understand that you'd have been aware, by that point in time, that there was something that was termed, for want of a better description, non-A, non-B hepatitis?

A. Yes.

Q. It was, by then, understood that some, perhaps most, cases of post-transfusion hepatitis would be attributable to non-A, non-B hepatitis, whatever it was, rather than hepatitis B?

A. Yes, but we had so few cases of post-transfusion hepatitis in those days, that yeah, some of them were still attributed to hepatitis B, and some to non-A, non-B.

Q. Now, in terms of your understanding of the potential seriousness of non-A, non-B hepatitis, you've described in your witness statement how your understanding changed over time, essentially through the course of the 1980s. I'm not going to go through everything you say in your statement but you've drawn attention to -- and you're not the first witness to have had done so -- to the publication of Sheila Sherlock.

So if we could have, Soumik, WITN4032023.

Sir, this is a publication by Sheila Sherlock, Professor of Medicine at the Royal Free, "Diseases of the Liver and Biliary System". This is the sixth edition which was published, I think, in 1981.

Then if we go to the next page -- sorry, keep going. That just gives the date of publication.

Yeah, so we've got there page 257 of the textbook, and again we've looked at this in earlier hearings with other witnesses, Professor Contreras, but we've got there the heading "Non-A, Non-B Hepatitis". We can see Professor Sherlock saying:

"The elimination of hepatitis A and hepatitis B from transfused blood did not eliminate post-transfusion hepatitis. Some of the cases were due to cytomegala infection but the majority were due to another virus or viruses termed non-A, non-B. This infection now accounts for about 75% of post-transfusion hepatitis, possibly 15-20% of sporadic hepatitis, depending on the geographic location. Haemophiliacs receiving factor concentrates obtained from commercial sources are particularly at risk. Non-A, non-B hepatitis is largely blood spread. It had also been reported with drug abuse, renal transplant recipients, in dialysis centres and in donors used for plasmapheresis."

So this is a textbook as I understand it you were familiar with at the time, so you'd have read and understood what was being set out here.

A. Yes.

Q. And you've explained you were -- you knew Professor Sherlock in any event --

A. Yes.

Q. -- for a range of reasons. If we go over the page, there's then a heading "Clinical course":

"The incubation period is about seven weeks, although a short incubation type (one to four weeks)

is also seen. The acute episode is usually mild and often anicteric. Extra-hepatic manifestations do not occur. Fulminant hepatitis is rare. The serum bilirubin and transaminase levels tend to be lower than with acute virus A or virus B infection. The serum immunoglobulin M is normal. The course may be prolonged, with serum transaminase levels waxing and waning for many months. A mild, chronic hepatitis develops in about a quarter, but this usually improves with time. Circulating immune complexes may contribute. Cirrhosis can develop."

Just ask you to bear that in mind.

And then if we carry on:

"In liver biopsies, in addition to the general [go to the next page] features of acute virus hepatitis, the picture is of one of marked sinusoidal and portal zone cellular infiltration ..."

Then there's a description of other changes that can sometimes be seen.

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

And you've drawn attention, I think, in your statement, Professor Contreras, to those last two sentences as representing in part your understanding

that non-A, non-B hepatitis was not necessarily as serious as you later understood it to be. Is that right?

A. Yeah, and -- yes, and we didn't see that much of post-transfusion hepatitis -- because she was talking about the general problem of non-A, non-B specific, and she includes in that haemophilia patients. And I was -- yeah, I was talking more of the transfusion of labile blood components.

Q. Now those last two sentences:

"The prognosis of this is, at the moment, uncertain and probably benign."

As I read it is talking about the mild chronic hepatitis that might develop. So the mild chronic hepatitis might be uncertain -- prognosis uncertain, probably benign?

A. Yeah.

Q. But reading the passage as a whole, you would also have understood that non-A, non-B hepatitis could lead to cirrhosis and had been observed to lead to changes in the liver. Is that fair?

A. Yes, but this is in the acute phase, and then -- then he said that the majority of them improved. So the changes in the liver were in the acute phase and in -- well, in the multiple -- multiply transfused. She

didn't see. She was referred patients from all over the world, Professor Sherlock. You know, you went to her clinic and it was the United Nations there. So she -- she saw a selected patient population. But, yes, I interpreted that as the acute phase and then they went to normal, as she said it.

Q. You've also in your statement explained that you would have read a number of other publications at the time because you read various medical journals. And you tell us you believe you would have read -- there's an article by Purcell and Alter that you've referenced, and indeed the Inquiry has looked at on a number of occasions in its hearings, an article by Dr Craske in the mid-seventies, and Dr Preston's 1978 publication. So you think you would have read those at the time?

A. Yes.

Q. If we look at your statement -- Soumik, can we have that statement --

SIR BRIAN LANGSTAFF: May I just ask one question? Can we just go back to that passage?

MS RICHARDS: WITN4032023, Soumik.

SIR BRIAN LANGSTAFF: The last paragraph. She isn't saying that non-A, non-B hepatitis normally resolves in its acute phase, is she, because she said it often progresses to a chronic phase?

A. Yes.

SIR BRIAN LANGSTAFF: Is one to understand from the word "mild" that, at the stage that it becomes chronic, it may not show very much by way of symptoms?

A. Yes.

SIR BRIAN LANGSTAFF: But one doesn't know -- the next sentence is one doesn't know what may happen after that?

A. Yes, but she says "probably benign", as well.

SIR BRIAN LANGSTAFF: Yes, "at the moment, uncertain but probably benign". I see, thank you.

MS RICHARDS: Yes. Sir, we've looked in earlier hearings at some of the other passages in the book but they're not passages that Professor Contreras has specifically referred to, I'm not proposing to ask her about the detail of them.

Sir, if we then go to your witness statement, page 75, please. So you've described in the preceding paragraphs in your statement the way in which subsequent editions of Professor Sherlock's book described non-A, non-B hepatitis in different terms. Then at paragraph 300, you say you're aware of publications which express contrary views, which you would almost certainly have read at the time, and then you give three examples that the Inquiry has

previously examined.

Then paragraph 301 you say this:

"I have reflected back on these publications and my interpretation today has not changed much from the one I had when I first read these papers. They do not point to serious chronic effects of [non-A, non-B] hepatitis. The situation in the USA was different from the UK, as the incidence of transfusion transmitted infections has always been higher there."

Just pausing there, if we leave aside the question of incidence, and the fact that there are more cases reported in the States than in the UK, which you may well be right about, that's -- why would that be relevant to an understanding of the seriousness of non-A, non-B hepatitis?

A. No, that wouldn't. The incidents would not.

Q. Then you go on to talk about interpreting Dr Preston's findings, the biopsy findings, which he described in that 1978 publication, as:

"... something particular to patients with haemophilia, ie [if we go over the top of the page] something related to repetitive immunological assaults. The paper by John Craske also dealt with patients with haemophilia."

Did you therefore, in your own thinking at the

time -- and I appreciate I'm asking you to go back to a point in time at which your understanding was different from how it is now, but did you therefore read these papers, do you think, as saying that the changes reported by Dr Craske, Dr Preston, were not viral in origin? Was that your understanding when you refer to "might be related to repetitive immunological assaults"?

A. Yeah, that might not have been viral in origin, and if they were, they were so repetitive that that viral load was so high, that it was different to somebody who was transfused with two or three units of blood.

Q. Do you recall whether that way of looking at these publications, these studies, was something that was discussed by you with colleagues, whether within the centre or externally? Were there virologists or indeed haemophilia clinicians with whom these issues about non-A, non-B were discussed at the time?

A. Yes, I vaguely remember discussing -- I think it was with Eric Preston -- that I said, "Well, couldn't" -- and in some of the papers that I read, there was this view that it could be an autoimmune disorder, that it was different and, yes, and I knew John Craske as well, but I cannot remember discussing very well, whether -- but there was some -- there was a view that

it could -- that the haemophilia patients had more -- a greater immunological assault, regular immunological assault.

Q. So what you described in your statement is you forming your own views and understanding of the significance of these different studies, your own understanding of seriousness of non-A, non-B hepatitis. Would it have been an issue upon which it would have been, at the very least, useful to have some form of central advice or steer or guidance from, whether from the Chief Medical Officer or through the Regional Transfusion Director meetings, or some other source? Rather than you being left to reach your own interpretation of what the medical literature was revealing?

A. Yes, perhaps it would have been useful to have some central advice of experts or advice from the CMO. But my problem is that we were not seeing the problem that my haemophilia director colleagues were seeing.

Q. What you say, just picking up upon that, to some extent, in paragraph 302 of your statement, you say:

"It is fair to say that my knowledge evolved over time with respect to the seriousness of this virus, because it takes a very long time for it to show its severe chronic effects in a proportion of infected subjects. Hence, I could not see at the time

an obvious health problem in the population, and did not do so until the effects of the virus began to manifest much later in time."

Now, this is going to be a very crude summary, Professor Contreras, but there might be two reasons why you're not seeing the effects of the virus presenting itself. It might be because there aren't any serious effects or it might be because it takes a very long time for those effects to show themselves, because this is a chronic condition where changes to the liver or symptoms might only become apparent many years after the event.

Do you recall whether you gave active consideration at the time, either yourself or with others, to the possibility that the reason you weren't seeing this was because it was long term, rather than because it wasn't a serious issue?

A. I can't remember, because I didn't know that there was a long-term effect so I couldn't have thought that there might be long-term effects, because we -- all we could see was the reports from the hospitals that we encouraged the hospitals to report to us, and we would see a maximum of four cases of post-transfusion hepatitis due to the transfusion of products that we provided, that means labile blood components. But

I couldn't know that there were going to be chronic effects.

Q. My next question is a general one, rather than necessarily specifically limited to non-A, non-B hepatitis. Would you agree, as a general proposition, that it may be in the nature of an infectious disease that it can take a period of time for the full implications of that condition to be clearly or comprehensively or conclusively understood. Would you agree with that?

A. I fully agree with that. Yeah, that's in the nature of all diseases, yeah.

Q. Again, this is a very general question, it's not related specifically to an issue about testing or screening for non-A, non-B hepatitis. But, given that, if one waits for the full implications to be clearly or conclusively understood, it may be too late by then to take preventative action as a general idea?

A. As a general, yes.

Q. Now, you told us that you had a greater understanding about hepatitis B and, obviously, that had been something that had been identified since the 1960s in particular. Can we just look at one of the articles that you referred to in your statement. It's PRSE0000381. It's the Purcell, Alter, Dienstag

article, 1976, "Non-A, non-B hepatitis", and if we could just go to page 4, it's a paragraph about halfway down the page beginning:

"Although type non-A, non-B hepatitis is associated with less severe acute illness than type B disease, as judged by frequency of jaundice and magnitude of SGPT elevations, the long-term prognosis for the two diseases may be similar."

Then there are various observations set out and there's reference to patients undergoing liver biopsy. Then the last sentence of the paragraph reads:

"Thus, chronic non-A, non-B hepatitis is not necessarily a benign infection and may be the cause of a significant proportion of chronic hepatitis not identifiable as type B disease."

Can you recall whether, late 1970s, first half of the 1980s, the extent to which consideration was given to the possibility that non-A, non-B hepatitis might follow a similar pattern to hepatitis B, as regards long-term effects of infection?

A. I just can't recall what I thought in the 1980s or 1990s. But what impressed me with this paper is that, at the end, they state that the only means of preventing -- perhaps that stuck in my mind -- of preventing the transmission of this disease is to have

all voluntary blood donors.
Q. You say, if we go back to your statement, then, Soumik, please, WITN5711001, page 78, and it's just the first sentence of paragraph 315, at the bottom of the page, you say:
"With respect to non-A, non-B hepatitis, my knowledge developed over time and in hindsight my appreciation of the seriousness was perhaps later than others in the medical community."
When you refer to being later than others in the medical community, which others in the medical community did you have in mind? I don't mean by name but in terms of what kind of clinicians are you identifying there who might have appreciated the seriousness earlier than you did?
A. The liver disease specialists and the haemophilia consultants or the doctors who dealt with haemophilia.
Q. Then if we look in your statement at page 86, paragraph 339, you refer that your view did change over time:
"... gradual appreciation that [non-A, non-B hepatitis] infection could, in fact, lead to chronic liver disease", and you talk about science and medicine being evolving subjects.
Then when you say:

"When the evidence was available, my view did change, but this took some time."
I appreciate it's difficult, looking back, Professor Contreras, but are you able to help us in understanding what you think the point in time was, the year was, when you would have realised that non-A, non-B hepatitis could indeed lead to chronic serious liver disease?
A. No, I cannot. I would be speculating.
Q. I appreciate it's a difficult question. If we just go back to page 75 of your statement, paragraph 299, you point there to the 8th edition of Professor Sherlock's book, the 1989 edition, and you set out a summary of what was said there, and you said there in the last sentence of that paragraph:
"I think this is really when I began to appreciate the true significance of [non-A, non-B] Hepatitis."
So is that -- would that be your best estimate that it's probably around 1989?
A. Yes.
Q. I want to come on to ask you now about the processes for donors to give blood and the donor screening processes at the North London Regional Transfusion Centre.

We can take the statement down, thank you, Soumik.
How would you decide roughly how much you needed to collect in terms of blood; how many donor sessions you might need to hold or how many donations you might need to try to gather?
A. Well, with our team and our donor organiser, we based it on historical data, as you saw with our business plan, and also in consultation with the hospitals. We had very strong links with the hospitals. So -- and we had our predictions on how much we would need, but I wouldn't do it on my own. I would do it with my team of consultants and managers and donor organisers.
Q. Is it right to understand that, in terms of numbers of donations you, by which I mean the centre, set its own targets?
A. Yes, yes.
Q. How common was it to have shortages?
A. When I took office as a director, it was quite common. We even had a contract with Oxford, with the Oxford Transfusion Centre, and I remembered that last night, I think, that to import blood on a regular basis, O positives or -- group O positive or group O negative, et cetera, and I don't remember having a contract with Scotland, but -- and we had to get help from other

centres because although we collected more than anybody else per thousand population, we still need -- our demand was greater than for any other centre.
Q. If you needed to try to increase the number of donations relatively quickly -- you talked earlier about some of the strategies, the importance of treating your donors well, you had the donor association, and so on, were there particular strategies as, in fact, quick fix strategies, in terms of publicity or advertising, that you might utilise?
A. Yeah, we could -- well, we didn't have much money for publicity but we could telephone the donors, we had, you know, this donor association also helped us to telephone donors, and we went to local radio, and local newspapers that were always extremely helpful, in order to increase our supply if we were short.
Q. Now, in terms of the staffing arrangements at donor sessions, we understand from looking at Regional Transfusion Director minutes -- meeting minutes, that in -- I think it was 1984, the Brentwood centre raised a question about whether nurses could, as it were, take the clinical lead at donor sessions, rather than having a medical officer. What was the position in relation to the North London Centre's donor sessions? Was there always a medical officer in attendance?

A. Yes, before Jean Harrison's brilliant idea to have nurses in teams, we had medical officers going to every mobile collection team and to every static clinic.
Q. You referred to Dr Harrison's idea as a brilliant one. Did that therefore change --
A. Yes.
Q. -- did nurses become trained to lead the sessions?
A. Yes, as it's happened in the Health Service. You had nurse -- consultant nurses, and yeah -- so yeah, it changed.
Q. In terms of the kind of arrangements that were made for donor sessions, the inspection report that we looked at earlier, I might give you some specific details rather than asking you to call on your memory, NHBT0006240, please, Soumik.

Sir, you'll recall we looked at the first page of this inspection report earlier.

If we go to page 4, bearing in mind this is 1989 and things may have changed, but we've got a description under the heading "Inspection, Blood Collection and Receipt" about the donor sessions. So it says:

"Blood collection takes place at 28 mobile sessions per week, including 5 using the special

'Bloodmobile' truck, in addition to the static donor clinics at Deansbrook Road, Edgware, the West End Donor Centre in Margaret Street and then in Luton."

Then it references to a mobile session taking place in a particular factory.

So throughout the 1980s, is it right to understand that there were three static donor clinics.
A. Yeah, the Luton clinic came into effect when I was a director.
Q. So those were permanent clinics --
A. Yes.
Q. -- where members of the public would turn up to donate blood?
A. Yeah.
Q. Then, in terms of the mobile sessions, what kind of locations did they go to? Were they usually workplaces or would they also be community settings?
A. Everywhere. Wherever we could find a hall that was large enough and the will of the managers, we went to churches, we went to universities, we went to hospitals, factories, and we had the bloodmobile that was stationed -- and at the three static clinics we dealt mainly with plasmapheresis and plateletpheresis. But we also had working donors and panel donors.
Q. Then I'll be coming on to records in a little while,

but we can see from the second paragraph on the screen a reference to records. So:

"Although the introduction of a computerised system of donor records is planned for later this year, the system currently in use is that of colour-coded cards. The record cards for all the donors on the appropriate panel are brought to each session; new donors are provided with buff-coloured cards."

Then it goes on to describe how a donor completes the medical checklist and consent form and then a series of labels would be issued. The donor's name and blood group -- that presumably is -- is manually recorded and a barcoded donation number labels are attached. The donors is given their record card and the remaining barcode labels and then they proceed to go to another table where their haemoglobin is tested.

Then if we go to the top of the next page, this obviously is the position as at 1989, so what's next described is not something that would have been in operation earlier in the 1980s. But it says:

"At this stage, donors are given the opportunity of confidentially identifying themselves as members of high risk groups for AIDS. This system is unique to

NLBTC and involves the donor ticking 'yes' or 'no' on a questionnaire asking them whether they belong to one (or more) of 7 defined risk groups. The questionnaire is ticked in a 'polling booth' type cubicle and is posted into a 'ballot box'. One of the many advantages of this procedure is that a donor in a risk group if he/she feels it is impossible not to donate, can identify the donation which can subsequently be removed and not used to treat patients."

Now, we'll look at the leaflets and questionnaires, as I say, in a while. But can I just understand how this worked, at least by 1989. There's the questionnaire that's described here, which I think was introduced in '84 or '85, from recollection, and there was a degree of privacy, is this right, to the way in which the donor could complete that?
A. Total privacy. If the premises had a little room, separate room, they would go into separate room. If not, we took screens so that they would be totally isolated, nobody could look at them, and then they could complete it and put it in a ballot box.
Q. Would the expectation then be that that donor would simply quietly leave?
A. Some of them would leave and some of them -- one of the papers that you provided to me states some of them

would tick the box and, say, because they felt pressurised by the workmates -- for example, if lots of people from a building site came to donate and one of them had a risk factor, they wouldn't not donate, so they would say, "I don't want my blood to be used for transfusion".

Q. I see. So they could still donate and therefore save face, as it were?

A. Yeah, but the majority of them --

Q. But the questionnaire would have had one of the barcode labels affixed to it --

A. Yeah.

Q. -- so you could identify that this was a donation where the donor had ticked "yes" to being in a high-risk group --

A. Yes.

Q. -- and so the donation would then subsequently be removed?

A. Withdrawn, yeah.

Q. That's then, I think, the explanation for the last sentence of that paragraph:

"One of the main advantages of this procedure is that a donor in a risk group, if he/she feels it is impossible not to donate, can identify the donation which can subsequently be removed and not used to

treat patients."

A. Yes.

Q. Then the description that continues is the donors are then led to a bleed bed by a donor attendant, and then the donation is taken.

A. **(Witness nodded)**

Q. Just while we're in this document, if we just go to page 12. This is about what subsequently happens and the inspection report describes the various stages that are undertaken. So this is about a later stage when the products are ready for issue.

Just picking it up in the second paragraph, under the heading "Blood Bank and Issue", I asked you earlier about the arrangements for supply of products to hospitals. This describes that:

"Orders for blood and blood products are either standing, regular orders or telephone orders. When hospitals 'phone in an order, a clerk notes the request on a notepad and transcribes it onto a duplicate order form. [A] copy is given to the Issue department ..."

Does that reflect what you referred to earlier where you'd have -- you'd known that there were orders that were regularly being sent to Great Ormond Street or the Royal Free, but if they needed something more

or something extra, they would phone in --

A. Yes.

Q. -- the hospital blood bank, and then the arrangement would be as described here?

A. Yes.

Q. Can we then look at some of the documentation relating to donor screening.

A. Can I just say that this document, I've just glanced at it, shows the difference that we had at different centres because we decided, after having done some trials, that we would not use lignocaine at donor sessions, because an -- a local anaesthetic. Because it was better to just go into the vein and donors preferred it. So that showed how different transfusion centres were.

Q. Soumik, could we then go to PRSE0004358, please. This is a document, Professor Contreras, that we in the Inquiry looked at with Dr Napier on Tuesday of this week. So this is the 1977 Memorandum on the Selection Medical Examination and Care of Blood Donors. So this would, I think, be the guidance that was in force when you became deputy director in 1980. There were then various other versions of it in the course of the 1980s.

If we go to the page 3, bottom of page 3, we can

see under the heading "Jaundice or Hepatitis", this records that:

"Individuals who give a history of jaundice or hepatitis or in whose blood anti-HBsAg 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 house 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 a sensitive method ..."

We'll come back to this issue in a few minutes, Professor Contreras, but was it your understanding, when you became deputy director in 1980, that, at the North London Centre, this was the practice --

A. Yes.

Q. -- that if you'd had hepatitis or jaundice in the last 12 months, you would be deferred, and you would be asked to come back at a later stage, but if you'd had hepatitis or jaundice two years ago, five years ago, ten years ago, you could be accepted as a donor?

A. Yes.

Q. If we go over the page, please, there's a heading "Examination of the donor". If we pick it up at paragraph 2, it says:

"(a) The medical history should be coupled with a careful assessment of the donor's appearance. The experienced doctor can detect at a glance the potentially unsuitable donor."

Then there are some examples given: poor physique, underweight, debilitated, undernourished, mentally unstable, "those bearing the obvious stigmata of disease should not be bled".

Would the arrangements at the North London Centre's donor sessions have meant that there would be a doctor who should be an experienced doctor at every donor session?

A. Yes.

Q. How realistic was it to expect a doctor to be able to detect at a glance the potentially unsuitable donor?

A. Well, we expected that the majority -- well, all donors are voluntary donors, so they are in good health. They feel okay to donate, you know? And the majority of our donors are repeat donors as well. And you could only see at a glance the physical appearance of a donor, and some -- very occasionally donors were rejected because they were -- well, underweight or if somebody looked as if they were going to faint or something like that, they would reject them as donors. But that was all that could -- you cannot really

predict that somebody has a hidden disease. Not a GP could do it even after an examination.

Q. So for the most part, even the experienced doctor is not going to able to look at a donor and know, "You've got hepatitis" or --

A. Oh, no.

Q. Or, "You've got HIV"?

A. Yeah.

Q. Now if we then just go to DHSC0003734_066.

This is a later version of the memorandum, but can we go to page 11, please, because what it's got here are the forms that I think were introduced with the 1977 memorandum.

So this is form NBTS 110A and is it right to understand that, at the North London Centre, this is a form that would have been given to all donors?

A. Yes.

Q. And so it says -- it asks them to tell the clerk if they've recently been in contact with a case of infectious disease or had any inoculations or vaccinations. It identifies certain illnesses which mean that they cannot donate, and then it says:

"If you have had any of the following conditions, please declare this and a decision will be made in your individual case by the Doctor."

Then the list includes:

"JAUNDICE or HEPATITIS (in the last year or contact with a case within 6 months)."

Now would it be right to understand that, therefore, the blood donor reading this would only need to declare jaundice or hepatitis if it had been in the last 12 months?

A. Yes.

Q. So this form wouldn't pick up any older cases of jaundice or hepatitis?

A. No, it wouldn't.

Q. Then if we go to the next page, this is a slightly more indistinct form, but this is the form, if we look halfway down the -- sorry, Soumik, if we actually go halfway down, if you keep it like that.

You've got NBTS 110 and, again, we'll see a reference in various communications you had, Professor Contreras, to form NBTS 110.

And then, as I understand it, if we look at the writing below this, there's a session date -- sorry, a session location is completed, a date, and then it says:

"To [all] blood donors.

"Please sign below to show you have read the accompanying notice NBTS 110A."

So the donor was required to sign this to show that they'd read the form that we've just looked at.

A. Yes.

Q. And that was -- again, I think, we'll come on to some of the tweaks that were made by North London to the form, but this was essentially a standard form across all Regional Transfusion Centres.

Now -- we can take that down -- we know, Professor Contreras, that the decision to readmit to the donor panel donors who had had jaundice or hepatitis longer ago than the last 12 months, was a decision made by Regional Transfusion Directors I think in 1977 or thereabouts, following the advice of an advisory group on testing for hepatitis B surface antigen and its antibodies. So it was before you took up your role as deputy director.

Do you recall having any concerns about that practice, that those with a history of jaundice or hepatitis could freely donate and didn't have to declare even that history?

A. No, I didn't have any concerns, because at the time I thought, and there was evidence, that the majority of cases of jaundice or hepatitis were due to hepatitis A, as is the case presently.

Q. If we look at DHSC0002179_067, this is a 1976

publication so, again, it pre-dates your appointment as deputy director in 1980, and it is from the International Society of Blood Transfusion. This part of the document is concerned with donor selection.

If we go to page 7, if we just look at the top paragraph first of all:

"The non-remunerated blood donor is the essential element around which every blood transfusion service is shaped. None may join the blood group whose blood may transmit disease to his fellows, or whose health may suffer as a result of his generosity."

Would it be right to understand that those two principles set out in that second paragraph were two of the guiding principles in relation to donor selection for the Blood Transfusion Service: there shouldn't be harm to the donor and there shouldn't be harm to the recipient?

We then have a heading "Examination of the donor", I'm not going to ask you to go through that, but there are some sample donor selection forms over the page.

Now, these ask, if we look at point 5, for example:

"Have you ever had hepatitis (yellow jaundice)?"

Then if we go to the next page, another sample form asks -- the first question is:

"Have you ever suffered from jaundice?"

Then if we go to page 12, this is -- there's a heading "Viral Hepatitis", which reads:

"In spite of recently developed tests for the detection of HBsAg, only a relatively small proportion of carriers can presently be detected. No routine screening test is presently available for the detection of hepatitis A virus, or of other viral agents that cause transfusion-associated hepatitis. It follows, therefore, that some general precautions should be taken in an attempt to reduce the risk of such viral agents being transmitted from donor to recipient.

"Prospective donors should be excluded if it is known that they ..."

Then there are number of exclusions set out here and on the next page, but it's the first one:

"Give a history of viral hepatitis at any time, except during the first months of life. (This rule may not be acceptable in all countries and may have to be modified where viral hepatitis is endemic.)"

So the advice of the International Society of Blood Transfusion in 1976 was: if you have a history

of viral hepatitis at any time you should be excluded.

Do you recall, first of all, whether you were ever aware of this particular advice?

A. I must have been because I've joined the ISBT, but many -- many of the documents from the ISBT and the WHO are mostly directed to those countries that do not have guidelines and, while you don't know anything about the population or the donor population, most of the donations are replacement donors or paid donors.

You know, I was a president of the ISBT so I remembered doing that, writing -- not myself, but signing to guidelines from all of the WHO.

So it's very different. I'm Chilean, you know. It's very different when you have a history of hepatitis in a country where the majority of the donors are not voluntary donors and where, even if you -- a history of jaundice could have been hepatitis B, a carrier of hepatitis B, but the systems in place were not good enough, and -- lots of times in the developing world you just couldn't test properly or you didn't have kits. So you have to have a belt-and-braces approach.

And this was international. So it had to be for African countries, South American countries, Asian countries as well. It wasn't really meant for

countries like the UK.

Q. It doesn't say that, does it?

A. No, it doesn't say.

Q. I mean -- and you refer to the World Health Organisation report (which I'm sure you were familiar with, but was provided to you I think in advance of your evidence) from 1952, which also records the same basic principle, that if you've a history of hepatitis, viral hepatitis, it should exclude you for all time.

There's nothing in those documents which say this -- I mean, obviously it says not acceptable in all countries, but there's nothing in those documents which says this is advice or a principle limited to developing countries or countries where there isn't a voluntary system?

A. No, it doesn't. But may I say that, first of all, the tests were not good enough. And we -- there was no evidence for that statement, either in ISBT or WHO. There was nothing to say that donors with a history of jaundice had -- were more -- were transmitting more hepatitis, by transfusion.

Q. If we just then move from 1976 and the International Society of Blood Transfusion to the Council of Europe's Committee of Ministers in 1983. So that's

NHBT0010651_004.

So this is concerned with Member States of the Council of Europe. It's not concerned with the world platform. And the specific recommendation here is directed at AIDS.

If we go over the page, you'll see the recommendation at the top of the page, point 1, is to take steps which include -- and this is the fourth paragraph down:

"- to provide all blood donors with information on [AIDS] so that those in risk groups will refrain from donating (an example of an information leaflet for donors is appended)."

We'll look at the AIDS leaflets used in England and Wales shortly.

But if we then go down the page, we can see the sample information unit that -- the passage in italics under the heading "Appendix" says:

"The present information leaflet for donors has been prepared and is used by the American Red Cross; it is given as an example for the convenience of National Blood Transfusion Services wishing to draw up their own information leaflet."

The rest of that page deals specifically with the issue of AIDS.

But if we go to the top of the next page, this American Red Cross leaflet appended to the Council of Europe's recommendation under the heading "Hepatitis", again envisages the permanent deferral of persons with a past history of viral hepatitis.

Do you recall whether -- or first of all, do you recall whether you ever saw this recommendation in or around 1983?

A. I couldn't say whether I saw it or not.

Q. So I think it will probably follow from that that you can recall whether this led to any discussion --

A. No.

Q. -- within the Blood Transfusion Service as to whether the practice of allowing people with a history of viral hepatitis to donate should be reviewed?

A. But what I knew -- what I remember is that we never took -- that the Blood Service never took those decisions on their own. It must have been on the advice of specialists in hepatitis or in --

Q. It is certainly right to say that the -- as I understand it, the decision of Regional Transfusion Directors to allow those with a history of viral hepatitis in 1977 to start donating reflected advice given by the advisory group on testing for hepatitis B surface antigen?

A. -- (overspeaking) --

Q. Can we then just, looking at later versions of the guidance for the selection, medical examination and care of blood donors, look at one that was adapted by the North London Centre.

So this is NHBT0057118. It's headed:

"North London Blood Transfusion Centre Guidance for the Selection, Medical Examination and Care of Blood Donors

"Compiled 1985

"Revised April 1987."

I'm not going to go through it in any particular detail, but it looks from this as though the North London Centre took the national guidance that had been agreed between Regional Transfusion Centres and then made some of its own changes or amendments or additions to it. Is that right, and if so, could you recall --

A. Vaguely.

Q. And can you recall what it was that led the Centre to want to reduce its own version?

A. I think that one of the issues was that the national guidelines wanted the donors to sign that they were not in a high-risk group of transmitting an infectious agent. And, you know, nobody in this room could know

whether we're in a risk group of transmitting some infectious agent. So I think that that was the main point. But I cannot remember very clearly.

Q. Just on that point you've made, Professor Contreras, I think there's some correspondence between you and Dr Gunson that may deal with that issue.

NHBT0009866.

This is a letter you wrote, 28 December 1989, to Dr Gunson, and it refers to the form NBTS 110, so the standard form that we looked at a few minutes ago. You say in the second paragraph:

"At [the North London BTC] we hold a considerable proportion of donor sessions in industry, and we do not send any correspondence to such donors. They are reminded by the local organisers of our visits and are asked to attend. In addition, 10% - 20% of our donors are first-time donors and a significant number of known donors change their donation venues without giving any notice (people in London move house and work quite regularly). These are the three main reasons for donors arriving at a session without having had the opportunity of reading the AIDS leaflet. We would need to have a member of staff acting as a receptionist at all donor sessions, ensuring that

all donors read the leaflet before they are asked to sign Form 110."

Then, if we go over the page:

"We have discussed NBTS 110 at length with the consultants at this centre and we would all oppose number 5 in your revised form."

I'm afraid we don't have the attachments to match to that.

"We do not think that we can ask anybody to sign confirming that 'they are not at risk'."

Just so I can understand what you were saying here, Professor Contreras, properly, you did ask donors to identify whether they were in specific risk groups; is that right?

A. Yeah.

Q. So it might be, "Are you homosexual?" In the course of the eighties, there were questions about whether someone had been in certain parts of the world. Indeed, I think that was a feature of forms at various different stages?

A. Yes.

Q. Intravenous drug use, sexual contact with people who were in such groups?

A. **(Witness nodded)**

Q. You'd ask those questions; is that right?

A. Yes.

Q. So is it right to understand that the question you were objecting to was a question which asked donors to confirm that -- that they were not at risk of --

A. Of transmitting some -- an agent transmissible by blood. You know, because those -- those were the main re-examination group categories, the ones that we said. But if you are the wife of a bisexual man, as we saw -- as the evidence when we counselled our donors, you have no idea that you are in a risk group. So a number of donors who come very willingly to donate do not know that their partner might have been a drug addict or might have been at risk of HIV transmission. So we could not ask donors to sign, "I'm not at risk of transmitting anything".

Q. And I think, just to complete the correspondence, Dr Gunson wrote to you in February 1990, NHBT0000077_065, 26 February:

"Dear Marcela,

"Roger ..."

That would have been Roger Moore?

A. Yes.

Q. "... has shown me your letter advising him that you do not propose to use the revised Form NBTS 110, and instead you will be using your own version."

And then third paragraph, Dr Gunson says:

"I do not have the authority to demand that you use a particular form for your donors to sign, all I ask is that you think very carefully about the action you take in this regard."

And he makes the point that this is a form that's been agreed by a majority of Regional Transfusion Centres.

You wrote back in March at NHBT0000189_079, and the second paragraph:

"I am most grateful for your concern regarding my lack of full compliance regarding NBTS 110. I understand your reasons for writing to me. However, as I stated at the meeting of the Management Committee, I agree with all the contents of the form except for the sentence stating that donors confirm they are not at risk of HIV infection. I know that you and most of our colleagues see this 'confirmation' within the context of the AIDS leaflet. I have discussed the matter at length with my consultant colleagues at the Centre and we all agree that we cannot ask prospective donors to confirm that they are not at risk. The proof for this lies in some of our recently confirmed HIV seropositives who genuinely did not think they were at risk."

Is it right to understand, therefore, that you used at the centre then a modified form NBTS 110, at this point in time, which did not include the question or the request to confirm that the person was not at risk of HIV infection? Because you thought it would be problematic for people to be able to answer that question?

A. No, because people didn't know. There was a proportion of the population who didn't know that they were at risk of transmission.

And also, you can transmit other agents that we were not testing for. We genuinely thought that if a donor signed "I'm not at risk" and then they were found to be positive for HIV, particularly for HIV, but -- or hepatitis B, you know, that -- and they had no idea that they were carrying those agents -- nobody knows what they're carrying, really, in their blood.

Q. But so that there is no misunderstanding, your donors were expected to identify if they were in specific defined at-risk groups?

A. Oh yes, they signed themselves. We were the only ones who had the self-exclusion questionnaire.

So, yeah, but -- if they were in at-risk groups, they self-excluded themselves, but this was a general statement.

Q. Would I be right to understand from what you've described and the correspondence that we've looked at, that although there was an expectation that Regional Transfusion Centres would use the same form across all centres, as the correspondence indicates, if an individual Regional Transfusion Centre wanted to do their own thing, you could? Dr Gunson could ask you not to, but he had no means of compelling you to do something different; is that right?
A. Yes.
Q. Can we then go back to your statement, WITN5711001.

If we look at paragraph 173, page 45, please. In fact 172 and 173.

So this was in the context of record-keeping, which we'll look at after lunch, but you say there you thought that the measures were adequate to prevent:

"... very adequate to prevent donors ... suspected of carrying blood-borne infections from continuing to give blood.

"173. Donors who were suspected of carrying infections were personally approached and counselled by a doctor", et cetera, et cetera.

Now, if we leave aside infections that are identified through testing, how often was it that a donor would be suspected, in the absence of a test,

of carrying an infection and excluded from donation? Whether on the basis of the doctor's assessment or signs such as weight loss or other problems in relation to health? Was it common for donors to be excluded on that basis?
A. No, it was very uncommon. The majority -- as I said, the majority of the people who come to donate are very healthy and they're very well informed.
Q. Can I then ask you about specific categories of donors who might be regarded as being at higher risk than others.

We can take the statement down, thank you, Soumik.

Intravenous drug users. What means were there of trying to ensure that patients or donors with any type of history of intravenous drug use did not give blood?
A. The self-exclusion questionnaire, you know, and all our leaflets that stated that. But still, we still found that some -- some of our publications show that they -- they had forgotten that they had used drugs intravenously. So it was -- we were asking them to state whether they had been -- they were intravenous drug users but a number of them had -- would have forgotten.

Q. So you were reliant upon donors not just truthfully but also reliably --
A. Yeah.
Q. -- recalling that they ought to be answering in a particular way.

Were questions about intravenous drug use asked before AIDS and the AIDS leaflets in 1983? So was that always a feature from the time you were there, in 1980, of the questioning?
A. I cannot remember.
Q. Military donors, if we can just come on to that as a category, and in particular US military donors.

If we just start, first of all, with NHBT0002981. This is a letter, 1990, to Roger Moore, the national director. This is from Dr Hewitt. But she records in the second sentence:

"We do ... collect a large number of donations from MOD establishments!"

So that would be British military establishments, presumably.

Again, had that always been a feature throughout the time you were there of the donor sessions, that you went to --
A. Yes.
Q. -- military bases?

A. Yes.
Q. Then if we look at NHBT0004776. This is a letter, it's again from Dr Hewitt to Dr Gunson, it's July 1992, headed "Donor Sessions in US Military Establishments".

It says:

"For many years until 1986 we held regular blood donor sessions at a US Military Establishment in Bedfordshire. This was the only US Establishment served by NLBTC but the donor session also served a number of UK civilian personnel."

Just pausing there, do you recall whether there was ever any thinking about whether military personnel, British or American, whichever, should be regarded as being at higher risk or should be regarded as a high-risk group? Was that ever part of the centre's thinking?
A. No.
Q. Was there ever any positive consideration given to it at all? In other words did the centre satisfy itself that military donors should not be regarded as high risk?
A. Yeah, the only thing I remember -- I recall is that what we discussed was that we did not want the military personnel lined up by the boss or by the

Captain or -- to give blood. We wanted it to be a fully voluntary act. So that was the only risk that could have been there, that their boss might have told them "You have to go and give blood", and we don't want any donors under pressure.

Q. There might, mightn't there, have been particular difficulties for a military donor in identifying themselves as ineligible because of being gay or because of intravenous drug use, and I think, as this and some other documents show, you couldn't be in a US military role and be gay; it was unlawful?

A. Yeah.

Q. Was consideration ever given to the fact that there might well be a pressure on donors not to answer truthfully because if they did they would be thrown out of the military?

A. Yes. But we learnt that, later on, when we had our first HIV positive, then we started thinking about it, that, you know, there were -- yeah, that they couldn't say that. But we had the self-exclusion questionnaire as well, and that -- even that was bypassed by some donors.

Q. I won't go to the remainder of the documents on this issue but I'll just give a couple of references for the transcript. So the second page of this letter

actually appears under a different reference, we don't need to put these up, Soumik, which is NHBT0004777 and the letter discusses an issue raised in 1986 about whether HIV results would have to be reported to the US military authorities, and that was discussed at a Regional Transfusion Directors meeting in January 1986, the reference for which is NHBT0018200.

The third category I just wanted to ask you about before we break, because I note the time, was prison donations, if we just look at JPAC0000002_039. This is a letter from Dr Barbara to Dr Bird, a haematologist at the Churchill Hospital in Oxford, August 1994, and if we look at the third paragraph, it says this:

"Certainly, prior to the introduction of HBsAg screening of donors in 1971 the prison population represented an attractive source of donors -- a truly 'captive' audience -- but in North London we noted HBsAg detection rates up to tenfold higher in donor sessions at prisons, compared with rates elsewhere. At the time we thought this might be due to increased levels of homosexuality: however, in the light of HCV epidemiology ... a considerable proportion of the HBV infections may have been drug associated."

Then skipping over a sentence:

"Certainly, the difference in rates was sufficiently obvious to prompt the cessation of blood collection from prisoners in North London in 1973 ..."

If we go over the page, this is one of the documents that Dr Barbara referred to, "HBsAg prevalence in Prisons, Borstals, [et cetera]". We can see the figures, first of all, for 1971: HBsAg rate in donors overall, 1 in 1,745; rate in prisons/borstals, 1 in 92, ie 19 times higher; and then for the first half of 1972, the rate in the overall population, 1 in 1,946; and then in prisons, borstals, 1 in 339, ie 5.7 times higher.

Is it right to understand, Professor Contreras, that when you were arrived at the North London Centre in your post as deputy director, the Centre did not collect from prisons or borstals --

A. Yes. We did not.

Q. -- and that didn't change?

A. It did never -- it never changed.

Q. Just one last document, if we may. MDIA0000002. This is a press article, a Blood Transfusion Service -- sorry, headline "'Hepatitis risk' in prisoners' blood":

"A blood transfusion service is refusing to accept blood from prisons. Dr Thomas Cleghorn,

director of the North London Blood Transfusion Centre ..."

Was he the predecessor to Dr Davies?

A. Yes.

Q. "... said last night that the risk of hepatitis was considerably higher in the blood of prisoners than it was outside. He criticised the crowding and standards of sanitation in prisons.

"Dr Cleghorn said that in a closed community such as a prison there was a good chance of hepatitis being incubated and not being detected by tests. If infected blood was transfused the consequences could be serious, and could result in death for the patient.

"The centre used to take blood from prisoners in Wormwood Scrubs and Pentonville but stopped the practice about a year ago. Dr Cleghorn said last night that about 800 prisoners had been blood donors. He was concerned, he said, about the safety of the blood he was passing on and not about prisoners' rehabilitation."

We know from other evidence, Professor Contreras, that other centres continued to collect blood from prisons during the 1970s and into the 1980s, with some not stopping until late 1984, possibly 1985. Were you aware of that?

A. Yes, in a way I was. Yes.
Q. Do you recall whether Regional Transfusion Directors were troubled by that? Was any step taken to try to persuade other centres to take a different course, either by you or by others?
A. No, because I wasn't -- that was never discussed at an RTD meeting that I remember, and because the decision had been taken before my time, I didn't -- I perhaps knew something that they were collecting blood from prisons but, no, I can't remember.
Q. And it's right to say you only became a director in February 1984 --
A. Yeah.
Q. -- so you wouldn't have been attending the RTD meetings prior to that in any event.
A. Yeah.
MS RICHARDS: Sir, I've gone past one o'clock for which I apologise. Perhaps we could take our lunch break now.
SIR BRIAN LANGSTAFF: Yes. Well, we'll take a break. We'll give everyone a full hour, shall we, and come back at 2.05. So 2.05, if you please.
(1.05 pm)
(The Luncheon Adjournment)
(2.05 pm)

MS RICHARDS: Professor Contreras, the next issue I'm going to ask you about is that of record-keeping. I'm going to ask you first to look quickly with me at two documents which we looked at earlier in the week with Dr Napier but, for the benefit of those who may not be familiar with them, the first is RLIT0000215. This is a 1952 report of the World Health Organisation's Expert Committee on Hepatitis. Soumik, if we can go to page 20, please.

This one of number of preventative measures which the Committee recommended in relation to the response to transfusion-transmitted hepatitis, "Maintenance of records":

"Subsidiary but important means of control are afforded by the maintenance of accurate records of origin, distribution, and administration of blood and blood-products. Such records should include:

"(1) Record of the names, etc, of donors contributing to each product;

"(2) Recording of batch numbers of products issued to hospitals and systematic distribution of products to hospitals."

Pausing there, (1) and (2), would be the responsibility of the Blood Transfusion Service centre to maintain?

A. Yes.
Q. Then (3), this would be the responsibility of the hospital, presumably, where treatment was administered?
A. Yes.
Q. So:

"Accurate recording in the patient's case-papers of the batch number of the product used, with the date of administration, and of the patient's name in the hospital record of products received and issued."

So would you agree those are basic principles but of fundamental importance?
A. Yes.
Q. Then we can see how that was, in particular in relation to category (3) of records, was emphasised in a 1973 document "Notes on Transfusion", HCDO0000861. So we can see the title of the document there, this the revised 1973 version, and if we go to page 3 -- and obviously this pre-dates your appointment as Regional Transfusion Director -- but we can see:

"This edition of 'Notes on Transfusion', like the four previous editions, has been prepared by the Committee of Regional Transfusion Directors of the Department of Health and Social Security and Welsh Office."

So your predecessors, as Regional Transfusion Directors, would have contributed to this.
A. Yes.
Q. It's presumably a document you were familiar with?
A. I'm sure I am, yes.
Q. Then if we go just to page 18, we've got the heading "Transfusion Records":

"A record of every transfusion should be made in the patient's case notes in addition to the details recorded in the transfusion laboratory. It is not always appreciated that the main reason for accurate recording is the protection of the patient."

Then I won't go through the details, but there is then set out what should be recorded in the patient records in the top half of the page, and then towards the bottom of the page it sets out what should be recorded in the laboratory records, and that continues -- if we just go to the next page -- continues over the page.

So it would be right to understand that these were the standards in terms of record-keeping that hospitals using blood or blood products were expected to maintain.
A. Yes.
Q. Now, I'm going to ask you to help us understand the

record-keeping in relation, first of all, to categories (1) and (2) from the World Health Organisation, so record keeping in relation to donors and then record-keeping from the centre in relation to the products that were sent out to hospitals.

In terms of donors, if we go to your witness statement, so if we could have back, Soumik, WITN5711001, and we go to page 43. You describe here the system at the North London Transfusion Centre in terms of records of donors. Something called 101 cards; is that right?

A. Yes.

Q. You tell us in paragraph 162, towards the bottom of the page that this method of record-keeping was in place when you became director and you didn't make any changes to the system.

If we just go back to look at paragraphs 160 and 161, the 101 card would have details of the donor, name, address, date of birth, donor history, and they'd have different colours for various reasons. Then there'd be donor session details, which you describe in paragraph 161 as well, and there will be bleed sheets, specific to each donor session.

So would it be right to understand that you would have -- for every session, you would have a list

of who had donated, is that right --

A. Yes.

Q. -- on the bleed sheets?

A. Yes.

Q. Then for every donor you'd have the 101 cards which set out their own personal history of donation?

A. Yes, and for the new donors, we had a buff card, 101 card, a new 101 card until they were grouped and they went to different colours.

Q. That, I think, helps us understand how records were kept in relation to donors. Could you then just explain for us what the record-keeping was in relation to what then happened to the donation? So the unit of old blood or red cell concentrate or whatever else it was that was processed at the centre, what records were associated with the production of that unit?

A. Every donation had a number attributed to it and, as I explained in one of the documents, we gave labels, additional labels with that unique donation number, and then later on we had a donation number and a donor number as well.

So if a unit, a pack of blood, was split into fresh frozen plasma and platelets at the blood centre, their number of the donation would be on the additional packs, because that pack was not separated

until it was labelled, you know, so you separated plasma or cryoprecipitate and platelets from the unit and they all had the same unique donation number.

Q. So at the point in time at which a blood product or component left the centre to go to a hospital, you would know or you would be capable of ascertaining from whom the original donation or donations came?

A. Yes. We could trace back to the donor.

Q. What, then, of the position in relation to the records that the hospital was supposed to maintain in relation both to entries in the patient records and then entries in the hospital's laboratory or blood bank records? Did you ever have access to that data?

A. No, I -- unless we were following up a unit or we followed up a report from a hospital of a transfusion-transmitted infection or an error or anything like that. Then we would have access to the records. Not routinely. But what we did was we had meetings with the medical laboratory scientific officers in charge of the blood banks and the consultant -- there was always a consultant haematologist in charge of a blood bank, and we had meetings to remind them of the importance of record-keeping.

But we didn't -- and we also issued an issue

note for every hospital with the numbers of all the units given to them, and they had to sign -- it was an original and a copy, and I think they kept the original and sent the copy back to us, signed that they had received all those units.

Q. Then if we can just look at a handful of documents about record-keeping, if we start at DHSC0101588, please, Soumik.

This is a letter, 9 March 1982, from you -- oh, no, sorry, over the page, it's from Dr Davies, your predecessor. Just look at the next page. So it's from your predecessor to Dr Walford and if we go back now to page 1, heading "Record Keeping in the NBTS and Hospital Blood Banks", it refers to a letter to Dr Wagstaff. And there was a degree of investigation or enquiry ongoing in the Department of Health at this time about record-keeping?

Then Dr Davies says in the second paragraph, second line:

"Anyone investigating our records [the centre's records] would have seen that all issues of blood and blood components are fully recorded and Hospital staff sign issue slips on receipt of the blood."

Was that the system that was in operation when you took over as director?

A. Yes.
Q. And that continued to be the system?
A. Yes.
Q. And in due course it became computerised?
A. Yes.
Q. But that was the basic system.

And then -- and Dr Davies goes on to talk about then the hospital records. He says, third paragraph, fourth line:

"At Edgware, as I am sure at every other Transfusion Centre, we have accurate records to Hospitals and of returns from Hospitals but we have no records of the 'final disposal', ie the recipients. If it is assumed that 3 units are used per transfusion, then last year approximately 53,000 patients received blood issued by Edgware. I foresee problems in persuading the many hospitals we supply to forward regular and accurate records of the recipients for the RTC to match up with recorded issues to the hospitals. I consider that once the hospital staff have accepted the blood it is their responsibility to keep records of the final disposal."

Was that your view as well?

A. Yes.
Q. And again, did that remain the position while you were

director, the hospital was expected to maintain its own records?

A. Yes. But it was much easier in my days because we had -- they had computerised systems and so they could -- like in a supermarket, they could run the reader through the coder bars.
Q. Now it does seem as though there were problems about the extent to which hospitals that you supplied were maintaining accurate records. I want to look at a couple of letters from 1988 in that regard.

If we start with NHBT0115386, please.

This is a letter from you to Dr Seymour at the North West Thames Regional Health Authority, 3 May 1988, and it says this:

"You asked me to send you a draft for a letter to District General Managers regarding record keeping of units of blood transfused in hospitals. I propose something along these lines ..."

And then this was your draft:

"The Director of North London Blood Transfusion Centre [that's you] has informed me that some clinicians, especially those in theatres and intensive care units, are not complying with the DHSS Circular on 'Record Keeping and Stock Control Arrangements ...'. The circular states clearly that records 'must

permit the tracing of any unit of blood from collection to transfusion or disposal'.

"Dr Contreras has informed me that, when trying to investigate the ultimate fate of blood or blood components involved in suspected cases of transfusion-transmitted HIV or HBV infection, it has been impossible in some cases for her or her staff to know, with certainty, whether a specific unit of blood was actually given to a particular patient, since no entry was made in the patient's notes. On all occasions, the records in the blood bank were adequate but the fact that blood or blood derivatives were issued for a named patient does not necessarily mean that they were actually given to the specific patient."

Then there's a reference to the new product liability regime. The letter in some respects speaks for itself.

Is it right to understand from this that this issue about record-keeping came to your attention because you'd been trying to trace what happened where you had the possibility of a donor who may have transmitted HIV or HBV?

A. It was before then. I always knew that a unit of blood given, or the components given, given by

a donor, should -- we should always know the ultimate -- somebody should know the ultimate fate of that unit transfused.

And it was -- I think it was before that letter when some units of plasma started disappearing, as well, that it emphasised the need for adequate record-keeping.

Q. And was it your experience that it was quite common to find that hospitals were not adequately discharging their record-keeping responsibilities?
A. Yes, it was quite common.
Q. This letter suggests that, at this point in time, the problem was predominantly in terms of the patient records, as opposed to the laboratory or blood bank records?
A. Yes, the blood bank records were always quite -- very good. And, you know, when they were issuing units, particularly -- as I said, it was particularly in theatre or ITU that units were not properly recorded.
Q. Then we can see there's a further letter in 1988 that you wrote, NHBT0085222, 13 September 1988, this particular letter is to a consultant haematologist at the Queen Charlotte's Hospital, and the first paragraph refers to you having made a visit to the blood transfusion unit at the hospital. Then you say:

"The purpose of this letter is to remind clinicians of the DHSS Circular on Record Keeping and Stock Control, which I enclose."

Then skipping over a few lines you say:

"We must ensure that the ultimate fate of a unit of blood, a blood component or a blood product is known beyond any doubt. I note that the system of record keeping in your Blood Transfusion Laboratory is very good. However, I am not quite sure whether clinicians are fully aware that they are responsible for ensuring that the donation numbers of the units transfused are entered in the patient's notes. I know that you supply self-adhesive forms for the donation numbers of the units cross-matched by your laboratory. However, clinicians must ensure that such forms are stuck on the patient's notes and, in addition, the person giving each unit of blood should enter the number, date and time of administration with a legible signature that will facilitate any further investigations in case of adverse reactions to transfusions. Accurate record keeping is vital and traceability of every unit of blood must always be maintained."

Then you go on to deal with another problem in the next paragraph:

"An essential part of record keeping involves adequately completed transfusion request forms as well as properly labelled tubes containing blood samples. I have noted that a large number of transfusion request forms at Queen Charlotte's are not completed in a satisfactory way; information is often lacking regarding previous pregnancies, transfusions, diagnosis, etc."

What was the transfusion request form and why was it important to have that completed comprehensively?

A. The transfusion request form is the request form from the clinician from the consultant treating the patient. Usually it was filled in by a junior doctor or senior registrar or registrar. It was the request form with the name of the patient, the date of birth of the patient, the hospital number -- it needed to have all those -- the diagnosis, and the haemoglobin, if red cells were needed, or the platelet count, if platelets were needed, and the reason for the transfusion. Every hospital had their own transfusion request forms.

Q. Would it be right to understand that one of the reasons why it was important to have such documents completed accurately is the reason you've given here:

the need to be able to trace every unit of blood but would it also be right to understand that recording the reason for transfusion would be important in terms of wider issues about transfusion practice to ensure that transfusions were only being given when they needed to be given?

A. Yes.

Q. We can take that down, thank you.

SIR BRIAN LANGSTAFF: Can I just ask, the theft that took place of plasma, was that about this time, 1980s?

A. Yes, sir. It was before I was -- when I was deputy director, it was between 1980 and 1984 and, yes, it occurred around that time.

SIR BRIAN LANGSTAFF: The plasma which was sent to the hospital from where it was taken, that would have been recorded in the way you've just described?

A. It should have been recorded.

SIR BRIAN LANGSTAFF: So if the hospital had been keeping proper records, they should have known where each unit of plasma had gone?

A. Yes, and that was what -- in effect, that was when the Department became worried about transfusion records, because the ultimate fate of many units of fresh frozen plasma could not be known.

SIR BRIAN LANGSTAFF: It must follow that because

presumably no one noticed for a while and because presumably the consultant thought they could get away with it, taking the plasma, that is some indication of the poor state of recording keeping by the hospital at the time?

A. Yes, sir.

SIR BRIAN LANGSTAFF: Yes, I see. Thank you.

MS RICHARDS: Professor Contreras gives, I think, an outline of her own involvement in relation to observing the then Chief Medical Laboratory Scientific Officer at the Edgware Centre in her statement at paragraph 44 for those who are interested in reading it.

If we put your statement back on again, WITN5711001, and we go to page 51, I'm going to come back to the issue about jaundice enquiry reports, that you deal with in paragraph 202.

Paragraph 203, you talk about the situation of a donor who was found to have been excluded by another Regional Transfusion Centre, and I think you explain in paragraph 204 that there was no scheme prior to the national information technology system which enabled proper data sharing between different Regional Transfusion Centres, which were, as you described, these independent autonomous centres.

So is it right to understand there was no system for enabling centre A to tell centre B the details of the donors they'd had excluded?

A. Yes, there was no system.

Q. And no way centre B could contact centre A and say, "We've got a donor here, have you got any records of that donor?" Was that possible?

A. Yes, if the donor told us that they'd been a donor at another centre, then we would immediately contact the other centre and say, "Could you please tell us whether this donor is fit and send us the 101 card for that donor".

Q. If we go over the page, please, Soumik, you, I think, essentially make that observation in paragraph 208:

"There was no mechanism for a centralised database shared with other RTCs about excluded donors. It was only when donors told us they had moved, but otherwise we did not really share information, until the national IT system was created ..."

Then the bottom of the page, paragraph 210:

"With respect as to whether I believe the measures in place between RTCs were adequate in preventing donors who were suspected of carrying blood-borne infections from continuing to give blood, I have to say I do not think the systems were adequate

because we did not really have a system that would have prevented the risk of an infectious donor donating somewhere else. All we could do was to advise donors known or suspected of carrying blood-borne infections that they should not continue donating, giving them the reasons for this advice."

Then you say in paragraph 211 that the donations by donors known to be carrying blood-borne infections would only have taken place where a donor was maliciously doing something, and you ever encountered such an event.

But it might be the case, might it not, Professor Contreras, that you could have a donor who hasn't actually been adequately counselled or given proper information, doesn't understand why they've been excluded from another centre, who may perfectly innocently, non-maliciously present themselves to a further centre. So that could happen?

A. Oh yes, that could happen, but I must say that with the papers I was sent, I was reminded of a donor that we had at our centre --

Q. I'm going to ask you to look at the --

A. Yeah.

Q. So that is NHBT0000030_007. I'm hoping we're thinking about the same thing. This is an article by

Dr Barbara, you and Dr Briggs. Is this the case you were thinking of?

A. I think it might be. It's a donor who came twice to give and he was positive, yeah.

Q. Yes, exactly. We can see it's set out in the first paragraph:

"In the absence of specific tests for non-A, non-B hepatitis viruses, evidence for their involvement in post-transfusion hepatitis ... can only be circumstantial. This report describes an example where two successive blood donations, spaced by 7 months from the same donor were both implicated in cases of [post-transfusion hepatitis]."

Then you describe a donation given as whole blood to a patient who became jaundiced six weeks after transfusion.

Then if we go to the top of the next column it talks about how the donor was:

"... asked to refrain from blood donation until further notice and his records were withdrawn from our routine donor file. Despite these recommendations, he returned as a new donor 7 months later and his donation was one of four units given as whole blood to a patient."

And so, is that the occasion you were thinking

of?

A. Yes.

Q. And can you help us in understanding how that occurred?

A. Well, you know, as I said, the first donation went into a patient who was -- one of the two units given to that patient, and the hospital, I think weeks or months after the transfusion, reported that the patient had hepatitis, elevated transaminases, I think.

So we went back to those donations and we had -- to those donors, and found that they were -- had I think abnormal ALTs or something, and we told those two donors not to -- to please not continue donating because we thought that they had an infectious agent.

So we withdrew that 101 from -- or we marked that 101 as non-suitable donor, and we counselled him personally. We always -- we never referred donors to the GP, but we -- Dr Hewitt was responsible to follow up those donors and counsel them, and she had a team of doctors to do this. So the donor was adequately counselled to please not come and donate again and we do not know why he came to donate again as a new donor.

And that then -- as soon as we knew that it had

been that donor -- and it was unfortunately after his unit had been transfused -- that we realised that the red cells had gone into a patient, so we informed the hospital concerned, the consultant concerned, and they followed up the patient and realised that that donor had transmitted non-A, non-B hepatitis.

Q. And leaving aside whatever the motivation of the donor was in coming back -- having been counselled not to -- coming back to donate, how was it that the centre's records didn't identify this as a person who had, only months previously, been advised not to donate?

A. Because if a donor comes as a new donor, and doesn't tell us, and we had all this collection of 101 cards, so there could be, you know, a hundred John Smiths in our panel. So we couldn't go through all our record system to identify that person as a previous donor -- until we were computerised.

Q. You anticipated my next question. So a computerised system would be likely to pick that up?

A. Oh, yes.

Q. But it wouldn't be picked up on a manual system if the donor told you they were a new donor?

A. Yes.

Q. Presumably if the donor said, "I've been here before", even if they didn't give details about what they'd

been told on the last occasion, would you then have -- rather than giving them the buff coloured new 101, would there then have been, before that donor donated or before their donation was used, a check on their old records?

A. Oh yes, we would inform the centre. We would give him or her a buff 101 card, because we didn't have the records there, but if I've donated a unit before, then we would immediately say, "This is not a new donor, please check that there are records for this donor."

Q. Would you expect that check ordinarily to be done if the system was working properly before any of the donation was used?

A. Before any component was made.

Q. Okay. Then just on the issue of being able to check records of donors from other centres, if we look at JPAC0000035_159, please.

The issue under discussion here, as we can see from the heading, is "Readmittance of blood donors who have tested repeatedly positive but are not confirmed HIV antibody positive". This is an undated document but we can see that it must be at some point after May 1987 because it refers to a meeting of the Expert Advisory Group on AIDS in May 1987.

I just wanted to draw your attention to

paragraphs 3 to 5:

"Dr Contreras drew attention of members to the organisational difficulties of the recommendation requiring that the records of donors who transfer to give blood at a new Centre be checked to ensure that previous donations had not been found antibody positive. EAGA members agreed that this recommendation should be considered further by the Regional Transfusion Directors Committee."

"At the meeting of the Regional Transfusion Directors Committee in July it was universally agreed that it would not be practical or even possible at some Centres to check previous records of donors in this way."

And that essentially remained the situation and remained a problem until there was a national database, effectively, a national IT system sometime after 1995?

A. Yes.

Q. If we then just go back to RLIT0000215, please. This is the World Health Organisation report. If we go to page 21 -- sorry, if we go to page 20, my apologies.

So we looked at the section on maintenance of records, and then we have a section on reporting. Second sentence:

"... the committee feels that useful additional information might be obtained by a simple follow-up system to detect cases of serum hepatitis following administration of blood and blood-products."

And then some further suggestions are made.

So is it fair to say that the importance of reporting cases of post-transfusion hepatitis have been recognised for decades?

A. Yes.

Q. Now in terms of the systems in place within England and Wales, I just want to look at a couple of documents that predate your time, just to see whether the system described was the system in operation when you took over.

So if we start with NHBT0016498, please.

You'll see, Professor Contreras, this is a Regional Transfusion Directors meeting in November 1973, so some years before you took up your post as deputy director.

If we go to page 7 -- I should have said Dr Davies, your predecessor, was at this meeting.

Page 7, second paragraph, describes:

"Dr Maycock [outlining] the present voluntary system used by RTCs to gather information about reactions and report them ..."

Then he records at (i):

"Cases of Serum Hepatitis were reported to Dr Maycock on a special form. This system had been in use since 1946."

Then he goes on to then deal with transfusion reactions and certain other reactions such as allergic reactions.

Then if we look further down towards the bottom of the page:

"It was recommended in Notes on Transfusion ... that serum hepatitis, reactions to infected blood and all severe reactions who'd be reported at once to RTDs. The reason for this is because appropriate action" --

Oh, the system has gone down.

Thank you.

At the bottom of the page:

"... appropriate action must be taken by the RTC without delay regarding donors or procedures within the centre."

Then if we -- sorry, I'll carry on:

"It was important for the same reasons that reactions associated with plasma or plasma fractions should be reported without delay to BPL."

Then if we go over the page, second sentence

says:

"The numbers of cases of serum hepatitis and other reactions reported varied widely between regions.

"The method of reporting was then discussed. Several Directors thought that reports to CSM [presumably Committee on Safety of Medicines] should be made by hospitals since the details of the yellow report card issued by CSM could only be completed in hospitals. After discussion it was agreed that if reports of adverse reactions concerning blood and blood products were to be made to CSM, such reports were best made by RTDs because they almost always heard of and investigated serious reaction associated with blood and blood products. It was not essential that the yellow card was used, providing the name of the doctor in charge of the patient was reported.

"After discussion it was agreed.

"a. That cases of serum hepatitis should continue to be reported to Dr Maycock on the usual form, to which a space for the name of the doctor in charge would be added.

"b. That any other serious reactions, eg to infected blood, would be reported to Dr Maycock, using, when appropriate the form 'Notification of

Transfusion Reaction'."

Then if we skip down a tiny bit, it says:

"It was further agreed that this subject should be reviewed early next year."

Now, that's obviously 1973.

Come 1980, when you take up your post as deputy director, was there still a system in place for reporting -- for the Regional Transfusion Centre to report cases of serum hepatitis, post-transfusion hepatitis, and if so, to whom?

A. There was -- as far as I can remember, there was a system of -- from North London Transfusion Centre, Dr Barbara collated all those cases, and sent -- and made a report, an annual report that was sent to the CDSC at the Public Health Laboratory Service. I think it was Dr Sheila Polakoff, who collated all -- it was like mandatory; I don't know whether it was mandatory but we sent all this -- were sent the -- the reporting was centralised at CDSC.

Q. So obviously the reports to the Regional Transfusion Centre and then the reports by the Regional Transfusion Centre, would it be right to expect that hospitals should report cases of hepatitis that might have been associated with the use of blood or blood product, you would expect hospitals to be reporting

that to you?

A. Yes.

Q. To what extent was that reliably done? It may be impossible for you to answer because you only know what's reported to you.

A. I think that, in my time -- because often the haematologists in charge of the blood bank would not know, but if there was -- if the -- if the haematologists in charge of the blood bank knew or if anybody knew that there might be an association between the hepatitis or any transfusion event, and the transfusion of a blood component, they would report it to us.

Q. So there's reports to you and then your recollection is, by the time you're there, the report is made by the centre, you think, on an annual basis, to CDSC.

A. Yes, well, once the report was made, once we were notified of a case of possible or probable transfusion-transmitted infection, then we would go to the hospital and we would contact the hospital, and investigate whether this was a real case of post-transfusion infection, and if it was a real case of post-transfusion infection, we would then go to the serum archive and investigate the units given to that patient and, if necessary, call up the donors

involved.
Q. Do you recall there being still in operation a yellow card scheme, to use the phrase --
A. No.
Q. You don't. If we then look at your statement, so if we have the witness statement back, please, Soumik, WITN5711001, and go to page 51, we can pick up at paragraph 202, I think, the system you were describing operated by Dr Barbara and his team. You say in the third line of paragraph 202:

"... Dr Barbara's team always prepared 'JE' (jaundice enquiry) files for any reports of post transfusion jaundice, or indeed of lab test positive results for viral hepatitis in patients following blood transfusion."

So that's the system in operation at North London. Other than, you think, reporting that on an annual basis to CDSC, was anything else done by way of reporting by the centre of such cases --
A. Err --
Q. -- to the Department of Health or anywhere else?
A. No, because the CDSC was acting, I think, on behalf of the Department of Health. So, you know, this report went to Dr Polakoff and to region -- when we were regional, to a regional medical officer.

Q. Do you have any recollection of roughly how many jaundice enquiry reports Dr Barbara's team might gather in a year?
A. Not really, no. I remember that, you know, the real cases of post-transfusion hepatitis were about for a year or something like that.
Q. If we then -- if we assume a case has been reported to you, and so Dr Barbara or his team are going to be completing the jaundice enquiry report, what are the steps that the centre would then be taking to investigate that?
A. Well, we would be immediately in touch -- the doctor concerned with that hospital and Dr Barbara would be immediately in touch with the hospital, and see if we could -- well, we would have access to the records. We would go to the hospital and have access to the records and investigate because, often, the cases that were attributed to blood transfusion, the donor had markers of a very longstanding hepatitis that was not attributable to transfusion.

So the steps were: investigate where it was a real case of post-transfusion hepatitis and then get samples from the patient, and investigate the archive samples because we always kept serum samples from all the donations that we collected and so Dr Barbara's

laboratory would go back to those archive samples and investigate them, and anyone -- anybody found positive or doubtful for positive, the donor would be contacted and we would sample that donor again, and if found positive, we would -- Dr Hewitt's team would advise them not to continue donating and so complete the jaundice enquiry.
Q. Having done all that, would you then, or the centre then, be taking the next step of seeking to trace the recipients, other recipients -- so not the one reported by the hospital in the hospital report but other recipients -- of donations over the years. Was that step also done?
A. Yes, yes.
Q. So a form of look-back, I suppose, but on a local basis, you would -- would you try to make contact?
A. Yeah, we would try to make contact and sometimes we were successful and sometimes we couldn't find the ultimate fate of those --
Q. And sorry, just thinking it through as I ask you the question, you would presumably be dependent upon, then, the reliability of hospital records?
A. **(Witness nodded)**
Q. Because you'd be able to see what had happened to a donation three years ago from donor X, because your

records ought to be capable, as I understand it, of telling you that components made from that donation had gone to Charing Cross Hospital, on such-and-such a date; is that right?
A. Yes.
Q. But you wouldn't know what use had been made of them by Charing Cross Hospital unless the hospital records had been completed?
A. Mm. **(Witness nodded)**
Q. Would that then be handed over to the hospital to follow up, to try to make contact with the patients who'd been treated with the suspect donation four years ago, or was that something the centre would be doing?
A. No, we had no authority to go back to the patient, so we -- if we knew -- if it was known that a recipient had contracted -- was -- that had the possibility of having been infected, then we would pass that information on either to the haematologist or the haematologist would pass it on to the relevant GP, or, if there was a clinician in charge of that patient, to the clinician in charge of the patient.
Q. If we just go to page 77 of your statement, you say in paragraph 306, as you've just told us, that:

"Whenever a case of post transfusion Hepatitis

was reported to our blood centre from hospitals in our region, we conducted full investigations with further testing of the patient samples and of the implicated donors to identify possible source of infection."

Then you say this:

"307. At NLBTC we tested for markers of Hepatitis B, including anti-HBc and LFTs."

Now can I just be clear what you're saying there. You're not, as I read your statement, saying that you screened all donations for anti-HBc.

A. That's right.

Q. You -- this was -- is this right: this was an additional investigation that you undertook on implicated donations?

A. Yes.

Q. And you'd be calling the donor back in?

A. Yes.

Q. Through Dr Hewitt's team or whoever it might have been, and asking them to submit to further tests?

A. Yes.

Q. So there wasn't routine across-the-board anti-HBc testing?

A. Sorry?

Q. There wasn't routine across-the-board anti-HBc testing?

A. Oh no, no, no. Only for our apheresis donors, but no, it wasn't across the board.

Q. Did you ever get any impression as to whether hospitals were either slow or reluctant to report cases of post-transfusion hepatitis or possible cases of post-transfusion hepatitis to you?

A. Not that I can remember.

Q. We can take the statement down. Actually, no, sorry, we'll keep the statement up and go to page 24.

I'm going to ask you next about a different topic, so self-sufficiency, supply of plasma to BPL.

If we start by looking -- sorry, Soumik, my fault, paragraph 88 rather than page. Page 24.

So you have said in paragraph 88 that you can't recall the exact plasma targets that were set before the year 1989/1990. We looked earlier at the targets that you had in relation to 1989 and 1990 onwards and your recollection, as set out in your statement at 89, was that:

"The targets ... must have been set by the Department of Health in conjunction with BPL."

So these are not targets in terms of numbers of donations which you set, this is the target of how much plasma you supplied to BPL?

A. Yes.

Q. We know from other material that it was in 1981, I think, that the pro rata system was introduced, whereby an amount of plasma would be supplied by a Regional Transfusion Centre to BPL and then there would be a pro rata delivery back of concentrate from BPL to the region.

Do you have any recollection, because this is before obviously you took over, but do you have any recollection of how well the pro rata system worked, and whether it secured sufficient Elstree Factor VIII concentrate?

A. There was never enough -- sufficient -- there was never sufficient Factor VIII concentrate from Elstree.

Q. Can we go to CBLA0001800, please.

This a report from Dr Gunson to the Central Blood Laboratories Authority, CBLA, headed "Plasma supply for self-sufficiency". It's a report dated January 1984. If we look at the second paragraph, Dr Gunson says this:

"During the latter part of 1983 ... informal comments from some RTDs gave cause for concern in that the targets which had been agreed as a planned programme were in jeopardy because of difficulties in obtaining the necessary funds. Accordingly, in December 1983, I wrote to each RTD asking for their

personal assessment of the situation with respect to obtaining the necessary quantity of plasma by 1986 and their views on their Region's attitude to the subsidising of other Regions who could not attain self-sufficiency. Their replies are summarised in the Appendix to this report.

"It will be noted that only three RTDs are confident that their RHA will support the programme for increasing the plasma supply. The remaining replies range between 'not hopeful of the necessary finance' to 'an inability to predict the outcome of discussions with the RHA'. Two factors in the replies were of significance."

And then the first was that many RHAs weren't willing to consider proposals on a more than a year-by-year basis, and the second factor was about demand for PPF.

If we could then turn to the next page, we've got the results of Dr Gunson's survey set out centre by centre, and if we go to page 3, we've got North West Thames.

Now, this is a survey that would have almost certainly, I think, have gone to Dr Davies rather than you, because it's late 1983, but we can see what's set out there:

"Target 18,500 Kg. Budget for 1984/5 has not yet been established but expects finances to be made available to allow this target to be met."

And then for 1985:

"Increases in the 1984/5 levels could not be made without additional space, and this has been agreed by Regional Medical Officer and RHA Development Department to be a priority. However, although RHA are aware of expansion in plasma supply, no official discussions have taken place and no finance allocated."

Now, just pausing there, you then took over as director in February '84. Can you recall the substance of any conversations you held with your regional medical officer about having sufficient funding to be able to provide enough plasma to BPL to meet your targets?

A. I remember having conversations with my regional medical officer and the regional treasurer about funding in general, because not only did we have to supply plasma to BPL but we had a large demand for fresh frozen plasma and platelets from hospitals. So there was a general problem of funding. Yeah, that's what I remember.

And I was passionate about self-sufficiency. So

I must have made a case also for plasma, for BPL, but we had the problem of, you know, supplying enough plasma for the hospitals, teaching hospitals and demanding hospitals, and supplying plasma to BPL.

Q. I think we probably see that point in the third comment, on the right-hand side, this is in a column headed "Confidence of RTD in ultimately achieving target":

"Every effort will be made to achieve targets but demands from teaching and specialised hospitals reduce availability of plasma and doubtful whether the region could become self-sufficient for Factor VIII."

In any event, I think it's right to understand from one of your earlier answers that there was not, at this point in time, enough BPL Factor VIII to meet all the needs of the Haemophilia Centres in the region that you supplied.

A. Yes.

Q. Now, in terms of plasmapheresis as a means of increasing the amount of plasma that might be available to provide, if we look at NHBT0016498, please, this is a set of minutes we've already looked at for a different purpose, November 1973, so again before your time. If we go now to page 4, the context of the discussion is something called

"Wedgwood Plates", which were I think something given to donors who gave lots of donations?

A. 100 donations.

Q. But if we just look at the bottom of the page we can pick up a discussion about plasmapheresis. It says:

"Dr Maycock suggested that, although Edgware was the only centre at present at which many donors gave 100 or more donations by plasmapheresis, more regions would eventually become involved in these awards."

So it would appear from this that, by 1973, at the North London Centre, plasmapheresis was already a well-established part of the system. I know you weren't director for a number of years, but is that your recollection, your understanding, that plasmapheresis was a longstanding part of the arrangements?

A. Yes, I remember -- because John Cleghorn, who was the director at the time, was pioneering plasmapheresis and he started with manual. I remember seeing manual plasmapheresis when you had to collect a pint of blood and then take it to the blood components, and then separate the plasma and return the red cells to the donor.

Q. If we go to NHBT0086659, this the draft of a letter to The Economist from you and two of your colleagues,

October 1987, I just want to pick up what's said in the second paragraph:

"... plasmapheresis is carried out at most of the 14 Regional Transfusion Centres in England and Wales, and plasmapheresis programmes are rapidly expanding. At the North London Blood Transfusion Service, Edgware, the first unpaid volunteers began donating plasmapheresis in 1967. The number of regular attenders now exceeds 2,500, and over 80% of these donors attend for donation once a fortnight."

So is it right to understand that your centre's experience was that plasmapheresis was a very good way of -- provided you had the necessary facilities which required funding, a very good way of increasing the amount of plasma that you could obtain and therefore supply?

A. Yes, the best way.

Q. You've told us in your statement that you -- there were three, you describe, state-of-the-art aphaeresis clinics as part of the centre's operations.

A. **(Witness nodded)**

Q. Is that right?

A. Yes, we had three, and they still exist. The Western Donor Centre, Luton and -- oh God, it's gone out of my mind, we had three plasmapheresis centres --

Q. And then --
A. -- and Edgware, of course!
Q. Then if we just go back to your statement, page 116, paragraphs 467 through to 472 of your statement set out your perception of the advantages and benefits of plasmapheresis. If we go to the next page, Soumik, and paragraph 472, you say:

"I therefore agree that plasmapheresis is a crucial technique to increase plasma yields and reduce wastage of red cells and in my view this has not changed. Self-sufficiency in plasma products is not achievable on the basis of recovered plasma without a considerable wastage of red cells. Such wastage would be immoral and unacceptable."

Now, the North London Centre, as you've described, was obviously adequately funded or reasonably well funded to undertake plasmapheresis, perhaps because Dr Cleghorn had been a pioneer in this field. Was it your understanding that other Regional Transfusion Centres were not in such a good position, at least at the beginning of the 1980s?
A. Yes, that's correct.
Q. Do you recall any discussions or any frustrations being expressed to you or concerns about the inability of other centres to do the kind of work that you would

be able to undertake?
A. Yes, I remember at Regional Transfusion Directors meetings frustration of some of our colleagues.
Q. More broadly in relation to self-sufficiency, can we look at a letter you wrote to Dr Gunson in 1990. NHBT0015646.

31 May 1990. And you say:

"I am writing on behalf of the Eastern Division of Consultants in Blood Transfusion."

So this would effectively be you, Tooting, Brentford and Cambridge, is that right?
A. Yes.
Q. "Members of the Division expressed their dissatisfaction about the lack of interest of the Department of Health in self-sufficiency. It was stated that it is not enough to say that 'ministers are committed to self-sufficiency' if this is not backed by actions and financial support. We firmly believe the time has come to reassess the situation regarding self-sufficiency."

Then you go on to set out a number of other concerns. You say:

"There are very good ethical and financial reasons for the encouragement of self-sufficiency."

And then there are specific concerns about the

relation to the position of BPL which I'm not going to trouble you with.

On the broader issue of what you say, there is a lack of interest in the Department of Health in self-sufficiency, that was your position in 1990. To what extent, if at all, was that your perception or the perception, to your knowledge, of your colleagues earlier in the decade?
A. I think it was always my perception.
Q. And if we then -- sorry to jump around, but if we go back to your witness statement, page 105, you say at paragraphs 420 and 421:

"With very few exceptions, the UK Blood Services have always been self-sufficient in labile blood components, ie red cells, FFP, cryoprecipitate and platelets.

"421. All I can say is that my perception was that the Department of Health decided not to appropriately fund and subsidise self-sufficiency in fractionated blood products."

Then if we go over to page 107, please -- sorry, page 106 next. 425, you say:

"With the exception of when the Minister of Health was Dr David Owen, I do not believe that the Department of Health took a genuine interest in

self-sufficiency in plasma derivatives from voluntary donors."

Then you refer to an issue relating to prices set for BPL and lack of incentive to collect plasma. And then, if we go to the next page, please, paragraph 432, you say this:

"There were two issues with regard to achieving self-sufficiency in fractionated plasma products:

"(a) The funding was not available;

"(b) BPL did not have capacity or technology to produce everything that was needed to achieve national self-sufficiency."

Then:

"433. If every centre had been funded like NLBTC we would have been flooded in plasma, with no problem in achieving self-sufficiency."

And then top of the next page, you say:

"My view of historical events has not changed ..."

And then if we can go to the bottom of this page, you say at paragraph 437:

"As I have stated, the possibility of collecting sufficient plasma from safe blood donors was always there, given the willing donor population in the UK."

Top of the next page:

"... but what was needed was the political will and funding from the government and the Department of Health to utilise the willing donor population to donate regularly by plasmapheresis. Even if we had collected all the required plasma for self-sufficiency in blood products, BPL did not have the capacity or state-of-the-art equipment to fractionate it all, nor the sophisticated equipment to produce the high-purity products available in the commercial market."

Does that continue to be your view of the position in relation to the non-achievement of self-sufficiency in blood products in the 1980s in the UK?

A. Yes, it continues to be my view.

Q. Then can I just ask you about the production of cryoprecipitate. That was presumably a blood component produced at the North London Centre?

A. Yes, of course.

Q. To what extent, if Haemophilia Centre Directors or the Department of Health had come to you in 1983, 1984, and asked you to increase the production of cryoprecipitate, as an interim measure in response to the AIDS crisis, to what extent would you have been able to do so?

A. To a large extent, but we were not asked to do it.

But we had the capability to do it.

Q. Was there ever any discussion with you by, first of all, the Department of Health about that possibility?

A. No. Never.

Q. What about the Haemophilia Centre Directors or centres that you supplied?

A. As far as I can recall, I cannot remember any haemophilia director asking me for cryoprecipitate -- for more cryoprecipitate than the usual. We produced a lot of cryoprecipitate, but that was usually for foetal maternal -- for maternal haemorrhages and massive transfusion.

MS RICHARDS: Sir, I'm going to move to another topic now, so perhaps we could take the break now, and then I can start with the next topic after the break.

SIR BRIAN LANGSTAFF: Yes. Well, we'll take a break until 3.40, in that case. 3.40.

(3.12 pm)

(A short break)

(3.42 pm)

MS RICHARDS: Professor Contreras, I'm going to ask you next about the practice of transfusion and the use of transfusions and steps taken by the centre in that regard. Can we start by looking at a document we've already looked at but a different page, HCDO0000861.

So we're back in the 1973 Notes on Transfusion, and if we go to page 4 for a useful summary, second and third paragraphs in bold print:

"A transfusion should never be given without a definite indication; not only is this in the patient's interest, since an element of risk is associated with every transfusion, but supplies of blood are not unlimited and with the ever-growing demand for blood it is imperative that it should not be used unnecessarily.

"The use of transfusion to correct moderate or slight degrees of anaemia that could be overcome as effectively, if more slowly, by other means seems unjustifiable unless some cogent reason for speed of recovery exists. In some instances failure to institute simpler and safer but equally effective treatment earlier leads to the quite unnecessary use of blood transfusion."

First of all, Professor, do you agree with what is set outs there?

A. Totally.

Q. Would you agree that what's set out there was nothing new, even in 1973?

A. I think so.

Q. If we then move forward in time to an article you

wrote in 1989, NHBT0057960, please. This a publication 1989, "New trends in Blood Transfusion, authored by you. If we go, please, in the first page, to the left-hand column, second paragraph, you say:

"Blood transfusion in clinical medicine has experienced significant changes in recent years and rapid developments continue to take place on many fronts. Numerous factors will determine the future use of blood and blood derivatives such as [and this was your first paragraph:

"1) The tendency towards a more rational use of blood and blood components for those patients who really need them. Education of clinicians on the proper use of blood is now becoming an accepted aspect of medical training. Responsible clinicians are re-examining the benefit-to-risk relationship of blood transfusion. However, there is a great deal of ground to be covered since many clinicians consider blood and blood components on the same level as any drug that they prescribe. In some countries, the establishment of Hospital Transfusion Committees has helped a great deal towards a more rational use of blood and it is expected that such committees will be established in more and more hospitals worldwide."

Then you set out a number of other factors, I'm

not proposing to go to. But it's this issue about a more rational use of blood and blood components that I want to explore with you.

Looking at really the period from 1980 onwards, when you became deputy director, in your experience, to what extent was the kind of guidance we saw in Notes on Transfusion cautioning against over-use of transfusion, to what extent was that faithfully adhered to by clinicians in your experience?

A. No. No, not until later.

Q. So is it right to understand that both unnecessary transfusion and over transfusion were problems?

A. Yes.

Q. That's why, as I understand your statement, you regarded it as an important part of the centre's responsibility to try to advise and educate treating clinicians on the principles and ethics of treating transfusion?

A. Yes.

Q. Do you have a sense of the extent to which that was done by other Regional Transfusion Centres outside of the North London Centre?

A. Not really.

Q. If we go back to your witness statement, page 92, you've set out from paragraph 367 onwards a number of

measures which were taken by the centre, so 367:

"An important initiative that the consultants and I were very committed to was liaison with the clinicians in the hospitals we served. We introduced the concept of Joint Transfusion Medicine consultant appointments ..."

What was that?

A. Region funded my centre for additional consultants, and so we offered joint appointments to some of our main user hospitals, some of the large teaching hospitals, and we were -- we initiated -- we were -- we initiated -- that we started that initiative that was -- that we funded half of the consultant or sometimes a full consultant, but to be half of the time at the Transfusion Centre, and half of the time running a blood transfusion department in a hospital, the blood bank and all aspects of transfusion in that hospital.

And that worked very well, and has continued, and that gave rise, I think, to the -- with other initiatives from our centre to the Better Blood Transfusion Initiative.

Q. We'll come on to that. Then paragraph 367 continues:

"... we educated clinicians in the *'appropriate use of blood'*, meaning that blood components should

only be used when strictly necessary and in the absence of alternatives."

Then paragraph 368:

"We started Hospital Transfusion Committees for education in transfusion medicine and to monitor blood component usage.

"We performed audits of the usage of red cells, FFP and platelets and showed that there was a great deal of unnecessary transfusions."

Bottom of the page:

"We wrote a number of publications and gave numerous lectures regarding the risks of blood transfusion and measures to increase its safety ..."

Go over the page:

"We organised meetings on transfusion-transmitted infections, to educate and update the medical community ..."

Then paragraph 373:

"In essence, we were the precursors of the 'Better Blood Transfusion Initiative' of the UK [Chief Medical Officers] which eventually managed to significantly reduce the usage of red cells and FFP in the country. The less blood components are used unnecessarily, the less possibility of transfusion-transmitted infections."

Now, I'm going to ask you in a moment about some of the individual initiatives but, first of all, can you assist us with understanding what the Better Blood Transfusion Initiative of the Chief Medical Officers was and when roughly that took place?

A. It was an initiative that came from the blood services to the Chief Medical Officers in -- the UK medical officer. So it came from -- also with the help of the -- our Scottish colleagues, who were also interested in appropriate use of blood, or what's now called patient blood management. And we went to the Department of Health and to the Chief Medical Officer and convinced him, with raw data, of our audits that we had done in blood transfusion, that now other consultants in other centres were doing, that there was inappropriate use of blood, of fresh frozen plasma, of red cells, of platelets. And that there was a great variation. For the same hip replacement you would have a hospital that on average used zero or one unit, and another hospital would use five or six units.

And we showed this data to the clinicians and we showed this data to the Chief Medical Officer and this happened with fresh frozen plasma, with red cells, with platelets, et cetera.

So the Chief Medical Officer was convinced that something needed to be done, and wrote circulars, aided by the Transfusion Service consultants, on the appropriate use of blood and, you know, I think that was the origin of the pre-admission clinics that many of you might have seen in hospitals, where the -- before you have elective surgery you go a month before that to have your haemoglobin done and your -- all tests, so that everything is corrected before you go to surgery, and not go to surgery with anaemia, for example.

So that was the Better Blood Transfusion and I think there were three circulars, and it's now called Patient Blood Management. And they also recommended that there should be a specialist in transfusion that were -- not only consultants in charge of blood transfusion but there were also nurses or medical laboratory scientific officers that were checking that blood was used appropriately and were educating junior doctors on the appropriate use of blood.

Q. And do you recall when that initiative was? If you don't, don't worry, because we can find out easily by other means.

A. I can't remember when the first one was.

to meetings to the College of Surgeons, College of Anaesthetists, so that we would -- and we involved them in transfusion medicine. We also educated at the hospital transfusion committee level, where there were representatives of surgeons, and we also educated them through audit, because we showed them the results of the audits and that we had meetings with surgeons or anaesthetists.

Q. Yes, you've said in your statement you performed audits of usage of blood cells, FFP, platelets, which showed a great deal of unnecessary transfusion. So you would follow that up, would you --

A. Yeah.

Q. -- with the hospital or centre that was audited?

A. Yes, yeah. We went to the hospitals and said: Here you are. You know, why, are you using so much -- what's the justification for you using five units for this type of surgery when this -- or, when the mean is so much and these hospitals are using so little?

So some clinicians did not know how much blood they were using.

Q. Do you recall if the training and education that the centre provided covered issues about patient consent to transfusion and the kind of information about risks that should be given to patients?

Q. Dealing with a number of the initiatives you described in your statement, in terms of the training and education of clinicians, did that involve you, your colleagues, going into hospitals in your area, and lecturing or holding workshops or seminars?

A. Yes. We were very, very involved. You know, since I started in this country, more or less. But we were involved in going to hospitals and asking to -- more or less to be invited and going to grand rounds and going to hospitals and educating the consultant haematologist and MLSOs, inviting clinicians to our centre. We had regular meetings, annual meetings, with consultants and MLSOs in charge of the blood banks to educate them about transfusion, and we also taught at all the medical schools that were in our catchment area and we lectured nationally and internationally.

Q. With the hospitals that you were going into, was your audience predominantly haematologists and the MLSOs, or would you seek to deliver training or education information, say, to gynaecologists and obstetricians or to surgeons?

A. Yes.

Q. Would it be across a range of different disciplines?

A. Yes, well, we -- we more or less asked to be invited

A. Yes, we tried, yeah. We tried to get involved in the consent form for hospitals and I think we managed it, through the Better Blood Transfusion initiative, to include transfusion as a risk in the patient consent form.

Q. Do you have any sense of -- it may be an impossible question but it's a question I particularly have been asked by Core Participants to ask.

Do you have any sense of what difference it might have made to overall infection levels if doctors had been educated on patient blood management at a much earlier stage?

A. I think it would certainly have made a difference, because, you know, sometimes -- top-up transfusions, for example, were not necessary, and -- well, as our audit showed, yes, it would have made a difference because much less blood was needed in a country. The less blood you give, the less infections you transmit.

Q. Can I ask you to look at one letter you wrote to the Department of Health in 1990, NHBT0000189_142, please. This is a letter you wrote, 31 May 1990, to Dr Hilary Pickles, she was a principal medical officer in the Department of Health. In the second line you say:

"I am writing to give you some information on what we have been doing at the North London Blood

Transfusion Service to improve knowledge of blood transfusion and promote sensible usage of blood and blood derivatives."

Then if we go towards the bottom of the page, you're dealing with a number of expects of the proposals for cross-charging which I'm not going to spend time on. The last two lines of the page:

"... an audit recently conducted by us in five major hospitals ... revealed no justification for the use of more than 50% of fresh frozen plasma ..."

Then if we go to the third paragraph on that page:

"The consultants at this Centre firmly believe that it is only through continuous contact with, and education of our user hospitals that we will be able to improve the practice of clinical blood transfusion and make the best use of blood derivatives. NLBTC supplies over 50 hospitals in the NHS, SHAs and in the private sector. These hospitals have each been allocated one consultant who pays regular visits and is available for help and advice."

Just pausing there, that practice of the allocation of a consultant, do you know when that started?

A. As soon as I was appointed, more or less, director and

I asked for more consultants, and we distributed to hospitals.

Q. Then it continues:

"During visits we discussed transfusion practices within the hospital and give clinical and technical advice when required. We monitor blood transfusion laboratory stocks and returns on a monthly basis and discuss the introduction of new forms of therapy ... which might increase demands on the transfusion service. We encourage blood donation in hospitals by staff and patients' relatives and are now starting to see much greater cooperation from hospital authorities ..."

Then if we go to the last paragraph on this page:

"We believe that the way forward in clinical blood transfusion is the establishment of Hospital Transfusion Committees with representatives from those clinical specialities most concerned with blood usage, including a nursing representative. Such committees should meet on a quarterly basis and should deal with matters such as transfusion practice within the hospital, use and abuse of blood and blood components, audit of the use of blood, etc. As a first step we recently conducted a retrospective audit in five major

hospitals supplied by NLBTC, looking at the practice of transfusion of platelets and fresh frozen plasma. It was necessary to search for a total of 600 case notes in order to provide 200 cases for the audit. Review included an assessment as to whether the transfusions were indicated. Results of this analysis were disappointing particularly for FFP, where only 21% of transfusions were indicated, and 60% were definitely not indicated. With respect to platelets, only 53% of transfusion were indicated while 19% were definitely not indicated. From this retrospective audit, we concluded that improvement in all aspects of transfusion practice is necessary. Education regarding the value of blood [top of the next page] components and areas in which their use cannot be justified is particularly needed. Hospital transfusion committees are now being established in the five audited hospitals and we intend to encourage a further five hospitals to move in this direction in the very near future. We view the audits as a means of education and not as a reason for reprimanding users."

I want to ask you two matters arising out of this letter, professor. The first is, can you recall what, if any, of the response of the Department of

Health was at that time to the kind of issues you were raising here?

A. Well, the ultimate responsible laid with them, but this was our local initiative. So, you know, I felt it was my duty to inform them of what we were doing and, you know, eventually it led to the CMO being interested in this aspect.

Q. Well, no doubt we can ask the Department of Health about that. Then the second matter I wanted to ask you about is about the hospital transfusion committees. So you describe here them being established in the five hospitals that you'd audited. Was that the first establishment of hospital transfusion committees in your area that you're aware of?

A. Yes. In my area, yes.

Q. Do you have any sense of how quick other regions were to pick up upon the establishment of hospital transfusion committees?

A. I think that some were quicker than others, but that's all I can say.

Q. What, essentially, was the purpose and remit of the hospital transfusion committee, in a nutshell?

A. It was to make clinicians aware of the usage of blood and of the risks of transfusion and of their own

practice of transfusion. Make clinicians aware of transfusion medicine, because it was a nonentity before, they took it like saline, you know. So it was mostly educational and to share information at hospital level on transfusion medicine.

Q. Would someone from your centre sit on the hospital transfusion committees established in your region?

A. Yes, always a consultant, you know, including me.

Q. I'm going to move, then, from transfusion practice to a new subject now -- the last, I think, topic for the afternoon -- and that's specifically in relation to AIDS and the response of the Blood Transfusion Service and, in particular, the response of the North London Regional Transfusion Centre.

First of all, in terms of your own knowledge about AIDS, you've told us in your statement that one of the publications to which the centre subscribed was the MMWR, and you would read that -- it would come to you, you'd read it and then you'd share it with colleagues at the centre. So, as I understand your statement, you were aware of the reports that emerged, 1981 and 1982, about this condition and you were aware of the first reports in, I think, July 1982 in the MMWRs in relation to patients with haemophilia, and then aware in December 1982 about the San Francisco

the multi-transfused child in California?

A. No, I cannot.

Q. So you recollect it was a pivotal moment in terms of your own knowledge --

A. Yeah, yeah.

Q. -- but you don't know the extent to which that view was shared by colleagues?

A. I must have shared it with Dr Barbara and Dr Hewitt but I can't remember what we discussed, yes.

Q. Would you agree that that report should have been a trigger for the National Blood Transfusion Service generally to consider what action -- or to consider whether action was required and, if so, what action, and to do so urgently?

A. Yes.

Q. Now, I'm just going to ask you to look at some documents from 1983, conscious as I do so that you were, at that stage, the deputy director and not the Regional Transfusion Director. So you weren't attending RTD meetings in the course of 1983.

But if we start with NHBT0092845_008, please.

This is a meeting, 12 May 1983, of the Eastern Division Consultants in the Blood Transfusion Service and we can see that Dr Davies was present, but you also were present.

baby; is that right?

A. Yes.

Q. If we just go back to your statement, Soumik, if we can have that up on the screen again, page 63, paragraph 251 you say this:

"I believe a pivotal moment in my view shifting" -- sorry, I should read the previous paragraph to make sense of that.

So you say in paragraph 250:

"At first, I did not link this disease, which was reported to be confined to homosexual men, with blood transfusion."

Then 251:

"I believe a pivotal moment in my view shifting was when I read a report by the CDC and MMWR of the possible admission of AIDS to a multi-transfused infant in San Francisco; the donor of the platelets transfused to the infant was a homosexual male subsequently found to have AIDS. I believe this report was published at the end of 1982."

Your recollection in terms of the date there is correct.

So can you recall what discussions were held, either within the centre or with other colleagues, following the report of the -- what had happened to

And am I right in understanding the divisional meetings weren't limited to the Regional Transfusion Directors, other consultants at the centres would attend these meetings?

A. Yeah.

Q. Now, if we just look down the page, over the page -- I'm trying to prove a negative here -- and to the next page. There's nothing I can see in this document which suggests any discussion about AIDS. Does that surprise you, that at May 1983 the Eastern Division has not got it high up on the agenda?

A. Now it surprises me. At the time I don't think it did.

Q. And then, still in May 1983, if we go to NHBT0109173, please.

If we just look at the bottom of the page, this is dated 23 May 1973. I've read that as just a typo and it should be 1983. It's dealing with AIDS so it clearly can't be '73, and I've assumed the rest of the date is probably correct.

It's from Dr Davies, your predecessor as director and, if we go to the top of the page, we can see it's -- this is directed to "All medical officers, receptionists", and then to you and Dr Brozovic for information.

And then we can read what Dr Davies was saying -- headed "AIDS":

"This subject has attracted considerable publicity and in view of the, not yet proven, possibility of transmission of blood and blood products, the Transfusion Service is involved. At the recent Transfusion Directors' Meeting [that's the regional directors meeting in May] it was agreed that donors should not be questioned about their private lives and until more information is known about AIDS, reasonable attempts should be made to advise homosexuals to refrain from giving blood. It is hoped that a pamphlet giving this advice will soon be available for distribution at donor clinics.

"In the meantime, there must be no questioning of donors about their private lives, and should a donor volunteer the information that he is homosexual (gay), tell him that current advice is that he should postpone giving blood until more information becomes available or a screening test for AIDS is developed. If he insists on giving -- accept without argument and bleed into a single pack -- there is no need to make a note on the 101 or the pack."

"Some reports suggest that the risk of AIDS increases with the level of promiscuity, and more so

if associated with drug abuse. If a donor volunteers the information that he is in this category and insists that he misses to give blood, inform him that until the AIDS risk has been clarified, his blood will be used for research and laboratory purposes only and not for transfusion. If he agrees to this condition -- bleed on the 'B' sheet -- use a single pack, and label 'FOR DR BARBARA AIDS', and enter 'HOLD' on the B bleed sheet."

I want to ask you about a number of aspects of this. If we go back to the first paragraph -- in fact if we just look at the whole -- that's perfect, Soumik, thank you.

So it appears to have been Dr Davies's firm view that there should be no questioning of donors about their private lives, which -- the inference I think might be drawn from this, that there would be no question to the donor, "Are you gay? Are you homosexual?" Was that your understanding of what was being suggested?

A. Yes.

Q. And did you agree with that, as far as you can recall?

A. Not really, because we thought that there was nothing -- I started thinking that there was nothing wrong in asking -- you know, thinking about the

patient, that there was nothing wrong in asking donors about their sexual practices.

Q. And then can you, in any event, help us understand what Dr Davies was proposing. In the event of a donor volunteering that they were gay, the suggestion is -- the advice is postpone giving blood. That's perfectly understandable. But then it says:

"If he insists on giving -- accept without argument and bleed into a single pack -- there is no need to make a note on the 101 or the pack."

Does that mean that the blood would be used?

A. No. No. It would go to the microbiology laboratory, to Dr Barbara, and it would -- I can't remember what it would -- what would be done, but we would not use that blood for transfusion.

Q. Is that right, Professor Contreras? Because we can see that's clear in the last paragraph, where Dr Davies appears to be dealing with the category of donor who volunteers that they are promiscuous and/or use drugs. And there there's a clear steer the blood will be used for research or laboratory purposes only and not for transfusion, and there's a description that that will go on the label, "FOR DR BARBARA AIDS", with the word "HOLD", so Dr Barbara would, in those circumstances, presumably know that this was blood

that was not to be used for transfusion.

A. Yeah.

Q. But in relation to the category of donor described in the second paragraph, who simply volunteers that they're gay --

A. Yeah.

Q. -- but insists on giving, Dr Davies says there's no need to make a notice on the 101, so that's the donor form, donor card, or the pack. So Dr Barbara or the other microbiologist would have no way of knowing, would they, that that was a unit of blood from a donor who had volunteered that they were gay?

A. Yeah, but then he says if he agrees to this condition, bleed on the B sheet. And the B sheet was not for transfusion, not for -- so I assume that it meant that it -- with the mechanism there, being bled on the B sheet, it meant that it was not for transfusion.

Q. I'd read that as limited only to the category of donor who is promiscuous or drug use, but perhaps we can ask Dr Barbara what his recollection is.

SIR BRIAN LANGSTAFF: Well, I think that my own interpretation of this would be if one looks at the last two paragraphs, the first of -- the second paragraph, the one beginning "In the meantime", that looks as though it's dealing with somebody who is gay

but is not -- doesn't say, "I'm promiscuous", and doesn't say, "I have been taking drugs by injection". Then the next paragraph, by contrast, deals with someone who may say they're gay, but certainly says, "I'm promiscuous", and, in particular, if the promiscuity is in any way associated with drug abuse. So that's a different category.

And it says:

"If the donor volunteers the information that he is in this category and insists ..."

So you've got, second paragraph, somebody who is not admitting to promiscuity or drug use, insists on giving. Last paragraph, someone who does say, "I'm promiscuous" or "I have used drugs", or both, and insists.

And then the difference is, in the second paragraph: you bleed into a single pack and don't make a note. Last paragraph: you do bleed into a pack but you do make a note.

That's how I've read it.

So I was reading as counsel has read it and it may be -- it's not your document, so it may be you haven't had a chance to look at it and think about it. But do you see the point I'm making?

A. Yes, yes, and I think it's very confusing. Yeah.

SIR BRIAN LANGSTAFF: It's not clear, is it?

A. No.

MS RICHARDS: So that's May 1983. You tell us in your witness statement that your recollection is that the centre started a draft of its own leaflet through Dr Davies and Dr Barbara, and then eventually the national leaflet was produced. Just in terms of the timings, I'm not going to take you to all the documents because we know the dates, Dr Wagstaff circulated what was intended to be a final version of the leaflet to Regional Transfusion Directors on 6 July. For the benefit of the transcript, but we don't need to go to it, that's NHBT0020668.

Then the first national leaflet was issued at the beginning of September, that's BPLL0007247, and I will ask you to look at that. Thank you.

This is the September 1983 leaflet:

"Will donors be questioned on sexual matters when they attend to give blood?

"Definitely not."

If we go to the next page, we've got the risk categories identified, "Who is at risk from AIDS?":

"Certain groups of people appear to be particularly susceptible; these are:

"1. Homosexual men who have many different

partners.

"2. Drug addicts, male and female, using injections.

"3. Sexual contacts of people suffering from AIDS.

Then the question:

"Can AIDS be transmitted by transfusion of blood and blood products?

"Almost certainly yes, but there is only the most remote chance of this happening with ordinary blood transfusions given in hospital."

We know the leaflet was then changed with later versions, so the reference to "homosexual men who have many different partners" became a reference to "practising homosexuals or bisexuals", and then in due course, just "homosexual". Do you have any thoughts on whether that took too long to make those changes and whether this first leaflet could or should have been in clearer and starker terms?

A. My personal view is that it could have been clearer, and we're talking to the male gay community. They didn't mind being asked these questions, but you have to remember that at that time, people didn't talk about their sexual activities or their sexual preferences. So it was very difficult for some of my

older colleagues to think that you could be open with donors and ask them questions. So I think it took too long.

Q. Now, we can take that down, thank you, Soumik.

In terms of the method of distribution of the leaflet, we know from a meeting of Regional Transfusion Directors in September 1983 -- I don't think we've given you those minutes, professor, because it wasn't a meeting you were at -- but centres were encouraged to use different methods of distribution and there were three main methods identified: sending the leaflet out with the call-up to donors, so that they could read it in the privacy of their own home and decide not to attend, handing it to the donor on an individual basis at sessions; or leaving it available in the session for donors to pick up.

I want just to ask you to look at a document which indicates what the practice was at Edgware at the North London Centre, so it's CBLA0001820. This is a document for the "Advisory Committee on the National Blood Transfusion Service, AIDS leaflet -- First Six Months Experience". Then if we look down the list, we can see:

"EDGWARE -- Available at Sessions

"[Number] used 4000, Stock 46,000."

The effect on donor response or attendance is described as "nil". Then the comment is:

"Donors say helpful and informative. High risk donors have asked will they ever be allowed to give blood again."

So it would appear that the method chosen for distribution at Edgware was the third method, to make it available at sessions, rather than sending it out with the call-up invitations or handing it individually to each donor. Do you recall any discussions about why that particular method of distribution was going to be adopted?

A. Yes, because it was -- well, we couldn't do it. We couldn't send it to the donors because we had postcards, so we couldn't enclose anything with a postcard, and we didn't have the staffing to give it individually to donors. So, at that time, it was available and some of the nurses or donor attendants said that we left it on top of the -- I think we left it on top of the chairs of each -- there were chairs in the waiting area, and the donor attendant said, well, some of them read it and some of them don't.

Q. We can look, I think, at how the practice changed or was tightened up to some extent but, first, just

taking it chronologically, if we could go to NHBT0092842. If we go to the second page, this now April 1984, so it's some months on from the leaflet first becoming available in September '83. This a meeting of the Eastern Division Consultants and we can see that you were in attendance. By this time, you are now the Regional Transfusion Director, having taken over in February 1984. Dr Hewitt, from North London is also there.

If we go, please, to page 4, third paragraph down is a heading "AIDS". Dr Rogers, who was chairing this -- which centre was Dr Rogers, can you recall?

A. Tooting.

Q. "Dr Rogers expressed the view that DHSS policy on homosexual donors had been 'too laid back'. It was felt that the AIDS leaflet should be revised to include reference to plasmapheresis donors, and that more positive publicity to discourage donation should be channelled through dedicated journals."

So three points made there. Policy being too laid back. Do you have any recollection of what that's referring to, whether it's the terms of the leaflet or something else?

A. I think it refers to the leaflet and not us being proactive enough.

Q. Then it says -- the second point is:

"... that the leaflet should be revised to include reference to plasmapheresis donors ..."

Do you know why that was being suggested?

A. I can't remember. It must have been because plasmapheresis donors donate so often, so the risk of transmitting an infection is multiplied.

Q. And then the third was:

"... more positive publicity to discourage donation ... through dedicated journals."

So using publications to try to get the message across about discouraging high-risk groups from donating.

A. Yes.

Q. Then in the middle of 1984, June/July 1984, as I understand it, you made a trip to the New York Blood Center.

A. Yes.

Q. What was the purpose of that trip and what did you learn that was of relevance or use to the way in which the centre operated back in Edgware?

A. Well, we were concerned -- as a team, we were concerned, because more and more publications were coming forward about transfusion-transmitted AIDS at that time. So -- and I had a strong link with the

New York Blood Center because my first tutor was working at the New York Blood Center, Professor Rubinstein. So, in conversation with him, he said, "Oh, we're -- we've got -- we're dealing with high-risk groups in a confidential manner", and so I said, "Well, we should go and see this", because there was -- everybody was so frightened of asking donors about their sexual practices, et cetera.

So I got money -- I convinced my Regional Health Authority to pay for a trip to -- for Dr Barbara and myself to go and see, personally, how the New York Blood Center was dealing with this, donors in high-risk groups of transmitting HIV.

And we went there, and we saw that the donors were quite happy. Especially because the demographics of New York is very similar to the London demographics, so ...

And we went to the donor sessions, and we saw that the donors were quite happy to answer this -- they had a self-exclusion questionnaire -- and to go into a cubicle and answer in confidence whether they were in a high-risk group and whether they wanted to exclude themselves or continue donations.

So we learnt from them, from then -- them, and we, on the plane back, we wrote our self-exclusion

questionnaire, and tested it in -- at the Western Donor Centre, at the plasmapheresis clinic -- the main plasmapheresis clinic at the time and then in the other plasmapheresis centres.

Q. And my understanding, from reading various articles I think that were subsequently published by you or your colleagues at North London, is it was in around July 1984, so not long after you came back, that you did the trial of the questionnaire in one of the clinics.

A. Yes.

Q. Then I'm not sure of the precise date, it may be that the reports will tell us, it was then rolled out at a later stage across the other donor session locations?

A. Yes.

Q. Then perhaps just the last document for today, if we go to NHBT0017776. This is a memo from you, 16 October 1984, to "All Medical Officers", "Re: AIDS Leaflet":

"Because the revised AIDS leaflet is not yet available from the DHSS, we have had our present leaflet overprinted. In the section 'Who is at risk from AIDS?' -- No. 1 has been altered to 'Practising homosexuals'. These leaflets should now be available

at all sessions -- the original leaflet is being withdrawn."

Just before we look at the next paragraph, is it right to understand that you essentially had got fed up for waiting for the revised leaflet to be produced by the Department so you took this crude way of --

A. Yes.

Q. Just printing over the existing one, changing the reference to "having had many sexual partners", whatever it was, to "practising homosexuals"?

A. Yes.

Q. Which was going to be the text of the new leaflet when it was eventually produced?

A. Yes.

Q. Then the second paragraph tells us:

"A further leaflet 'Some Reasons Why You Should Not Give Blood' is also being distributed -- for donors to read before seeing the receptionist. We hope this will: (i) save some donors an unnecessary wait and (ii) focus attention on the AIDS leaflet."

So this is an additional document that was being produced at the North London Centre; is that right?

A. Yes.

Q. Do you recall what the text of it was at all?

A. It had the list of reasons why you should not give

blood, but emphasising the AIDS risk.

MS RICHARDS: Sir, given the time, I've still got a number of questions in relation to this topic, I'm not going to complete it within the next few minutes, so perhaps we could break until the morning.

SIR BRIAN LANGSTAFF: Well, I think that's very sensible.

Professor, we'll take a break now, until ten o'clock in the morning. Thank you very much so far and we look forward to seeing you then, at 10.00.

Ten o'clock tomorrow.

(4.30 pm)

(Adjourned until 10.00 am the following day)

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