Thursday, 14 January 2021

(10.00 am)

(Proceedings delayed)

(10.15 am)

SIR BRIAN LANGSTAFF: I am very sorry, Dr Shirley, that you have been kept waiting this morning. There are one or two things which I need to say to those who are watching online, so if you just forgive me for one moment before I ask you to take the oath.

I am sorry too to those who are watching from home about the delay there's been this morning. Most regrettable.

In any event, what I shall do today is alert you to something which is a risk in the evidence we're going to hear, and the risk is that Dr Shirley will mention the name or counsel will mention the name of somebody who gave evidence under an anonymity order earlier on this year or last year. So what I'm going to do is I'm going to make a restriction order, you will have been used to this when witnesses gave evidence earlier, and the restriction order is to prevent the publication of anything at all, in any way, whether online or in writing or in photographic form or by talking about the details, which may lead to the identification of that particular person. We

do take confidentiality very seriously indeed.

I ought to remind those of you who are watching on Zoom -- it's about a third, roughly, of the daily cohort who follow the Inquiry online -- that back in September I made an order in any event just restricting the disclosure of anything that was heard on Zoom, because Zoom was not time-delayed. As you know, if anything inadvertently is mentioned in this hearing room, the live feed on YouTube can be halted. It's a delayed feed. You get it about two or three minutes after the witness has said whatever the witness has said or the question has been asked, and that gives time for that to be edited out so that you don't see or hear something you shouldn't and it minimises the risk of information being passed around.

Zoom is immediate and so it's just as if you are here in the hearing room. And just as in the hearing room, when those of you who are listening online have been here, you may hear things which should not have been said inadvertently were referred to, which you won't have repeated to anyone because you understood very well that there was a restriction order over it. The same applies, of course, when you are watching on Zoom. It feels remote, possibly, but the principle is just the same.

So back in September, when we began our hearings using the Zoom platform as well as YouTube, I made this order, and I just remind you of it because it applies to all our online hearings, and I'm afraid, for the reasons I gave you earlier, we're going to have rather more of those than we had ever planned for.

What I ordered then, and just let me remind you of it, was this: unless express permission is given by me or by the solicitor to the Inquiry acting on my behalf, evidence given to the Inquiry in oral hearings and broadcast by live feed accessible on the Zoom platform must be kept confidential and must not be disclosed or published in any form unless and until such evidence is broadcast on the time-delayed YouTube platform and/or a transcript published on the Inquiry's website.

Any information that is redacted from the time-delayed feed and/or the transcript of proceedings must not be repeated, disclosed, or duplicated to any third party.

Now, that order remains in force for the duration of the Inquiry and at all times thereafter unless otherwise ordered. I may, of course, vary or revoke it by making a further order during the course

of the Inquiry.

Just so there's no doubt about it so far as today's proceedings are concerned and the risk to which I referred earlier, there is a specific restriction order which I now make. It's additional. In one sense it doesn't add anything to what you have just heard but let me repeat it anyway, and it relates to witness 1303, W1303. That witness gave oral evidence at a hearing on 11 October 2019 and was granted anonymity. But I made an anonymity order. During the oral evidence of Dr Shirley, that witness will be referred to as Mrs AJ.

I make this order: the name and address of witness 1303, the name of her late husband and the name of any other member of the witness's family and any other identifying information, such as the witness's image or a description of their appearance, cannot be disclosed or published in any form unless express permission is given by me or by the solicitor to the Inquiry acting on my behalf.

Witness 1303 must be referred to only as Mrs AJ. This order remains in force for the duration of the Inquiry and at all times thereafter unless otherwise ordered. I may vary or revoke the order by making a further order during the course of the

Inquiry. That's taken me a little time, even further time, out of this morning, so I'm sorry once again, Dr Shirley.

Let me just check that my details are correct as to where you are. You are at home, I think, are you?

THE WITNESS: That's correct, yes.

SIR BRIAN LANGSTAFF: You are on your own, are you?

THE WITNESS: Yes, apart from Luke, who is the IT specialist.

SIR BRIAN LANGSTAFF: He's our Inquiry member of staff, and I think he is outside, is he, at the moment?

THE WITNESS: Yes.

SIR BRIAN LANGSTAFF: So let me describe, for your benefit, what you are, in a sense, looking at.

I think you are looking at me at the moment. I sit in a room which is designed for about 200 people. At the moment it contains a total of eight and we are all socially distanced. You will have seen that I'm still wearing a mask, hence my rather odd appearance when it's -- to make it easier to talk.

Ms Richards will be the only person during the course of proceedings, except on occasions for me, who is without a mask, and we are sitting well apart from

each other.

But you are not talking just to us. You are talking to a much wider group of people. There will be somewhere between 100 and 200, probably, judging by the attendances earlier this week, and let me describe to you where they are. They are at home or elsewhere following remotely either on Zoom or YouTube, and you're talking, therefore, to them as well as to us.

I've described the scene. Let me hand matters over now to Ms Richards.

MS RICHARDS: I think first Dr Shirley will need to be sworn in by Mary.

SIR BRIAN LANGSTAFF: Yes.

DR JANET ANN SHIRLEY, affirmed

Questions by MS RICHARDS

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

A. Yes, I can.

Q. Good.

I'm going to start by asking you a little about your career. You qualified as a doctor at the Royal Free Hospital in 1971; is that right?

A. That's correct.

Q. And you worked for a period in a junior capacity on the liver unit under Dame Sheila Sherlock?

A. Yes.

Q. You held various general medical posts and then, in 1974, you began various haematology posts at the Kingston Hospital; is that correct?

A. Yes, but the first post was not specifically a haematology post; it was a general pathology post and I spent six months in each of the four pathology disciplines.

Q. You were at the Kingston rotating around the haematology disciplines between 1974 and 1978, first as a registrar and then as a senior registrar?

A. That's correct.

Q. Then from 1978 to 1980, you were a senior registrar at St Thomas' Hospital?

A. Yes.

Q. And your rotations there included the haemophilia centre. Was this your first experience of working with patients with bleeding disorders?

A. Yes, it was, apart from some experience of patients with low platelet counts when I was at Kingston Hospital.

Q. Well, I may ask you a little more about St Thomas' a while later.

You also, during that 1978 to 1980 period, had a placement for a short period of time at the Blood Transfusion Centre in Tooting, I think?

A. Yes, I did.

Q. What did that entail?

A. I don't actually remember very much about it. It was a shorter time than it should have been as far as I can remember because there were problems with finding places for senior registrars in blood transfusion -- the blood transfusion centres.

I would have spent time looking at how the orders for blood products came in and how they were issued to different hospitals and also I would have spent -- I spent some time at the donor centre seeing how donors were managed. That's really all I can remember about it, I'm afraid.

Q. In what year had you taken your MRCPath exam?

A. In 1979.

Q. You then, in February 1980, were appointed as a consultant haematologist at Frimley Park Hospital, and you remained in that post until May of 1997.

A. That's correct.

Q. Now, you've explained in your witness statement that you, in that capacity, were responsible for providing a clinical and laboratory haematology service to the population served by that hospital.

So you were dealing with a range of haematology services; is that correct?

A. That is correct.
Q. But amongst other matters, your statement tells us you developed an associate haemophilia centre there, and I'll come back to that in due course, but that's correct in outline?
A. Yes.
Q. You also say in your statement that you set up and chaired the hospital transfusion committee. When was that? When was it set up?
A. I can't remember. I think I set it up when I was clinical director for pathology.
Q. So that would have been a number of years later. You were clinical director for pathology for the last six years of your time at Frimley Park?
A. Yes.
Q. Then 1997 to November 2000 you were medical director of and a consultant haematologist at the King Edward VII Hospital. Did you have any involvement during that time with the care of patients with bleeding disorders?
A. Patients with bleeding disorders, yes, but not patients with haemophilia.
Q. Did you have any involvement with the care and treatment of patients with in HIV or hepatitis during that period?

A. No, I didn't.
Q. Then April 2001 to January 2011 you were consultant haematologist at the Royal Surrey County Hospital and also, for the first five years, associate medical director. To what extent did your role there involve the care of patients with haemophilia or other clotting disorders?
A. Again, I dealt with patients with bleeding disorders but not with haemophilia patients. So I dealt with patients with low platelet counts and patients with von Willebrand's disease and a few other patients with rarer clotting disorders. But because it wasn't a haemophilia centre, I didn't deal with haemophilia patients.
Q. You retired, did you, in 2011?
A. Yes, I did.
Q. Now, coming back then to the Frimley Park haemophilia centre, you've said in your statement that you developed that as an associate haemophilia centre and it was designated as such between 1980 and 1981.
Can you assist us with how and why an associate haemophilia centre came to be established at Frimley Park?
A. The reason why was because some patients with haemophilia were turning up at the hospital with

a bleeding problem because their main centre was a long way away, and it seemed a good idea from the patients' point of view to set up a facility at Frimley Park Hospital as an associate haemophilia centre.
I can't remember exactly when it was set up. It wasn't there in 1980 when I arrived as a consultant but it was there by 1981 because I was at one of the Haemophilia Centre Directors' Organisation meetings. And I would probably have discussed it with the haemophilia reference centre at St Thomas' Hospital about how to go about setting it up and what was required because that was where I had qualified.
Q. Was it your idea to develop the services as an associate centre there or were you asked to do so by the hospital?
A. No, it was my idea. It was part -- when I went there, when I went to Frimley Park as a consultant haematologist there were no clinical haematology facilities. It had been purely a laboratory service with haematology advice given to patients with haematological disorders who were admitted under the general physicians, and I was asked by the hospital to set up a clinical haematology service, which I set about doing by setting up haematology out-patient

clinics, gaining access to beds for haematology patients which would be under my care, rather than the general physicians, and as part of that also setting up the associate haemophilia centre.
Q. Now, as you've told us, at some point between 1980 and the autumn of 1981, when you attended your first UKHCDO meeting, the service there had been designated as an associate centre. Can you recall anything about what the process was of designation? Who was it who accorded you the title -- or Frimley Park -- the title of associate centre and allocated a centre number to the service?
A. I honestly can't remember. I'm sure somebody would have come to make sure that the blood transfusion laboratory had the wherewithal to safely store cryoprecipitate and Factor VIII and also to reconstitute it, and I would imagine that somebody would have had a discussion with me about how I was going to manage the centre -- obviously, somebody told us that we would need to set up the haemophilia patients' register and we were already sending returns of blood products used to the National Blood Transfusion Service centre at Tooting, but I really can't remember what the process was.
Q. Is this right, that the patients that you saw at

Frimley Park, generally at least, under the auspices of the haemophilia centre, would ordinarily be registered with another centre as well? They would be registered with a reference centre or another main centre.

A. That's correct. We were really set up to be able to manage routine out-patient follow ups so that they didn't have to travel long distances and also to manage them if they had a bleeding problem.

Q. You explained in your statement that the reference centres with whom your patients were mostly registered would either have been Oxford, the Royal Free or St Thomas'?

A. Yes, and also boys at the Lord Mayor Treloar College.

Q. The expectation you explain in your statement was that such a patient would once or twice a year attend their reference centre but, if they needed supplies for their home treatment or if they had a bleed, they might then present to Frimley Park on the basis that it was closer, it was their most local facility; is that right?

A. That's correct.

Q. If we just look at your statement -- I'll ask for it to go up on screen as well, it's WITN3901019 and if we could go please, Soumik, to page 5, we can see in

paragraph 5 a description of Frimley Park as an associate centre:

"Associate centres were small Haemophilia Centres which did not always have the medical and laboratory facilities for comprehensive full-time care but which provided treatment for most of their local patients most of the time. Patients attended for regular home treatment supplies or for treatment of minor bleeds but were also under the care of a Reference Centre or other designated Haemophilia Centre for regular tests and treatment of any major problem. Associate Haemophilia Centres had suitable medical staff to give the treatment, correct storage facilities for the concentrate and had to co-operate with the main Centre in record-keeping. Major haemorrhages and surgery were still managed at the main Centre where full laboratory backup was available."

Then you go on to say a few lines further down:

"Patients were asked to attend the main Centre once or twice a year, for routine tests, such as coagulation factor levels, hepatitis and the presence or absence of inhibitors."

Is that all correct?

A. Yes, it is.

Q. We can take that down, thanks, Soumik.

How did the relationship between the reference centre and you at Frimley Park generally work?

A. Usually, the reference centre would refer a patient who lived in the area of Frimley Park Hospital to say would you take over this patient for day-to-day management, and would give me the details of the patient's diagnosis, the level of the clotting factors, what tests had been carried out, whether, for example, they were hepatitis B positive, and then I would see them in my out-patient clinic, check on their general health, you know, whether they'd experienced any problems since their last visit and I would then write to the director of their main centre telling what had happened at the out-patients. If I had carried out any blood tests, I would send those results and I would be relying on the main centre to see them at least once a year in order to direct me if there were any changes in patient management.

Q. You said also in your statement if you were concerned about a patient you could contact the reference centre by phone to ask for advice.

A. That's correct.

Q. Although you had the reference centre to contact in

the way you described, would you agree nonetheless that as a matter of principle clinicians in associate centres giving treatment would still need to keep up-to-date with developments relating to bleeding disorders and treatments for bleeding disorders?

A. We would need to keep up-to-date but you need to understand that we had to keep up-to-date with an awful lot of other haematological diseases. So our ability to be really up-to-date would not be as great as the clinicians at the main centres.

Q. We'll perhaps come back to that in a little more detail later.

You've again set out in your statement what your role was as consultant haematologist and director of the associate centre, and I just want to ask you a little more about some of the responsibilities you've described. You had to keep a register of patients seen at the centre. How was that register kept?

A. We had a book in the blood transfusion department. So we would have the names of the patients, their diagnosis, their factor level, and then we would -- and whether they were hepatitis B positive and obviously, later on, whether they were hepatitis C positive or HIV positive, and what blood products had

been issued and used for them.
Q. Was that register shared with any other organisation, the reference centre or the -- Oxford, for the purposes of its database?
A. Not as far as I recollect.
Q. Then the second responsibility you describe in your statement is prescribing and supervising the use of blood products to haemophilia patients and patients with other bleeding disorders.
A. Yes.
Q. And that would involve you taking a decision in relation to an individual patient, having regard potentially to what the reference centre had told you about that patient, but you taking a decision as to what products to use on any given occasion when you were prescribing treatment?
A. That's correct.
Q. It was also part of your responsibility to submit annual returns to Oxford?
A. Yes.
Q. And you've explained also in your statement that it was part of your responsibility to review patients regularly in the out-patient department and ensure that they were reviewed on an at least annual basis at their main centre?

A. Yes.
Q. If you had a newly diagnosed patient you would refer them to the reference centre for registration and assessment. Was that a common occurrence?
A. Well, common because of new patients or common that I referred them?
Q. Common to have a patient who was newly diagnosed.
A. I suppose we had one or two patients a year. Obviously, there were children that developed a bleeding problem and were diagnosed as potentially having a coagulation disorder, and then there would sometimes be milder haemophiliacs who hadn't had a problem in the past but who presented with a bleed after trauma or after surgery. And then there were women with history of bleeding after or during childbirth or with menorrhagia who were diagnosed as von Willebrand's disease. So anybody who hadn't previously been diagnosed that I suspected had a bleeding disorder I would refer to a reference centre for diagnosis.
Q. Then you've also said in your statement that your responsibilities included attending meetings of Haemophilia Centre Directors whenever possible to liaise with other centre directors and to keep abreast of developments. You didn't, I think, attend every

annual UKHCDO meeting, you attended in 1981 and again in the autumn of 1983 and then some later ones.
Why was it that you didn't attend every single year?
A. Well, 1982 I was pregnant, so I wouldn't have attended because I would have been on maternity leave. I was a single-handed haematologist for the first five years I was at Frimley, so I had to manage all the haematological problems and we didn't have pagers or mobile telephones, so I couldn't be very far away from the hospital for a long period of time, and also because I had two small children at home I didn't want to be away from home overnight because I had to look after the children. So I only attended those meetings that I could get there and back in a day.
Q. How then, more broadly, did you keep abreast of developments?
A. I mean, I relied on, obviously, the meetings, the minutes of the meetings, discussions with Haemophilia Centre Directors about issues regarding patients. I regularly took the BMJ and the haematology -- British Journal of Haematology. We had one copy of each in the laboratory and I used to have a look at that whenever I had time. But, to be honest, I didn't have an awful lot of time with my job and my family.

Q. Were there any other haematologists at Frimley Park at the time with whom you could confer?
A. Not until I appointed a second haematologist. There was a consultant at the Royal Surrey that I used to consult if I had problems with non-bleeding patients. If I had problems with bleeding patients, then I used to phone usually Dr Savidge at St Thomas' Hospital and then when Dr Bevan went to St Thomas' Hospital I used to phone him on a regular basis.
Q. On average, in the first part of the 1980s -- so 1980 up to around 1985 -- are you able to assist with how many bleeding disorder patients you would typically see in a year?
A. I really can't remember. Most of the patients I saw were mild or moderate haemophilia patients and also I did have a cohort of boys who were at Lord Mayor Treloar College whom I saw on a regular basis. It's very difficult to say but probably -- I mean, I'm guessing here really, but probably about 20.
Q. If we look at the 1983 annual returns -- and I think they are the only returns we have for the first half of the 1980s -- if we go to HCDO0000208_004 please, Soumik. So we can see these are annual returns for 1983. Centre 123, was the centre's number. You're identified as the director. This is total number of

haemophilia A patients treated during the year 4, total number of von Willebrand's disease patients treated during the year 1.

So we'll come on to the haemophilia B in a moment but it looks like in terms of actual treatment you've got five patients with haemophilia A or von Willebrand's that year. Would there also be patients that you would see which wouldn't be reflected in the annual return because you weren't, in fact, providing them with treatment?

A. Yes, that's correct, and also there might have been patients that I saw who were treated with DDAVP later on which weren't on the -- I don't think they were on the haemophilia returns because I think it was -- the returns were only regarding patients who had been given factor concentrates.

Q. Or we can see cryoprecipitate. If we just look at what was being used here, there's a small amount of cryoprecipitate used for a von Willebrand patient in hospital, and then we can see NHS Factor VIII concentrate being used in hospital, the number of units given there 4,290, and then for home treatment a larger number, 110,670 units, and then we can see Armour Factor VIII concentrate a small amount used in hospital 1,225 units, and then 19,100 units used for

home treatment.

I do not know whether you can answer this when we don't have the other returns but does anything about this strike you as unusual or does this look pretty typical, as far as you can recall?

A. This looks pretty typical. I have since had some returns for, I think, in the 1990s and I think there were about six patients there. So it seems that this is fairly typical.

Q. For the sake of completeness, the annual return for the same year, 1983, in terms of patients with antibodies recorded that you treated, none, and then we'll just look at the return for haemophilia B patients. So that's, Soumik, HCDO0000208_006.

A. We didn't treat any inhibitor patients. They were always treated at their main centre.

Q. Okay. Then this is haemophilia B for 1983, two patients treated during the year and the product used is NHS Factor IX concentrate for hospital treatment.

I wanted to ask you next about the arrangements for acquiring cryoprecipitate and factor concentrates.

We can take that down, Soumik, thank you.

You have said in your statement that you had no input at all into decisions about the selection and purchase of blood products, and both NHS and

commercial products were obtained by Tooting Regional Transfusion Centre and then you obtained your supplies from Tooting. Is that correct?

A. It is.

Q. Did the same apply in relation to cryoprecipitate? Did you obtain your supplies of that from Tooting or did the hospital have its own internal supplies?

A. No, it came from Tooting.

Q. Do you know how Tooting decided what products to keep in stock at the transfusion centre and then supply to you?

A. No, I don't.

Q. Did you ever make any representations to Tooting about wanting to have different products or particular products that you can recall?

A. I don't remember doing so.

Q. You said also in your statement that you would then order products from the Tooting Regional Transfusion Centre. Can you tell us how that worked? Was it on an individual patient basis or periodically?

A. We did keep a supply of Factor VIII in the blood transfusion department so that if a bleeding -- sorry, and cryoprecipitate as well, so that if we had a bleeding patient we had some on site but we only kept a very small amount, enough for an initial dose,

and then if a patient had an ongoing bleeding problem we would order product from Tooting, saying the number of units that we required, and they would courier it down to us so we could get supplies on an emergency basis from Tooting that would be sent down immediately.

Q. So if you wanted cryoprecipitate you would presumably simply say you wanted cryoprecipitate.

A. Yes.

Q. If you wanted Factor VIII concentrates, did you specify NHS or commercial or a particular type of commercial, or did you simply say we need some Factor VIII concentrates?

A. We simply said we needed Factor VIII concentrate.

Q. So whether a patient, an individual patient, received NHS concentrate manufactured by BPL, or a Scottish concentrate manufactured in Edinburgh, or a commercial concentrate, and if so which one, would ultimately depend simply on whatever it was that Tooting supplied to you?

A. Yes.

Q. Did you ever have any discussions, that you can recall, with Tooting about any shortages of NHS product and whether it would be possible to obtain more NHS product, rather than having to rely upon

commercial?
A. I don't remember any such discussions.
Q. If you had a patient who was on home treatment and, as I understand it, the home treatment programmes were not set up by you but by the reference centre; is that right?
A. That's right.
Q. So if you had a patient, say, from Oxford, who was on home treatment and who was ordinarily receiving NHS concentrate, and Dr Richard would write to you saying this is what the patient receives, how would you be able to secure that that treatment continued with the same concentrate?
A. I don't remember anybody at Oxford being on home treatment. There were patients at St Thomas' I remember being on home treatment, and St Thomas' used to send down the supplies to us. So they obtained the treatment and then sent it -- they either sent it to us and patients picked it up from the hospital blood bank or they sent it direct to the patients' homes.
Q. Now, you've indicated most of your patients were mild or moderate. On the occasions that you saw patients with a severe bleeding disorder, if this arose at all, what was your first line of treatment for them? I'm

talking here about 1980 through to 1985.
A. I don't remember a patient who was a severe haemophiliac coming in with a bleeding disorder, bleeding problem, because as far as I can remember -- no, sorry, we would have had some.
I'm just trying to think. Most -- those with a severe bleeding disorder would have a programme for treatment from their main centre. So we would have some information saying what number of units of what product were normally given for that patient if they had a bleed and, therefore, we would endeavour to get what was written down as the programme of treatment for them.
Q. So is this right, in the case of a severe treatment you wouldn't usually be taking a decision yourself as to what treatment they required, you would be following the treatment mapped out by the reference centre?
A. Yes, as far as I can remember.
Q. So -- dealing here with haemophilia A for current purposes -- those patients in respect of whom you were taking a decision would ordinarily be mild or perhaps moderate haemophilia A patients?
A. Yes.
Q. You have said in your statement that cryoprecipitate

was your product of choice in the first instance. Is that right?
A. That's correct.
Q. Then if that didn't lead to a sufficient level, factor level, you would then turn to concentrates?
A. Yes.
Q. What about DDAVP? When did you first start using DDAVP?
A. I really can't remember. I would have started using it as soon as it became a generally recognised treatment for boosting Factor VIII levels in patients with von Willebrand's disease and mild haemophilia. But I can't remember when that was.
Q. Can you recall whether you had any experience of using DDAVP at St Thomas'?
A. I don't.
Q. Was DDAVP something you also had to obtain from Tooting or was that something that would be held in stock at Frimley Park?
A. It would be held in the hospital pharmacy at Frimley Park.
Q. Then, in terms of patients who were previously untreated or minimally treated patients, was there any particular policy or approach that you had in relation to such patients who you were seeing for the first

time?
A. As far as I can remember, I would treat them with cryoprecipitate. Obviously, if they were mild or moderate, once I started using DDAVP I would use DDAVP first.
Q. What was your understanding, in the first half of the 1980s, of the relative risks of commercial concentrates and NHS concentrates?
A. My view was that NHS concentrates were safer to use because they came from volunteer donors as opposed to paid donors.
Q. And what was --
A. That was with respect really, to begin with, to hepatitis, and it was only in about '83/'84 that I had any knowledge of transmission of HIV through blood products.
Q. What about your understanding of the relative risks of cryoprecipitate versus concentrate?
A. Cryoprecipitate had fewer risks of transmitting viruses because each pack was made from an individual donor; so you weren't exposing a patient to a large pool of donors.
Q. Now, if we come on specifically to the question of hepatitis, you worked in a very junior capacity in 1971 under Dame Sheila Sherlock at the liver unit at

the Royal Free. What, if anything, can you recall learning about hepatitis during that period?
A. There were patients whose chronic liver disease was a result of hepatitis B, and you could diagnose that because there were tests for hepatitis B. There were other patients who had hepatitis, chronic active hepatitis or cirrhosis, for which no causative agent could be identified. Some of those were thought to be autoimmune and some of them were thought to be possibly due to a viral agent as yet unidentified.
Q. Do you recall knowing at that time or, indeed, at any later stage in the 70s about the various outbreaks of hepatitis that occurred at hospitals in which significant numbers of patients became ill and indeed some medical staff died? There was an outbreak in Edinburgh, there was an outbreak in Guy's Hospital and some elsewhere. Do you remember learning about those?
A. No, I don't.
Q. During the time you were at St Thomas' you worked under Professor Ingram and Dr Savidge I think?
A. Yes.
Q. What can you recall, if anything, of them teaching you about hepatitis, the risks of transmission and the potential seriousness of hepatitis?
A. I can't remember having any specific teaching about

that. My recollection of working with them was mainly learning about the different types of bleeding disorders and how to manage haemophilia patients if they presented with a bleeding problem.
Q. Did you, however, become aware during the period you were working at St Thomas', if you weren't already aware of it, of what was by now referred to as non-A, non-B hepatitis?
A. I don't remember learning about that until when I took up my consultant post, but I might have -- it's such a long time ago I really can't remember.
Q. Was it something that was studied as part of the MRCPath qualification when you took the exam in 1979?
A. No, I don't remember us having to study anything about hepatitis.
Q. The Inquiry has looked at and heard from clinicians about the significance of research carried out under Professor Preston in Sheffield, published in The Lancet in 1978, liver biopsies undertaken and results of those liver biopsies. Do you recall learning about that at all?
A. No.
Q. You've said in your statement that you understood at a point in time that non-A, non-B hepatitis was more severe than hepatitis B. Where did that understanding

come from and how did your understanding of non-A, non-B hepatitis develop?
A. I think it probably mainly came from attendance at the Haemophilia Centre Directors' Organisation's meetings and the minutes from those. And, I mean, I did attend haematology conferences and I could have picked up information there as well.
Q. Just dealing with hepatitis B for a moment, was hepatitis B testing of patients with haemophilia or other bleeding disorders undertaken at Frimley Park or did you rely upon the reference centres for that?
A. I usually relied upon the reference centres for that. But if there was no record of whether a patient had been tested for hepatitis B, then I would arrange for a blood test.
Q. Again, dealing specifically for present purposes with hepatitis B, would you tell the patient that you were testing them for hepatitis B?
A. Yes, I usually told my patients what I was taking blood samples for.
Q. Would you tell patients the results of the hepatitis B test?
A. Yes, I would definitely tell them the results.
Q. But then returning to non-A, non-B hepatitis, do you think at the time you took up your post in 1980 that

you at least knew that blood or blood products could transmit a form of hepatitis, non-A, non-B or whatever one might want to call it, as well as hepatitis B?
A. I don't know. I mean, I know I knew about it by 1984 but I don't know exactly when I gained that knowledge.
Q. Was it ever your understanding that non-A, non-B hepatitis was something mild or harmless or inconsequential, or whatever it was that you understood existed did you always understand it to have potentially severe consequences?
A. Yes, I understood that it could cause chronic liver disease.
Q. Do you accept that, as a matter of principle, patients receiving a form of treatment which could infect them with a virus that could lead to chronic liver disease should be informed about that in advance so that they could decide for themselves if that was a risk they wanted to take?
A. It's very difficult looking back to the early 1980s when things were very different. Obviously nowadays one would tell patients that. I do not -- as I said, all my patients were registered at a main centre, which had the support of haemophilia nurses and other staff, and in my view it was their responsibility to have those sorts of discussions with the patients that

they were looking after.
Q. Before I ask you a little more about that, can I just go back to my earlier question. Whether it was the responsibility of the reference centre or your responsibility, do you accept that even in the first half of the 1980s, as opposed to the 21st century, patients should have been given some information about the risks of their treatment, including the possibility of developing hepatitis?
A. Yes, they should have done. I think most haemophiliacs were aware of the problems associated with hepatitis.
Q. Severe haemophiliacs might have some understanding. It would perhaps depend upon what they were told, whether they were a member of The Haemophilia Society. Most of the patients you were seeing, you told us, were mild or moderate haemophiliacs. What's the factual basis for your view that they would have an understanding of hepatitis if you never discussed that with them?
A. I don't know whether they would have had knowledge of it or not. I didn't -- I don't remember discussing with a patient that my treatment might transmit hepatitis. A lot of the patients I had, even if they were mild or moderate haemophiliacs, were already

hepatitis B positive when I saw them for the first time, as a result of having received treatment for things like dental extractions in the past.
Q. You've said in your statement, and you told us a few moments ago, that it was your view that it was the responsibility of the patient's reference centre to have had discussions with the patient about matters such as risks of hepatitis. Why was that your view? If you're the treating clinician, isn't it your responsibility to ensure that your patient is giving proper consent to the treatment, and that involves them understanding the risks of that treatment?
A. A lot of the treatment -- well, yes, the treatment that I was giving was usually in an emergency situation. It was often administered by a senior house officer. A lot of this would have been out-of-hours and I would have been at home. I didn't have the support of a haemophilia nurse who would, as I understand it -- at the main centres would have these sorts of discussions with patients before they had treatment.
Q. You see, Dr Shirley, the evidence the Inquiry's heard from patients treated at bigger centres, at reference centres, much of it, not all but much of it, has been to the effect that patients weren't given information

about the risks of non-A, non-B hepatitis.
Did you ever ask either the patient or the reference centre what information they provided to the patient so that you could know whether your assumption was correct or not?
A. No, I didn't.
Q. Do you accept, at least with the benefit of hindsight, that the practice you're describing ran the risk that patients were receiving treatment in circumstances where the potential risks of that treatment had not been explained to them?
A. Yes, that is eminently possible. On the other side of the coin, if it was a severe bleed that could lead to disability or death, one would want to go ahead and treat the patient.
Q. It's still the patient's decision, though. It may well be that a patient facing very severe consequences of the kind you describe would choose to go ahead with the treatment, but it's still, as a matter of principle, their decision as to what risks to run. Would you accept that?
A. It is their decision and we would take that very seriously nowadays but attitudes in the early 1980s were considerably different from the attitudes today. Medicine was a lot more paternalistic and patients

were not given the amount of information that they would be given nowadays.
Q. Do you recall whether there came a point in time in the course of the 1980s or the 1990s, whenever it was, where your approach changed and you did start explaining to patients the risks of non-A, non-B hepatitis?
A. By the time I was fully aware of the risks, heat-treated Factor VIII was becoming available, and where at all possible I was putting patients into the 8Y trial so that I could make sure that they were getting heat-treated product.
Q. Does that mean that you didn't tell them of the risks because you thought that the product, the heat-treated 8Y product, wouldn't give rise to a risk of hepatitis?
A. I would tell those patients that I was checking their liver function tests on a regular basis to find out whether the product was transmitting non-A, non-B hepatitis.
Q. And did you tell them by this time, so we're talking 1985, 1986 --
A. 1985.
Q. Did you give them some information about what non-A, non-B hepatitis was and that it could lead to, potentially lead to chronic liver disease?

A. I can't remember because I haven't had access to the trial protocol and what patient information was attached to that protocol. I would have followed the guidelines in the protocol.

Q. Do you accept, as a matter of principle -- I appreciate that I'm asking you about events a long time ago -- but do you accept that, as a matter of principle, whatever the protocol said, and it may indeed have said precisely this, patients receiving those heat-treated products 8Y should be told about non-A, non-B hepatitis and, if it was transmitted to them, what it could entail?

A. It's very difficult because, as I said, things were very different in the early -- in the 1980s, compared to how they are today, and people's attitudes were different and we didn't tell patients nearly as much about the risks of treatment as we would nowadays. So, yes, nowadays I accept that, as a matter of principle, that is the correct thing to do but I can't say that in the 1980s it would have been considered the correct thing to do as a matter of principle then.

SIR BRIAN LANGSTAFF: May I ask a question? You've said that when you spoke to patients about their participation in the 8Y trial, you said you were taking liver function tests to see if the 8Y gave them

non-A, non-B hepatitis.

A. Yes.

SIR BRIAN LANGSTAFF: Did you also tell them -- did anyone say, look, why are you giving me something that could give me hepatitis, anything of that sort, or did you head that off at the pass by saying: the treatment you have already been having carried that risk anyway?

A. I can't remember what sort of discussions I had with patients about the 8Y protocol at the time. I'm sorry, but I can't remember.

SIR BRIAN LANGSTAFF: Just for a moment, I pictured myself sitting there, as you are consulting with me and saying "I am going to take this test to see if what I'm giving you is giving you a disease", and the questions I think I might ask, and might always have felt inclined to ask, even in the 1980s, would be, "Well, what will that do to me if I get it" or "Why are you giving me something that will give me a disease?" Do you remember any conversation at all like that?

A. I don't but, as a matter of principle, if patients ask me that sort of question I would answer as frankly as I could and give them as much information as I had available.

SIR BRIAN LANGSTAFF: That wouldn't require your going

back to the protocol for the trial, would it?

A. No, no.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Sir, I'm going to move on to HIV and AIDS. I know we started a little late but, bearing in mind people would have been online since 10, is this a convenient moment to break?

SIR BRIAN LANGSTAFF: Yes, we normally have a break shortly after 11 for half-an-hour. It allows you to take some refreshment and have a break. So we'll do that and come back at 10 to 12.

So 10 to 12, please, Dr Shirley.

A. Okay, thank you.

SIR BRIAN LANGSTAFF: The chances are you are not going to discuss it with anyone, certainly not with Luke, but you mustn't in any event discuss your evidence with anyone at all, either the questions you have been asked or those you might you think you might later be asked to give -- anything else you like, but not your evidence. I'll see you at 11.50. Thank you very much.

A. Thank you, Sir Brian.

(11.20 am)

(A short break)

(11.50 am)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Dr Shirley, as far as you can recall, how and when did you become aware that AIDS might be transmissible by blood or blood products?

A. As far as I can remember, it would have been about 1983.

Q. Were you aware of or did you see the reports that came from the Centers for Disease Control in July and December 1982 reporting cases of AIDS in haemophiliacs and in transfused patients?

A. No.

Q. Now, if we could have up on screen, please, PRSE0002410, this is an article from the New England Journal of Medicine in January 1983. It's one I think of three articles in the course of that month on this issue. This particular one is 13 January. It's called "AIDS and preventative treatment in haemophilia".

If we could go to the second page please, Soumik, and zoom in on the last paragraph on the left-hand column -- so the bottom of the left-hand column. You will see here the author says this:

"The fact that haemophiliacs are at risk for AIDS is becoming clear. If the use of cryoprecipitate will minimise this risk, the current home-infusion

programme needs to be revised."

Then it talks about the data being consistent with a greater potential for AIDS in the population treated with concentrate.

"Physicians involved in the care of haemophiliacs must now be alert to this risk. Preventing the complications of the present treatment may have to take precedence over preventing the complications of haemophilia itself."

Do you recall whether you saw this at the time in January 1983 or later in the course of 1983?

A. I wouldn't have done because I didn't read that journal.

Q. There were various reports in the ordinary media, I think New Scientist in January and February 1983, of concerns about AIDS and possible risks to haemophiliacs. I won't take you to the details of them but do you recall whether you saw any of those in early '83?

A. I don't remember.

Q. Soumik, could we then go to HCDO0000517_001.

Now, this is a letter sent out by UKHCDO. It's from Dr Craske, Dr Rizza and Dr Bloom, sent as far as we understand to all Haemophilia Centre Directors, dated 22 March 1983, about AIDS, and it refers -- it

circulates papers and refers to setting up of a system for the reporting of possible cases.

If we go to HCDO0000517_002, please, Soumik, this is a report we understand to have been circulated with that letter, Dr Shirley. It's from Dr Craske dated 1 March 1983. And we can see it provides information about cases of AIDS.

If we go to the second page, we can see towards the middle of the page it provides information about high mortality rates. And then, if we go to the third page, please, Soumik, we can see under the heading "Aetiology" there's a discussion about theories that have been advanced. The first is drugs, and that's discounted. The second is the immuno-suppressive effect of cytomegalovirus, and Dr Craske says that seems unlikely.

Then if we go over the page reason 3 is "an infectious agent with a similar epidemiology to that of hepatitis B", and Dr Craske goes on to say in the following paragraph:

"If (3) is the most likely cause, then it is possible that such an agent might be present in the plasma pools used to prepare commercial Factor VIII and IX concentrate manufactured from donor plasma collected in the USA."

Do you recall receiving this letter with its enclosures in March of 1983, Dr Shirley?

A. No, I don't.

Q. If you did receive it, and, as I say, our understanding is the intention was it was sent to all directors, would you have read it at the time?

A. Yes.

Q. Is it possible that this was the basis for your developing understanding of the risks of AIDS from blood products in the course of 1983?

A. Probably.

Q. If we then go, please, Soumik, to HCDO0000270_004, you'll see, Dr Shirley, this is a letter dated 24 June 1983. If we go to the second page, we can see it's authored by Professor Bloom and Dr Rizza.

Go back to the first page, please.

It's headed "[AIDS]". It refers to a meeting of Reference Centre Directors held on 13 May 1983 "to discuss this problem in haemophilia, its implications and our recommendations". It refers to one possible case having been reported. Then it says this:

"At the above mentioned meeting on May 13th the following general recommendations were agreed.

"1. For mildly affected patients with haemophilia A or von Willebrand's disease and minor

legions, treatment with DDAVP should be considered. Because of the increased risk of transmitting hepatitis by means of large pool concentrates in such patients, this is in any case the usual practice of many Directors.

"2. For treatment of children and mildly affected patients or patients unexposed to imported concentrates many Directors already reserve supplies of NHS concentrates (cryoprecipitate or freeze-dried) and it would be circumspect to continue this policy.

"It was agreed that there is as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy but the situation will be constantly reviewed."

Then it goes on to make some of further points.

Now, again, our understanding is this was sent to all directors. Do you recall receiving it?

A. I don't.

Q. If it was received, would you have read it?

A. Yes.

Q. Now, if we look at paragraph 1, you'll see there that the recommendation is to consider DDAVP for mildly affected patients with haemophilia A or for patients with von Willebrand's disease.

Can you assist us with whether that was by this time, June 1983, your policy at Frimley Park?
A. I can't put a date on when I started using DDAVP. I just know that I started using DDAVP for von Willebrand's disease patients and mildly affected haemophilia patients as soon as it became a recognised treatment. So I think I would have been using it at this time but I can't say categorically that I was.
Q. Would you agree that if you weren't by then using it that on receipt of this letter your policy should have changed so that DDAVP became the first line of treatment for such patients?
A. Yes.
Q. In terms of paragraph 2, treatment of children and mildly affected patients or patients unexposed to imported concentrates, the recommendation there is that it's circumspect to continue with a policy of reserving policies of NHS materials. It doesn't distinguish between cryoprecipitate or concentrates but refers to both.
You didn't, as I understand your earlier evidence, have any such policy because you simply depended upon what Tooting provided by way of concentrates. Did you on receipt of this or at any point in 1983 consciously shift away at all from

commercial concentrates, at least for the treatment of children or previously unexposed patients or mildly affected patients?
A. My recollection is that I used cryoprecipitate as first line treatment for these patients.
Q. You don't recall receipt of this recommendation leading you to have any conversations with Tooting to try to avoid them sending you commercial concentrates?
A. No, I don't.
Q. If we then go to PRSE0004440, please, Soumik. You'll see Dr Shirley these are the minutes of a UKHCDO meeting on 17 October 1983, and if we go to the second page, please, and we look towards -- in the second half of the page, if you follow it down alphabetically, we can see that you were in attendance at that meeting.
A. Yes.
Q. As I understand it from your evidence and from looking at the minutes, this would have been the second meeting you attended. You had attended in 1981, you did not attend in 1982 for the reasons you explained, but you attended again in 1983.
If we go to page 10, please, Soumik, and we look at the second half of the page under the heading "Any Other Business", you can see there the record of

a discussion:
"Dr Chisholm raised the problem of patients refusing to take up commercial Factor VIII concentrate because of the AIDS scare. She wondered in view of the worry of the patients whether the Directors could revert to using cryoprecipitate for home therapy. Professor Bloom replied that he felt that there was no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. Dr Chisholm pointed out that there was a further problem in her region because of problems in getting large amounts of commercial concentrates, whereas she could get unlimited supplies of cryoprecipitate. Other Directors reported that they had the same problems. After discussion it was agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way."
Do you recall that discussion at all?
A. No, I don't.
Q. If we go to the next page and we look at the paragraph number 10 under the heading "Current situation regarding AIDS", Dr Craske is reported to have

presented a paper, and then if we look a few lines down it says:
"There was some discussion regarding the two cases of AIDS in haemophiliacs in the United Kingdom and Dr Scott gave details about his case."
Then there's further discussion about forms and documents and steps that Dr Craske was going to undertake.
Dr Scott was the director in Bristol and the case he was describing was the case of a haemophiliac patient in Bristol who, by this time, had died of AIDS in the weeks or couple of months preceding this meeting. Do you recall that?
A. No, I don't.
Q. Do you recall learning anything at all about either the first case of AIDS in a haemophiliac patient, which was the Cardiff case, or the second case, the Bristol case; did you recall learning about that at all?
A. No, I don't.
Q. Now, this was autumn of 1983 and it may be reasonable to think that the risks of AIDS would have been a key topic for discussion amongst Haemophilia Centre Directors at this meeting, not just at the formal minuted sessions but in the informal conversations

that directors might have had.

Do you recall anything about any discussions you had in relation to AIDS at that meeting?

A. No, I don't. It was such a long time ago and, as I've said before, the haemophilia side was a small proportion of my workload and to be able to remember what discussions I had at meetings 40 years ago is impossible, I'm afraid.

Q. Did you take any proactive steps in the course of 1983 or 1984 to keep up-to-date with developments about the risks of AIDS, for what may have been a very small number of your patients but was nonetheless the risk of a very serious, probably fatal, illness?

A. I don't remember taking any proactive steps to keep up-to-date. Obviously, I would have had the information from the Haemophilia Centre Directors Organisation meetings and minutes and I'm sure, at that time, that at meetings of the Royal College of Pathologists or the British Society for Haematologists this is a subject that would have been discussed, and I attended those meetings whenever I could.

Q. But you don't recall anything about any particular -- the content of any particular discussions?

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

Q. If we then go to HCDO0000394_117, please, Soumik.

These are notes of a meeting of the Reference Centre Directors at Elstree on 10 December 1984, and we can see that those attending included Dr Kernoff from the Royal Free, Dr Rizza from Oxford, Dr Savidge from St Thomas'; so three of the reference centres that you had dealings with.

Were you aware that such a meeting was taking place?

A. No, I wouldn't have been aware, unless it had been mentioned in the previous minutes of the general meeting of the directors.

Q. Were you aware that by this time, by 10 December 1984, it was known that patients in Edinburgh treated with NHS concentrate had been tested positive for HTLV-III?

A. I think the only thing I was aware of at that time was that the vast majority of haemophilia patients who had become positive for HIV had received commercial factor, but that there were one or two patients in the country who had seroconverted after receiving NHS factor.

Q. Do you consider that the fact that a whole cohort of patients in Scotland had been infected as a result of, or seemingly as a result of, treatment with Scottish NHS product, that that should have been immediately notified to directors such as yourself, who were not

Reference Centre Directors and not privy to the internal discussions going on within UKHCDO?

A. Yes, it should have been. To be honest, until what you've just said, I didn't know that a whole cohort of patients had been infected from a Scottish blood product. This is the first I've heard of it.

Q. Did Dr Savidge, Dr Rizza or Dr Kernoff, or any of their colleagues at the three reference centres with whom you had dealings, Oxford, St Thomas', Royal Free, did they at any time in December 1984 or early January 1985, after this meeting, make contact with you, who -- you were dealing with some of their patients, to pass on to you what had been discussed at this meeting?

A. No, I don't think so.

Q. If we look at HCDO0000270_007, this is the document that was produced following the meeting on 10 December. It's called "AIDS Advisory Document" and, as you know, it's dated 14 December 1984. Do I understand correctly that this is a document which you did receive but you don't think you received it before Christmas 1984?

A. I can't say definitely that I did receive this document but I can't imagine that I did not receive it. I think it very unlikely that I would have

received it before January 1984, given the fact that it would have been put in the post and then we're looking at Christmas and New Year. So it's unlikely that I would have read it until January.

SIR BRIAN LANGSTAFF: Just a point about dating, I think you mean January 1985.

A. Yes, sorry, I do. It's January 1985.

SIR BRIAN LANGSTAFF: While on dating, if I may just raise one point in case I've misunderstood, you mentioned the knowledge of the Edinburgh outbreak. It didn't break in the press until 20 December.

MS RICHARDS: That's right.

SIR BRIAN LANGSTAFF: Just so that I make sure I've got that right. There was no other way of knowing of it except by the internal grapevine presumably.

MS RICHARDS: Presumably. We explored obviously with Professor Ludlam in his evidence in December when he became aware, late October/early November, the meetings and discussions that took place, and then we have the meeting on 10 December.

SIR BRIAN LANGSTAFF: Yes, he knew.

MS RICHARDS: Yes, and others knew.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Precisely who knew is a matter that we may need to explore further but you're absolutely right,

sir, in terms of the press publication in the national media it was 20 December.

SIR BRIAN LANGSTAFF: And it was exactly that that led to the meeting on the 19th about which we've heard quite a lot of evidence.

MS RICHARDS: In Edinburgh, yes.

SIR BRIAN LANGSTAFF: I'm sorry for that interjection.

MS RICHARDS: I think it may follow from the answers you gave earlier, Dr Shirley, that you didn't see the press reporting on 20 December which reported the infection of patients in Edinburgh.

A. No.

Q. If we look at this document we can see it says, under the heading of "Background":

"In the UK there have been 102 cases with three reported haemophiliacs. No doubt other cases are developing in the haemophilic population."

Then if we go over the page, we can see at the top of the page, it says:

"It seems probable that HTLV-III has been incorporated into at least one BPL and one Scottish batch of Factor VIII. Recipients are being followed up."

Then if we go to the bottom half of this page please, Soumik, we can see:

"Options in probable decreasing order of safety from AIDS for haemophilia A.

"1. Heated UK concentrate (note: still NANB hepatitis risk).

"2. Single donor cryo or FFP.

"3. Heated imported concentrate (note: still NANB hepatitis risk).

"4. Unheated UK concentrate.

"5. Unheated imported concentrate -- almost certain to be contaminated."

So in terms of the safety, imported unheated concentrate the least safe but next least safe is unheated UK concentrate. Then if we look at the recommendations:

"1. Concentrate still needed ...

"2. Use DDAVP in mild haemophilia A and von Willebrand's if possible."

Then if we go to the top of the next page:

"3. For Haemophilia A needing blood products

"(a) 'Virgin' Patients those not previously exposed to concentrate, and children use cryo or heated NHS Factor VIII (if available).

"(b) Severe and Moderate haemophiliacs previously treated with Factor VIII use heat-treated NHS Factor VIII, if available or heat-treated US

commercial."

Now, as far as you can recall, once you had received this, and assuming, as I think you accept, is likely that you did, did you then adhere to its recommendations and cease using unheated NHS or commercial concentrates?

A. I can't say whether I did or not. I can't remember. I do know that further on into 1984 I was using the 8Y product.

Q. I think you mean 1985?

A. Oh, '85, yes. Sorry.

Q. Do you agree that what we see set out here, in particular the fact that HTLV-III had been incorporated into NHS product, the options in decreasing order of safety and the recommendations, those are key matters which any Haemophilia Centre Director would want to know about as soon as possible?

A. Yes, and I always followed the guidelines that were relevant at the time. So once I had received this document, I think I would have followed the recommendations, but because I can't remember, I can't say definitely that I did.

Q. In terms of the materials that you received from UKHCDO in 1983 and 1984, obviously there are minutes of meetings, there are the letters that we've looked

at and then there's this, were they always only sent by post?

A. As far as I can remember, because we didn't have any computerisation for sending this sort of document and I can't remember when fax machines came in. Once fax machines were in the laboratory, we would have received these documents by fax, I think.

Q. Do you accept that, as a matter of principle, once in, let's say, the spring of 1983, that you'd become aware from the UKHCDO, materials that we've looked at that there was at least a connection between use of blood products and risk of AIDS, do you accept that patients should have been told that?

A. Yes, I think they probably should have been told that.

Q. Did you tell your patients that you were treating, in the course of 1983 and 1984, that concentrates might carry a risk of AIDS?

A. I don't recall telling patients that.

Q. Do you accept that was wrong?

A. It's wrong by today's guidelines and thinking. It's very difficult, looking back 40 years, to say that what happened then was wrong in the light of today's knowledge and what we do today.

Q. You've described a paternalistic approach and you're not the first witness, by any stretch of the

imagination, to have done so but, nonetheless, it was still, was it not, the case, even in the early 1980s, that there was a concept of informed consent. Patients should be given some information about the risks of treatment, even in the 1980s.

A. Yes, yes, I think they probably should have been.

Q. Of all the risks that you're going to spell out to a patient, isn't the risk, even if you think it's a small one, isn't the risk of contracting a disease known to have a very high mortality rate, poorly understood, no real known treatment, isn't that the kind of risk that it's most important to spell out, so the patient can decide for themselves if they wish to run it?

A. Yes.

Q. Just returning then to the topic of the use of heat-treated products in the course of 1985, Dr Shirley, can we look at BPLL0002371_034. We can see that this is a letter dated 5 February 1985, written by you to Dr Snape at BPL in response to a letter from Dr Snape dated 24 January, and you're asking for heat-treated BPL product for a haemophiliac child according to BPL's protocols.

Can you recall whether at this time, in early 1985, you were only using heat-treated concentrate

A. Given that directive from the Haemophilia Centre Reference Directors' Organisation, and knowing that I have always tried to follow guidelines, I think I probably would have, where at all possible, given heat-treated products.

What I can't say is whether I was always able to get heat-treated products from Tooting or whether they were still supplying my blood transfusion department with any NHS unheated products.

Q. Then if we go, please, to BPLL0010362, this is a delivery note signed by you receiving a consignment of what I think is probably by this time 8Y. It's dated -- or it's despatched on 8 October 1985. It's in respect of five patients. And then it says this, two paragraphs under the box where the patients' names have been redacted:

"The physician should assess and record the efficacy of at least the first infusion of this product received by each patient, take blood samples for tests of HTLV-III antibody and undertake follow-up for possible infection with hepatitis viruses."

A. Sorry, I can't see where that is.

Q. If you look at the box where there are names redacted --

A. Yes.

obtained from Dr Snape in the way we see here, on a named-patient basis, or did you start receiving heated commercial concentrate from Tooting as well?

A. I do not know whether we were getting heat-treated commercial concentrate from Tooting as well.

Excuse me, could I go and get a glass of water?

SIR BRIAN LANGSTAFF: Yes, of course.

A. Thank you. *(Pause)*

Sorry, I forgot to bring it back with me after our break.

SIR BRIAN LANGSTAFF: Don't worry. Any time you want or feel you need a break, just ask.

A. Thank you.

SIR BRIAN LANGSTAFF: I was going to observe, your answer I think was in respect of commercial concentrate, heat-treated commercial concentrate. This is asking Dr Snape of the Blood Products Laboratory for heat-treated Factor VIII concentrate. Presumably, given his position, that would be NHS, do you think?

A. Yes, yes.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: I think from your earlier answers you're not able to say one way or another whether, in the course of the first part of 1985, you continued using unheated concentrates?

Q. -- and then the next paragraph begins -- thank you, Soumik.

A. Oh, yes, fine. Thank you.

Q. It's the second paragraph there:

"The physician should assess and record ..."

A. Right, okay, thank you.

Q. So is this describing the trial or study of 8Y in which your patients were participating and you were participating?

A. I don't know. I've not seen the study trial protocol so I don't know whether this batch of heat-treated NHS product was sent to me for patients in the trial or whether it was sent to me for other patients.

Q. We can see you're being asked here to take blood samples for tests of HTLV-III and undertake follow-up for possible infection with hepatitis viruses.

A. Yes.

Q. Did the patients who you were treating with this product, did you explain to them that you would be taking samples for tests of HTLV-III as requested by BPL and that you would be undertaking follow-up for possible infection with hepatitis viruses?

A. Yes, I would have explained to the patients why they were having to have these extra samples taken. I'm not sure that this is the 8Y trial because, as far as

I know, the 8Y trial we were only taking samples for liver function tests.

Q. For the sake of completeness, I don't think it answers what you don't know, Dr Shirley, but we'll just look at BPLL0006186_002.

So this is an internal memo dated 10 March 1986. I'm not suggesting you would have seen it at the time, Dr Shirley, but it's recorded as an "Interim report on surveillance for [non A, non B hepatitis] after first infusions of 8Y and 9A into deficient patients", and it says in the first paragraph:

"This is an interim collation of data kindly provided by Dr Rizza, Dr Colvin, Dr Kernoff, Dr Hill, Dr Daly [et cetera, et cetera] and Dr Shirley."

So you did supply data about your patients and whether there was any indication that they were developing non-A, non-B hepatitis to Dr Snape as part of this study, I think?

A. Yes, as part of the 8Y study. What I'm saying is that previous document you put up, where there were also bloods being taken for other hepatitis viruses and HTLV-III, I wasn't aware that the 8Y trial took those other blood samples, so I can't say whether that previous document referred to the 8Y trial or to

something else.

Q. I understand.

We can take that down, thank you, Soumik.

Now in your statement you say you recall only one patient at Frimley Park being infected with HIV but you say that there could have been others who were diagnosed at their reference centre. Just so that I understand that correctly, we'll come on to the one patient who you know was infected in a few moments, you can't, as I understand it, exclude the possibility that patients were infected with HIV as a result of their treatment at Frimley Park but whose diagnosis was picked up by their reference centre rather than by you. Is that correct?

A. I only know of one patient that was infected by the treatment I gave at Frimley Park Hospital. There are other patients who were sent to me from their reference centres who had already been diagnosed with HIV.

Q. I want to ask you about that one patient, who I'm going to refer to for reasons I know you understand as Mr AJ. I'm not going to go through every aspect of his care and treatment and you have provided a witness statement in response to Mrs AJ's statement which deals with a number of matters, but I do want to ask

you some questions about it, hopefully without going to too many of the underlying documents.

If you need to see any of the underlying documents, Dr Shirley, please indicate, because we do have them available.

This was a patient registered with Oxford Haemophilia Centre as their main reference centre; is that right?

A. That's correct.

Q. And it was a patient with mild haemophilia A who'd had treatment on only three occasions between 1968 and 1971, so they were -- he was a patient who had been minimally treated?

A. There was a question over what level of haemophilia he had because his Factor VIII levels, as measured in the laboratory, tended to be lower than one would expect from his clinical course. So he was actually thought to be a moderate haemophiliac, not a mild haemophiliac.

Q. The --

A. I would like to say at this point that I have always remembered this patient because I have always felt very sorry and guilty about the fact that he developed HIV as a result of the treatment that I gave him.

Q. Thank you.

This was a patient who presented at Frimley Park on 17 December 1984 and the significance of that date is obvious. It's a week after the meeting at BPL we've been looking at. It post-dates at least the date of the draft of the AIDS advisory document. Is this right, he was treated, first of all, with cryoprecipitate and then over the following days treated with concentrates, not commercial concentrates, NHS concentrates, on several occasions?

A. That's correct.

Q. Is the fact that he was treated with NHS concentrates, rather than commercial concentrates, anything other than the luck of the draw of Tooting, so to speak, or the bad luck of the draw of Tooting, that's what Tooting sent, or was there a conscious decision on your part by December 1984 not to use commercial concentrates?

A. I think I probably was trying to avoid using commercial concentrates because of the much higher number of patients that were infected with HIV as a result.

Q. The records suggest that he was treated with more than one batch and that the batches included, as well as BPL products, a Scottish product. Do you know why that was the case? Was it common to receive Scottish

products from Tooting?
A. I don't remember receiving Scottish products from Tooting. As far as I remember, we generally got BPL products. With regard to the batches, it was a question of what we were sent from Tooting.
Q. Now, why was it that this patient was not treated in the first instance with DDAVP, given that was the recommendation from UKHCDO in June 1983?
A. Because for the type of bleed that he had, it was known that DDAVP would not have increased his Factor VIII level to what was the recommended treatment level for the severe muscle bleed that he had.
Q. When you say that was known, what's the basis for that knowledge?
A. Well, DDAVP generally would increase the Factor VIII level by a small amount. It increased the Factor VIII level much better in von Willebrand patients than it did in haemophilia patients and for somebody like this patient, who had a Factor VIII level of somewhere between 1 and 5 per cent, when you're needing to get the Factor VIII level up to over 40 per cent, you're not going to achieve that with DDAVP.
Q. Now, why having started with cryoprecipitate would you not continue with cryoprecipitate for a longer period

of time, given that it was safer product in terms of the risks of viral transmission?
A. It was because the Factor VIII levels that were being achieved with cryoprecipitate weren't reaching the level recommended for the treatment of his severe muscle bleed, and if the bleed wasn't stopped, then there was a very high risk of permanent disability.
Q. Given that you knew by this time at least of the risk of AIDS associated with concentrates, albeit that your understanding was that the risk was more greatly associated with commercial concentrates, did it not occur to you to contact Dr Rizza, as the consultant at the reference centre where the patient was registered, to seek any kind of advice?
A. No, I didn't. I was going by the guidelines in the Haemophilia Centre Directors Handbook, and my understanding was that there was a very low risk of contracting HIV from Factor VIII concentrates and NHS Factor VIII concentrates.
Q. Did you tell this patient of the possible risk of AIDS from the receipt of concentrates?
A. No, I didn't.
Q. Do you think you should have done?
A. In hindsight, yes, I think I should have done.
Q. If you had been in receipt of the AIDS advisory

document that we looked at, the 14 December document, by this time, do you think your treatment of him would have been different?
A. Yes, I think I would have attempted to get hold of heated product, heated concentrate.
Q. Do you agree that a system which led to you treating this patient in late December 1984, in ignorance of what the Reference Centre Directors had by now decided was the right course, was a system in which something had gone fundamentally wrong?
A. I think it was a system that reflected what was available at the time. We didn't have the quick communication possibilities that we have nowadays.
Q. You had -- and this is -- when I say "you", I'm not talking about you specifically, Dr Shirley, but phones existed.
A. Yes.
Q. Materials can be sent out speedily by post, they don't have to wait around for days. There are means of communicating albeit not with the same instantaneous ability that we may have nowadays. Do you think that the Reference Centre Directors should have done more to ensure that directors such as yourself were better informed as soon as they knew of the greater risk from NHS concentrates?

A. Yes, I think they should have. Obviously, they sent round the AIDS advisory document. It was drafted on 14 December. Whether it went into the post that day, I don't know. It was a Friday. The earliest I could possibly have got it would have been the Monday, and it might have been later because of Christmas post, and then it would have to go through the hospital postal system to get to my desk. So for most of -- most documents sent by post there would be a two or three-day delay before I had them on my desk.
Q. Now as a result of that treatment this patient was infected with HIV, and I'm going to ask you to look at one document from his records. It's WITN3901013. I think that's right, sorry.

We can see it's a letter dated 6 August 1985, and if we look at the fourth paragraph, please, Soumik:

"He has had no symptoms of a recent flu-like illness and we are slightly concerned that this may be in relation to some viral infection."

That refers to the findings set out earlier in the letter:

"We must however, also keep in mind the possibility of the HTLV-III virus being present in this gentleman and causing this problem. We have

therefore arranged for him to have [amongst other things, an HTLV-III test]. This was not mentioned to him, purely that we were looking for some underlying viral infection. We have taken the necessary precautions here and do not think that the patient should be alerted until we have evidence that this is necessary."

It's sent out by a doctor who is described as Senior House Officer to you. This patient was tested for HTLV-III, therefore, without his knowledge and consent, wasn't he?

A. That's correct.

Q. And as I understand your statement, that was the approach that was taken more generally to the testing of your other patients for HTLV-III. They were tested without their knowledge and consent.

A. Yes.

Q. Why?

A. Because at that time patients were having trouble getting things like life insurance, travel insurance, if they mentioned that they had had a test for HTLV-III, whether or not the result that test was negative. And we were worried that if patients were told that they were being tested for HTLV-III they wouldn't be able to get insurance because they'd have

to answer the question, have you ever had a test for HTLV-III, and then the insurance companies would have refused to insure them.

Q. Was that your decision to test patients without their consent for HTLV-III or was that the hospital's decision?

A. As far as I can remember, it was the hospital's decision.

Q. Would you accept that by proceeding in that way, in terms of the insurance concern that you raise, you were actually putting patients in the position of unwittingly misleading their insurers, which could invalidate any insurance subsequently obtained?

A. Yes, it's a very difficult situation, isn't it? You're sort of between a rock and a hard place in deciding what's the best thing to do.

Q. Were other tests, hepatitis B, hepatitis C in due course, or other tests, performed without patients' knowledge and consent?

A. No. I mean, when this particular patient developed signs of possible hepatitis in March 1985, he was told that he was being tested for viral infections which could cause hepatitis, and he was told when we had the results that he had got non-A, non-B hepatitis.

Q. So the approach that you took or the hospital took to

not telling patients that they were being tested was exclusively in relation to HTLV-III, was it?

A. Yes, that's right. There was a lot of debate at the time about whether patients should be told that they were being tested for HTLV-III.

Q. We can take the letter down, Soumik.

This is August of 1985 in relation to this particular patient. Do you recall why there had been no steps to arrange the testing of your patients earlier than August 1985?

A. Because I didn't think that the patient would have contracted HIV. I think that was the reason that he wasn't tested sooner. I think it was because during 1985 it became more widely known that quite a few haemophiliacs had developed HIV as a result of being given British blood product and that then we were advised to start testing our patients for HIV.

Q. We'll just look at one further document in relation to this patient WITN3901015, please, Soumik. So this is a letter which you wrote on 28 August 1985 to Dr Rizza. We can see from the first paragraph that it follows a telephone discussion you have had with Dr Rizza. You set out matters of history and then, if we go on to the second page, if we look at the second paragraph on that page:

"As a routine we took blood to test for anti-HTLV-III antibody since we're trying to do this on all the haemophilia patients who attend for follow-up. I enclose a photocopy of the results we have received from the Middlesex ... As you can see, they feel that these results suggest recent seroconversion."

So is this right: by August of 1985, you were endeavouring to test all your haemophilia patients for HTLV-III?

A. Yes, I think by then we were being advised that we should test all our patients. When I say being advised, that would have been by the UK Haemophilia Centre Directors Organisation.

Q. Now, you were here at the end of August writing to Dr Rizza to tell him that this patient's HTLV-III result was a positive one. You didn't tell the patient for another few weeks. Why was Dr Rizza being alerted before the patient? Was it not imperative to get the patient in, not least because of the risk of infecting partners?

A. I think I probably left it until his next scheduled out-patient appointment.

Q. Do you accept that that ran a risk that in the intervening period the patient could -- this is as

a matter of principle, rather than relating to the specifics of the case -- could have passed on an infection to their partner?

A. I can't -- I suspect part of it may have been that I didn't really know an awful lot about HIV because it wasn't something that I came across very often. I had a very busy out-patient clinic. It was difficult to fit in patients at short notice. There wasn't a specific haemophilia clinic. I saw the haemophilia patients in the same clinic as I saw all the other haematology patients.

With the laboratory test you get a positive but you always have to confirm it on a repeat test, in case it's a false positive. So I probably didn't feel it was imperative to get him back early.

Q. In terms of the subsequent care and treatment of that patient, or any other patient infected with HIV, your statement suggests that you were not involved with ongoing treatment of HIV. That was the responsibility of the main centre; is that correct? Is that how matters were arranged?

A. Yes, that's correct. So patients would either be managed by somebody at their main centre who was a specialist in HIV, or patients at Frimley Park were managed by a consultant who sub-specialised in HIV.

Q. When a test for hepatitis C became available, you were, I think, involved in arranging for your patients to be tested. We can see, if we look at a couple of documents, HCDO0000119_051, this is a letter, it's between the Public Health Laboratory Service and Colindale and Ms Spooner at Oxford, but it says:

"I gather Dr Shirley is presently routinely screening her haemophiliac patients for anti-HCV."

Then if we look at another document, HCDO0000119_053, we can see this is what triggered the letter. You have sent hepatitis survey reports for patients who tested hepatitis C antibody positive to Oxford, and if go over the page, just by way of example -- we don't need to look at all the details -- we can see there a patient, if we look at the top of the page, a few lines down:

"Approximate date onset of hepatitis: Picked up on routine screening."

If go down the page towards the bottom table we can see there in the table it says "Hepatitis C ABS positive, 19 February 1991", and there were a few further results enclosed with this document.

Is it right to understand from this that, certainly by the early part of 1991, you were routinely screening for hepatitis C your haemophilia

patients?

A. Yes. Sorry, can I just go back to the HIV?

Q. Yes, of course.

A. With regard to testing and counselling patients, I worked closely with the consultant microbiologist, and I was guided to quite a large extent by what she recommended for the testing of patients who might have HIV.

Q. Just to return then to hepatitis C, do we correctly understand from these documents that in early 1991 you were routinely testing your patients for hepatitis C, a test now, by that time, being available?

A. Yes, I think the Haemophilia Centre Directors Organisation was asking all the Haemophilia Centre Directors to do this.

Q. As far as you can recall, were you arranging for all of your patients to be tested, all of your haemophilia bleeding disorder patients to be tested for hepatitis C?

A. Those that had no record of having been tested.

Q. Was that undertaken with the advance knowledge and consent of the patient?

A. I -- again, it's not something that I can remember but, I mean, I usually told them at their out-patient's attendance what we were taking -- what

tests we were taking their blood samples for.

Q. Did you have any involvement thereafter with the treatment of any of your patients for hepatitis C, for example with interferon?

A. No, I didn't.

Q. Were there arrangements in place for referrals to liver specialists for patients who were infected with hepatitis C?

A. Not at Frimley Park, not for my haemophilia patients. I would have told their main centre what the result was, and I would have expected them to do the referrals because they had the facilities in place.

Q. Do you recall anything of your involvement with the hepatitis C look-back programme in the 1990s?

A. Yes.

Q. What can you tell us?

A. I remember we had to do a hepatitis C look-back and we had to identify batches of product that had been used for patients. So we had to go through the blood transfusion records, the blood bank records, to see whether any of the batches that had been identified had been used for patients at Frimley Park Hospital.

Q. Do you recall whether there were many or any patients identified through that process who were then tested and tested positive for hepatitis C?

A. I can't remember.
Q. Just going back to the question of risks of HTLV-III AIDS and what was available by way of information and guidance in 1984, you've said in your statement you wish you'd been given more guidance from UKHCDO and the Blood Transfusion Service about treatment and products. What type of advice or guidance would you as an Associate Director, with a practice ranging across a wide range of haematology, as you've described, what sort of advice or guidance would you have found most beneficial, do you think?
A. I think, as far as I can remember, that December 1984 document was the first time that we were given any guidance on what product we should use in what type of patient, and I think if we had had that sort of guidance issued through the 1980s, it would have been -- it would have been easier for consultants to know that they were giving the right treatment and also, I think, it would have enabled consultants like myself to put pressure on the regional Blood Transfusion Services to give us certain types of product.
MS RICHARDS: Sir, I note the time. I've pretty much come to the end of my questions for Dr Shirley. If we could take the lunch break now and invite recognised

legal representatives of Core Participants to send over the course of the lunch break to me and Mr Boukraa any questions they would wish us to consider arising out of Dr Shirley's evidence, that would be useful.
SIR BRIAN LANGSTAFF: We will do that in a couple of minutes, within which I want to ask you something which arises out of the evidence you have given.
You were talking about being between a rock and a hard place; do you remember that?
A. Yes.
SIR BRIAN LANGSTAFF: You were describing that the advice that you had had from the UKHCDO was to test every patient that you saw who had haemophilia and test them for HIV, HTLV-III.
A. Yes.
SIR BRIAN LANGSTAFF: So this was advice that was widely circulated and widely understood from the UKHCDO.
A. As far as I can remember.
Q. The policy that the hospital adopted, for anyone who was given such a test was not to tell them that they were being tested for HIV HTLV-III infection.
A. Yes.
SIR BRIAN LANGSTAFF: So you're following a recognised protocol by not saying, you're following a recognised

protocol by testing. The reason that you understood the hospital was saying don't tell the patient, because that's what you would normally want to do, it's what you did in other cases -- you told us earlier you told your patients what you were testing them for.
A. Yes.
SIR BRIAN LANGSTAFF: So you want to tell the patient but you don't because the hospital's view is it's going to affect or might affect their insurance.
A. Yes.
SIR BRIAN LANGSTAFF: Did it ever occur to you, or, for that matter, those who were in a similar position that you spoke to, that insurers were very likely to know that the general recommendation from the doctor's organisation was that every haemophiliac should be tested for HIV and, therefore, they would naturally assume that, if you happen to have haemophilia, you would be testing for that or tested for that particular condition?
A. I don't think that ever crossed my mind. I didn't think about what access insurers had to protocols or -- it wasn't a protocol, as such, it was a request that we test. It never entered my head that the insurers would have had knowledge of the UK

Haemophilia Centre Directors Organisation asking Haemophilia Centre Directors to test their haemophilia patients for HIV.
SIR BRIAN LANGSTAFF: Because there'd be no secret about that advice to doctors from the UKHCDO, would there, as far as you know?
A. As far as I know but, I mean, I don't know how many people knew about the organisation.
SIR BRIAN LANGSTAFF: If it had occurred to you, you said, right towards the end of your evidence, that in other respects you might have been in a position to put pressure on the local blood supply services to provide different product, and you're describing the position of a consultant occasionally being able to apply pressure to improve services or question practices. You would have been in a position, do you think, would you, to have raised it with the hospital, saying, "Well, surely everyone knows that if you happen to be someone who suffers from haemophilia that you're likely to be tested, can we have a different approach here?" Something along those lines? It obviously didn't occur to you but do you think it would have done if you'd known, if you'd thought about it?
A. I did have discussions with the consultant microbiologist about whether we should or should not

tell patients that -- because it wasn't just haemophilia patients, obviously, that were being tested for HIV, and I did have discussions with the consultant microbiologist about what we should be telling the patients about the testing for HIV and I do remember that the general consensus was that we would tell them if they tested positive but not if they tested negative.

SIR BRIAN LANGSTAFF: By the "general consensus", there are two people in this conversation so far that you are describing, who formed the general consensus; do you remember?

A. It was the sort of thing that was discussed over lunch amongst consultants at the hospital, because the gastroenterologists and other specialists, other physicians, would also have had patients that they needed to test for HIV.

SIR BRIAN LANGSTAFF: So this is a matter of general discussion which -- but the hospital itself had the policy, you say, or are you referring there to the outcome of this general discussion?

A. The hospital wouldn't have had a written policy. The consultant body would have had a view on how to go about HIV testing of patients.

SIR BRIAN LANGSTAFF: I see. So this is really

a collegiate approach that you were taking?

A. I think so, yes.

SIR BRIAN LANGSTAFF: Thank you very much. That is very helpful. We will take a break now until 5 past 2. 5 past 2, if you please.

A. Okay, thank you.

(1.04 pm)

(Luncheon Adjournment)

(2.05 pm)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Dr Shirley, I have some questions which I have been asked to ask you by Core Participants, so they will dot around from topic to topic.

A. Okay.

Q. You referred to a book maintained at Frimley Park which collated information about the patient, their diagnosis, their treatment and so on. I know you left Frimley Park a number of years ago but do you happen to know if that book exists or what became of it?

A. No, I don't.

Q. Then in relation to the patient, Mr AJ, that we were talking about before lunch, I have been asked to ask whether that patient was part of any trial at the time his treatment was given in December 1984?

A. No, he wasn't.

Q. Then in relation to Scottish concentrate, I know you said I think you had no awareness of -- you don't remember being aware of a Scottish concentrate being one of the products that was administered to that patient. Do you recall whether you received more generally Scottish concentrates on other occasions and whether you used them on other patients?

A. No, I don't, and I only know that one vial of Scottish concentrate was used in that patient because it's on his blood transfusion records which I have access to.

Q. So it's not something you've got any independent memory of, receiving and using Scottish concentrates?

A. No.

Q. When you were giving your explanation as to why you and your colleagues concluded that patients being tested for HTLV-III wouldn't be told that they'd be tested, the possible impact on insurance, was that something that you considered later when you were arranging tests for hepatitis C? Did you consider the implications for insurance at that stage and, if not, why not?

A. No. Because I wasn't aware that there were any insurance implications with regard to hepatitis C, although in hindsight I presume there would have been. But it didn't carry the same stigma that HIV did in

the 1980s, so it was a slightly different situation.

Q. Now, your evidence in relation to the first part of the 1980s and your arrangements with Tooting was that when you were ordering products from Tooting you didn't specify NHS or commercial. Given that -- your understanding certainly in the course of 1984 that comparatively commercial concentrates posed a higher risk than NHS concentrates, why didn't you raise that with Tooting?

A. I probably thought that it wasn't my place to do so. We relied on Tooting to give us what they had available. There was no self-sufficiency in blood products in the UK and I -- probably naively, I took the view that what was given to me was what they had, and that they didn't have any choice in what they were supplying.

Q. You also in your evidence this morning explained that you were running, again, in the first half of the 80s, the haematology department single-handedly, and that contributed to the fact that you wouldn't necessarily be able to attend all conferences or keep as up-to-date as a haemophilia specialist might do so.

Did it cross your mind or the hospital's mind that you could have used perhaps more junior doctors working under you, or working in the haematology

department, to help keep up-to-date with developments, send them to conferences, send them in your place to the UKHCDO meetings you couldn't attend?

A. I didn't have any junior staff. One SHO in general medicine was assigned to me part-time to help with the haematology clinics and haematology in-patients, but I didn't have any staff specifically assigned to me, so I couldn't have asked them to go to conferences in my stead.

Q. Then in the course of the 1980s, was there any kind of either formal or informal auditing of associate centres such as yours by UKHCDO or by connected reference centres?

A. No, I don't think so. And I don't remember anybody coming to audit the setup at Frimley Park Hospital.

Q. Did any of the consultants at the reference centres that you were dealing with -- so Royal Free, St Thomas', Oxford -- did they ever actually visit Frimley Park in the 80s?

A. No, they didn't.

Q. Then in relation to the batches, which you would have understood by August 1985 one of those batches had led to the infection of the patient that we were discussing before lunch, Mr AJ, what, if any, steps were taken by you or, to your knowledge, others to

follow up those batches?

A. I sent Dr Rizza a list of the batches of the Factor VIII concentrates that I had used in the patient, and asked for him to follow these up. And I also later -- I think I sent it to the blood transfusion authority, a list of the units of cryoprecipitate I had used on this patient, to see if any of those had been contaminated. But I was never given any information as to whether they had identified HIV contamination in any of the products I had used on this patient.

Q. So the units of cryoprecipitate you contacted Tooting, the concentrates, Dr Rizza, and you never received an answer either from the Transfusion Service or from Oxford as to any particular batch?

A. No, I didn't. To this day I have no idea whether what I gave the patient is what caused his HIV. I've assumed it was but I've got no proof.

Q. Just in relation to that, you've no reason to think it's anything other than his treatment at Frimley Park that gave rise to the HTLV-III, have you?

A. No, I haven't. I asked all the relevant lifestyle questions and the replies were negative, so the only way I can think of that he got his HIV was through the blood products that I gave him. But as I've said,

I've got no firm proof about that.

Q. Because you don't know what happened to any tracing exercise?

A. Yes, that's right.

Q. You said in your evidence before lunch that December 1984 and the AIDS advisory document was the first time you can remember guidance being given on product use. Would you accept that the June 1983 letter that we looked at, which recommended directors continuing with a policy of DDAVP or reserving NHS products for certain categories of patients, was -- did you understand that to be some form of guidance on product use from UKHCDO?

A. Yes, it was some form of guidance. And that may be why I used NHS product in Mr AJ. It may have been as a result of that that I used NHS product for him, because I knew that he hadn't had any product for a very long time.

Q. Now, you referred at one point in your evidence to if you're giving emergency treatment that may impact upon the extent to which you would provide full and detailed information to patients about the risks of treatment. You referred also to bleeds that might lead to disability. Would you accept, first of all, that the kind of bleed that Mr AJ, the patient, was

experiencing, that wasn't an emergency or life-threatening situation, was it?

A. It wasn't life-threatening but it was an emergency in as much as if he didn't receive prompt treatment it could have led to permanent disability.

Q. But there was nothing about the circumstances in which his treatment was required that would have precluded a conversation about risks and giving the patient a choice?

A. No, there wasn't.

Q. To what extent were -- or what proportion of bleeds that you customarily treated in the first half of the 80s were life-threatening? Was that something that you ever came across?

A. No, it wasn't.

Q. You referred to the Haemophilia Centre Directors handbook in the course of your evidence, and I think there's been a request for clarification of what that is. I'm going to ask you to look at one of the documents you exhibited to your witness statement and see whether that's what you were referring to.

Soumik, could we have WITN3901020. If we go to the next page, please, I'm looking -- I'm not sure what page it is but I am looking --

A. I think you need to go back for the cover.

Q. It should be under that reference something that looks like this.
A. Otherwise I've got it here and I can put it up. If you go back again, you should have the cover -- that's it.
Q. "Haemophilia Centre Handbook.
"Notes for Doctors and Nurses involved in the Care of Patients with Congenital Coagulation Disorders.
"Compiled by Jennifer Voke, Colin Madgwick and Katharine Dormandy.
"Published by IMMUNO LTD."
And we can see your name handwritten at the top.
Is this the book you were referring to, the handbook you were referring to?
A. Yes, it is. And that's what I used from the time I became a consultant. Well, in fact, I used it all through my practice because the actual management of the patients didn't significantly change. It was the products that changed. And the other thing that changed was the advent of using DDAVP. But all the other information in the handbook was still extant at the time that I retired.
Q. Do you have a complete copy of the handbook?

A. Yes, I do.
Q. In that case, we may ask you to provide it to us.
But you had it when you started a consultant in 1980?
A. Yes.
Q. Do you know when it was published? We see the reference to Katharine Dormandy, who had sadly died by then.
A. No. I mean, I can look in it now and see if it's got a publish date --
Q. Well, I think perhaps we can --
A. -- if you would like me to.
Q. Yes, if you have it to hand, by all means.
A. Yes, I do.
(Pause)
First published by Immuno in 1980.
Q. Okay, thank you.
So, as you say, it wouldn't have contained necessarily information about -- well, it wouldn't have contained information about products that weren't necessarily in general use at the time. It also wouldn't contain information that was up-to-date about developing knowledge of risks, would it?
A. It didn't have information about developing knowledge of risk. It has a list of NHS therapeutic materials

and commercial concentrates and contact numbers for those organisations.
Q. Thank you. Last question, Dr Shirley: I asked you before lunch about the delay in communicating the test result to Mr AJ.
A. Yes.
Q. Did you understand at that time that HTLV-III could be passed on through sexual transmission?
A. I certainly did by the time I saw him in October because I gave him relevant information about it. I can't say whether I -- I probably knew about it in August but I can't say definitely that I did.
Q. As I said last question, I am handed some further questions, so if you would just give me a moment please, Dr Shirley.
A. I mean, the other thing was that if I did know about it, the evidence was that there was a very low risk to sexual partners. There were very few that had been identified as having caught HIV from their sexual partners outside of -- outside of the homosexual population. In the heterosexual population there was very little evidence that there was a high risk.
Q. Do you know what your sources of understanding were by summer or autumn of 1985 about the risks of heterosexual sexual transmission? Would it have been

UKHCDO or would you have had other sources?
A. No, it would have been information that I had received through other sources and probably from the consultant dealing with HIV at the hospital.
Q. Then, sorry, one additional question, Dr Shirley: when communicating the HIV diagnosis to your patient, what safety advice did you give, as far as you can recall, if any, about reducing risks of transmission to others?
A. I certainly talked about using a condom. I can't remember what else, but I have actually noted that in the patient's notes, and I gave them the booklet, the DHSS booklet, on safer sex.
MS RICHARDS: Sir, those are the additional questions I'm proposing to ask. Before I ask Dr Shirley if she has anything to add, do you have further questions?

Questions by SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: Yes, I do. In the light of your answers about sexual transmission, I'm just looking at some of my own notes because, whatever the consultant in HIV knew, my understanding was that it was as early as 1981/82 that the CDC became aware that there had been instances of sexual transmission, including marital sexual transmission between a man and a woman. So that's just what surprised me, just so that you

know why I haven't -- I'm not going to ask you any questions about that because you have told us what you were told by someone who knew a bit more perhaps than you did, at least that's what you thought.

Can I ask you this: in the early 1980s I imagine, but you can tell me if I'm right or wrong, that you, like many people, got their news from newspapers; am I right?

A. I probably more often got it from the radio because, to be honest, being a full-time haematology consultant and having a young family I didn't have much time for reading newspapers. So it was probably from the radio or television.

SIR BRIAN LANGSTAFF: This is not supposed to be an indelicate question but you were married, were you?

A. Yes.

SIR BRIAN LANGSTAFF: Did your husband take a paper?

A. I can't remember whether we took a paper. I think he probably took a paper when he went up to London to work and he would have brought -- he would have brought the, sort of, Evening Standard home with him.

SIR BRIAN LANGSTAFF: Yes.

A. But, to be honest, by the time I put the children to bed and cooked the supper, I didn't have much time for anything else.

SIR BRIAN LANGSTAFF: So it wasn't from that source, at any rate, that you became aware, as you've told us you were aware at an early stage, that somehow, for some reason, NHS concentrates were safer than commercial concentrates. Can you tell us why you thought that, do you think?

A. Really, because the -- at the meetings of the UK Haemophilia Centre Directors Organisation, it was generally felt that UK concentrates were safer because they were from volunteer donors, as opposed to the commercial concentrates, which were made from blood donated by paid donors.

SIR BRIAN LANGSTAFF: On the face of it, just looking at that information as it stands, the fact that someone is paid for a donation compared to whether someone gives it free has nothing, on the face of it, directly to say about the safety of the blood which is donated. So what did you understand to lie behind the question of the benefits of being voluntary rather than paid?

A. Because it was thought that in the US, particularly, a lot of the paid donors were homeless and IV drug abusers and, therefore, there was a greater risk of transmitting viruses from pools made from that type of donor.

SIR BRIAN LANGSTAFF: So the safety was a matter of virus

transmission?

A. Yes.

SIR BRIAN LANGSTAFF: And it was more likely, because of the source of the raw material, that the NHS concentrate you thought would be safer than the US concentrate from dubious sources?

A. That's correct.

SIR BRIAN LANGSTAFF: The question about -- so that would make it safer, I suppose, and you saw it this way because of the risk of hepatitis?

A. That's correct.

SIR BRIAN LANGSTAFF: At the time you thought that hepatitis was hepatitis either generally or hepatitis B, you didn't know directly at that stage about non-A, non-B when you started at Frimley Park?

A. Well, I certainly knew about non-A, non-B by 1985, and I can't say how soon before that I knew.

SIR BRIAN LANGSTAFF: Yes, but when you went to Frimley Park, I think you told us that you already knew or felt that NHS concentrate was safer.

A. Yes.

SIR BRIAN LANGSTAFF: Did that -- that resulted plainly in others in the UKHCDO and others in the field of looking after those suffering from haemophilia to prefer, where they could, to use NHS concentrate.

A. I think generally we would have preferred it if the UK had been self-sufficient in the production of factor concentrates because we felt they were safer.

SIR BRIAN LANGSTAFF: This would be safety not just in some minor aspect because safety enough to prefer one product over another if you had the choice.

A. Sorry, I didn't understand the question.

SIR BRIAN LANGSTAFF: Well, what you have just described about self-sufficiency is really a question of what was available, isn't it?

A. Yes.

SIR BRIAN LANGSTAFF: You're saying, well, if you had limited -- sorry, unlimited availability of NHS and unlimited availability of commercial concentrate, you would always have chosen NHS concentrate by preference?

A. That's correct.

SIR BRIAN LANGSTAFF: That suggests that you thought that the risk of hepatitis was sufficient to make a real difference.

A. Yes. I thought that the risk of viral contamination -- no, with regard to hepatitis B, most patients were infected with hepatitis B whether it was NHS concentrate or commercial concentrate but, as we went into the 1980s, it was felt that there was less

risk of contamination with other viruses in NHS concentrate than in commercial concentrates.

SIR BRIAN LANGSTAFF: And sufficient, as you have told us, to make a difference in what you would actually use?

A. Yes.

SIR BRIAN LANGSTAFF: Or choose to use, if you had the choice.

A. Yes.

SIR BRIAN LANGSTAFF: Just looking --

A. But at Frimley I often didn't have the choice.

SIR BRIAN LANGSTAFF: No, you have said that very clearly. You relied upon what was available at Tooting.

A. Yes.

SIR BRIAN LANGSTAFF: Can I just ask you in relation to that, did you ever have visitors coming to the area who happened to be haemophiliacs who required product to manage their condition?

A. We did very occasionally have a visitor who wasn't on home treatment and had a bleed and needed to have some treatment.

SIR BRIAN LANGSTAFF: We have been told in the Inquiry that a number of people were warned by their regular doctor that if they needed to get any treatment while they were away from home on holiday, they should always make sure that they asked for and it would be

whatever concentrate they happened to be on. So if they were from Scotland, they might be advised "Whatever you do, don't have any English product have some Scottish product". We've heard examples of that.

Did you have anything like that said to you do you remember?

A. I don't remember that happening.

SIR BRIAN LANGSTAFF: If it had been, do you think you would have been able to go to Tooting and say, "Look, I've got someone here who's been told he really ought to be on Scottish concentrate", or Armour, whatever it may be, "Can you get me some?" Do you think you could have done that?

A. Yes, I think so. Whether Tooting would have been able to access it, I don't know, but there's no reason why I couldn't have gone to Tooting and said could they get this particular product.

SIR BRIAN LANGSTAFF: So you wouldn't have felt it was a lost cause at the start to do that?

A. No, no, I think I could have done that.

SIR BRIAN LANGSTAFF: So your sense was that in particular cases they might have been able to get hold of the product you wanted.

A. Yes. I think one of the ways they might have been able to get hold of it is to ring round some of the

haemophilia centres in London to find out if they had got that product because some of them would have got their product from other transfusion centres, such as Colindale, and so if Tooting didn't have something, they might have been able to access it from somewhere else.

SIR BRIAN LANGSTAFF: You're not far away, I think, from the centre at Treloars.

A. No, that's right. I mean, I don't know whether they -- I don't know what arrangements they had for having product available there. I mean, obviously, they must have had some way of storing blood product but I don't know anything about their facilities.

SIR BRIAN LANGSTAFF: No. The reason I mention that, it's been the recollection of a couple of the witnesses who we have evidence from, who went to school at Treloars, that Dr Aronstam sometimes spoke about what was in the fridge and said, "Well, the best is the Scottish and the next best is", and so on. So, plainly, if that's right, he had a choice of what he might be able to offer the lads who were at his school or under his care.

So it suggests that there was some availability, at any rate, in that location, albeit maybe supplied from Oxford, of those particular

products. So it rather backs up what you're saying, that perhaps Tooting could have rung round and obtained what was necessary.

Can I ask something slightly different: you were engaged in the study in respect of 8Y?

A. Yes.

Q. You did it, I suspect, because you thought it would be useful for such a study to be undertaken.

A. That's correct. I mean, over my time as a consultant there were a few studies generally in haematology, not just in haemophilia patients, that I entered patients into because I thought it would be useful to gain the knowledge and I felt, in a way, it was my duty if I had suitable patients to enter them into trials.

SIR BRIAN LANGSTAFF: What did you think might be the useful outcome of the 8Y study?

A. That it didn't -- that the heat treatment prevented transmission of viruses in the 8Y product.

SIR BRIAN LANGSTAFF: You put that in the plural: viruses. So it's not just a question of HTLV-III but a question of other viruses too?

A. Yes. I mean, I was particularly thinking of hepatitis viruses and HIV, with respect to the heat treatment of the 8Y product.

SIR BRIAN LANGSTAFF: Was it, do you think, more the

hepatitis viruses because it was, I think, generally regarded that one way or the other the commercial products and the NHS too had sorted the problem there had been with HIV or HTLV-III; do you think it may have been more the hepatitis than the HIV or not?

A. I think it was more the hepatitis because it was the hepatitis side of things that I was asked to follow up, with taking regular blood samples for liver function tests from the patients who were part of the 8Y trial.

SIR BRIAN LANGSTAFF: So at that stage, at any rate in 1985, you saw it as a real benefit to the medical fraternity and their patients to be able to eliminate, if one possibly could, or significantly reduce the amount of hepatitis non-A, non-B which was being transmitted by blood and blood products?

A. Yes.

SIR BRIAN LANGSTAFF: Now, when you were asked a moment or two ago after lunch by Ms Richards why it was that you think you used NHS product on Mr AJ, you said you thought that might have been because of the fairly vague guidelines which the UKHCDO had promulgated back in June 1983, preferring NHS concentrate --

A. Yes.

SIR BRIAN LANGSTAFF: -- or cryoprecipitate.

A. Yes.

SIR BRIAN LANGSTAFF: But that itself suggests that you might have had, or felt that you had, a choice of what product to use. It wasn't simply what came off the shelf at Tooting.

A. I think what was recommended at that time was that patients who were receiving concentrates for the first time or who had previously received concentrates early on, like the beginning of the 1970s, and hadn't had any since, that it was better to use NHS products in those patients. Whereas patients who had received a lot of commercial product in the past, if you had to choose between using commercial product in that sort of patient or NHS product, and then you had another patient who had received very little product, then you would be using the NHS product in the very little treated patient and the commercial product in the patients who'd received a lot of commercial product in the past.

SIR BRIAN LANGSTAFF: I think my question was really more about your relationship with the supplies that you got -- with Tooting, as far as supplies were concerned.

A. Yes.

SIR BRIAN LANGSTAFF: Some of your evidence given earlier

might have suggested that you took what you got because you had no alternative. Tooting were there supplying you with what may be commercial concentrate, it might have been NHS concentrate, but you took what you got.

The answer that I was asking you about was one where you seem to be suggesting that you had made a deliberate choice to use NHS concentrate. In other words, it wasn't just a question of what you've been given, it's a question that you could make a choice between NHS, at any rate, and commercial concentrate at that time. That's what my question was about.

A. It's difficult to know, looking back, whether we would have had NHS concentrate and commercial concentrate in the blood bank at Frimley Park Hospital at the same time or whether we were in a situation where we could say to -- by the mid-1980s, whether we could say to Tooting "We've got a patient here that hasn't had very much Factor VIII in the past and can you please send NHS product for this patient". I can't say definitely whether that was the situation or not but, obviously, I used NHS concentrate in this particular patient. I can't say whether it was because we specifically requested NHS concentrate or whether, at that time, Tooting was able to provide us with NHS concentrate

rather than commercial concentrate.

SIR BRIAN LANGSTAFF: Now from the answers you have given me earlier, the advantage of NHS over commercial was the lower risk of a virus being in the NHS concentrate, and it must follow, I suppose, that there is a greater risk the greater number of batches one uses of a particular concentrate.

A. Yes.

SIR BRIAN LANGSTAFF: So if you are having dedicated supplies for somebody who might be at risk if they get one of the batches which is contaminated, it might be sensible, might it, to see that they can always have the same batch. It's something that we've heard in this Inquiry as being batch dedication.

A. Yes, it would be sensible.

SIR BRIAN LANGSTAFF: In this particular case, the case of Mr AJ, do I understand that he had a number of transfusions, infusions from different batches?

A. He did. He had a number of transfusions on a number of different days. And I suspect that that happened because we were asking on a daily basis for Tooting to send us Factor VIII and it was what they sent us.

SIR BRIAN LANGSTAFF: So this wasn't a question of your saying, "Well, he's got a bleed in the iliopsoas muscle, he needs -- he will need quite a lot of

treatment, cryoprecipitate isn't working well enough, needs some concentrate, let's get enough in to cover him while he's here"; that wasn't the way it worked?

A. Well, we didn't know how much he was going to use because he was being assessed on a daily basis as to how his symptoms were progressing and whether he needed any more concentrate, and then I felt and it was recommended that for a psoas bleed, for rehabilitation, that you should cover the first few physiotherapy sessions with Factor VIII, until you were quite certain that he wasn't going to bleed again as a result of the physiotherapy.

So at the beginning I would not have known how much Factor VIII he was likely to use.

SIR BRIAN LANGSTAFF: You wouldn't have been able to estimate that, do you think?

A. No. I mean, the cryoprecipitate didn't give him a high enough Factor VIII level in the blood so I then gave him a dose of Factor VIII, which raised the level quite substantially. I think I was giving him 800 units. And then I reduced that to 500 units and that was giving an adequate response. So those were response-related, and it would have been difficult to ascertain how much overall the patient was likely to need.

SIR BRIAN LANGSTAFF: Now, let me change to something else. When do you think you were first aware that a UK haemophiliac, Scotland, England, Northern Ireland, Wales, UK haemophiliac, had died of AIDS?

A. I certainly wouldn't have known before 1983, so I think it would have been 1983 or 1984, round about that time.

SIR BRIAN LANGSTAFF: We heard the day before yesterday from Dr Bevan, when he was trying to tell us what happened when. He had a number of very clear pictures, which he painted vividly for us, of certain events which had happened that made him remember, these sort of things which stand out in memory. You know the sort of thing that may happen? If you are talking to your children about incidents in their childhood, you will remember some of the events which happened long ago. That's the way we work, isn't it?

A. Yes.

SIR BRIAN LANGSTAFF: Is there any particular picture which stands out in your mind in 1982, '83, '84 about the particular risks of treatment, treatment generally, of those who had the condition of haemophilia?

A. No, I can't think of anything that really stood out in my mind until my treatment of this particular patient

at the end of 1984. You have to remember that I was also looking after haematological malignancies, leukaemias, lymphomas, maternity cases, surgical bleeding cases; now, I remember some of those from an earlier time but I don't remember anything in particular about haemophilia, HIV and -- and really, it's this patient that stands out in my mind as the time that I really became aware of the issues regarding HIV in haemophilia patients.

SIR BRIAN LANGSTAFF: The last thing I want to ask you about is this: you told us earlier how you would see the patients, often mild to moderate, who suffered from haemophilia, but others too, I suppose, when you were meeting them at out-patient appointments, fairly routine out-patient appointments.

You also mentioned that people who were on home treatment would have picked up their supplies from the blood bank. So was that an occasion, do you think, when they were picking up their supplies from the blood bank, that you might have seen them or did they just come in, pick up their supplies and go away without speaking to you?

A. Generally, they came to the blood bank and picked up their supplies and went away. I occasionally saw them if I happened to be passing and then a lot of the

others had their supplies sent to them direct at home, so I wouldn't have had any interaction with those patients --

SIR BRIAN LANGSTAFF: Did you see them at all -- sorry.

A. -- except at routine out-patient appointments.

SIR BRIAN LANGSTAFF: Would you know, with the out-patient appointment, whether they had had an interim visit to the reference centre, such St Thomas' or Oxford, wherever they were primarily receiving their treatment?

A. Yes, I would normally ask when they had last attended their haemophilia reference centre.

SIR BRIAN LANGSTAFF: The reason I'm asking you about this is you mentioned about the fact that you thought that haemophiliacs generally were aware of the risks that they might get hepatitis from treatment.

A. Mmm.

SIR BRIAN LANGSTAFF: They wouldn't necessarily have been quite so aware of the risk that they might get an infection which could lead to AIDS from their treatment in 1983, when you first became alerted to it by the various materials that Ms Richards took you to. Did you ever -- do you remember saying to any of them during your out-patient attendance, "I do have to tell you that there is now -- I should warn you there is

now a risk in your going on having these blood products that you might be taking something which could lead to AIDS"?

A. No, I don't remember doing that.

SIR BRIAN LANGSTAFF: Do you think you did?

A. I don't think so, I don't think so, because I would have thought that their main centre would do it. If you're -- my recollection is that with those sorts of conversations you normally would have somebody like a haemophilia nurse to be able to take the patient and deal with their questions and everything in a fuller way. I didn't have that sort of facility available and if you're going to tell somebody something like that, you really need some sort of backup with information for them to be able to ask more questions and to come back, and I was on my own, didn't have any sort of nursing backup, and I just didn't feel that I had the capacity to be able to do that.

SIR BRIAN LANGSTAFF: What information did you have about what the reference centre was actually telling or not telling the patient?

A. I didn't have any information that I can recollect.

SIR BRIAN LANGSTAFF: Well, that's all that I have to ask. Thank you very much.

Further questions by MS RICHARDS

MS RICHARDS: Sir, there is just one further matter I wanted to ask Dr Shirley about in light of the questions and answers.

Could we have up on screen, please, BART0002269. I should say this is a document that Dr Shirley herself refers to in her witness statement.

We can see these are the minutes of the Haemophilia Centre Directors meeting from the autumn of 1984, 27 September 1984. We can see the location was Cardiff and you're not down as attending. Is that because it would have been too far away for you to attend and get back the same day?

A. Yes, that's correct.

Q. But you would have received the minutes, although we don't know when they were sent out.

A. Yes, yes.

Q. Could we go to page 12, please and look at the bottom of the page under the heading "AIDS". It refers to Dr Craske referring directors to a report on the current situation regarding AIDS, outlining the progress to date within the UK Haemophilia Centre Directors study and reviewing the literature. Directors were asked to give special attention to the work on HTLV-III then he refers to the AIDS survey. Then he says this, and this is the sentence you picked

out in your witness statement, Dr Shirley:

"So far no patients who have only received NHS concentrates had shown [HTLV-III positive] results."

Then he goes on to say:

"HTLV-III testing had only been available since August 1984 and he would only give Directors reports on the results when he was sure of the information."

Now, in terms of that sentence, or part of a sentence, "So far no patients who have only received NHS concentrates have shown [HTLV-III plus] results", you point to it in your statement, I think, please correct me if I've misunderstood, as an indication reinforcing your view that NHS concentrates were safer than commercial concentrates. Was that what you were trying to convey in your statement?

A. Yes.

Q. Would you accept that this is not -- it doesn't exactly read, or it might be thought it doesn't exactly read as a ringing endorsement of the safety of NHS concentrates. It's saying not "We're not expecting there to be any positive results", rather it's saying "So far no patients who have only received NHS concentrates have shown HTLV-III plus results", but it goes on to explain testing's only been available since the previous month.

A. Yes, but it would suggest that it would be better to give patients NHS concentrates than commercial concentrates.

Q. But it wouldn't provide, would it, a basis for being confident that NHS concentrates themselves were free of risk?

A. No, it wouldn't but, from my point of view, it would have been reassuring that there was a much lower risk with UK concentrates.

Q. Thank you. That was the document I wanted to ask you about, as you had referred to it in your statement.

Dr Shirley, do you have anything further that you wanted to add?

A. No, I don't think so, thank you.

MS RICHARDS: Sir.

SIR BRIAN LANGSTAFF: Well, Dr Shirley, can I thank you very much for giving evidence. It's always difficult, I think, particularly when you had so many other things to think about at the time, not only clinical commitments but your young family as well, to remember back. What you have been very helpful in doing is painting us, nonetheless, a picture of what it was like to be a director of a very small -- that is by comparison to some of the other centres we've heard -- very small centre, an associate centre, treating those

who had haemophilia in the period between 1980 and, in particular, the evidence you've given, 1986.

Can I thank you for the insights you've given us into what it was like and the way in which your information and product choice was affected by others in the field, although you did have, as you accept, some responsibility yourself. It's been very valuable to listen to that and can I thank you for that and your attempting as best you can to remember back and to ask what may have seemed to you at times to be rather searching and probing questions. But thank you.

A. Thank you. Well, I'm glad I've been of help.

SIR BRIAN LANGSTAFF: You have.

MS RICHARDS: Sir, that's the evidence for today and tomorrow we have Professor Collins.

SIR BRIAN LANGSTAFF: Yes. So tomorrow at ten o'clock Professor Collins.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Thank you very much.

(2.57 pm)

(Adjourned until 10.00 am the following day)

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