

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

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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

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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.

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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

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1 Inquiry. That's taken me a little time, even further
 2 time, out of this morning, so I'm sorry once again,
 3 Dr Shirley.
 4 Let me just check that my details are correct
 5 as to where you are. You are at home, I think, are
 6 you?
 7 **THE WITNESS:** That's correct, yes.
 8 **SIR BRIAN LANGSTAFF:** You are on your own, are you?
 9 **THE WITNESS:** Yes, apart from Luke, who is the
 10 IT specialist.
 11 **SIR BRIAN LANGSTAFF:** He's our Inquiry member of staff,
 12 and I think he is outside, is he, at the moment?
 13 **THE WITNESS:** Yes.
 14 **SIR BRIAN LANGSTAFF:** So let me describe, for your
 15 benefit, what you are, in a sense, looking at.
 16 I think you are looking at me at the moment.
 17 I sit in a room which is designed for about
 18 200 people. At the moment it contains a total of
 19 eight and we are all socially distanced. You will
 20 have seen that I'm still wearing a mask, hence my
 21 rather odd appearance when it's -- to make it easier
 22 to talk.
 23 Ms Richards will be the only person during the
 24 course of proceedings, except on occasions for me, who
 25 is without a mask, and we are sitting well apart from

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1 **Q.** You held various general medical posts and then,
 2 in 1974, you began various haematology posts at the
 3 Kingston Hospital; is that correct?
 4 **A.** Yes, but the first post was not specifically
 5 a haematology post; it was a general pathology post
 6 and I spent six months in each of the four pathology
 7 disciplines.
 8 **Q.** You were at the Kingston rotating around the
 9 haematology disciplines between 1974 and 1978, first
 10 as a registrar and then as a senior registrar?
 11 **A.** That's correct.
 12 **Q.** Then from 1978 to 1980, you were a senior registrar at
 13 St Thomas' Hospital?
 14 **A.** Yes.
 15 **Q.** And your rotations there included the haemophilia
 16 centre. Was this your first experience of working
 17 with patients with bleeding disorders?
 18 **A.** Yes, it was, apart from some experience of patients
 19 with low platelet counts when I was at
 20 Kingston Hospital.
 21 **Q.** Well, I may ask you a little more about St Thomas'
 22 a while later.
 23 You also, during that 1978 to 1980 period, had
 24 a placement for a short period of time at the Blood
 25 Transfusion Centre in Tooting, I think?

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1 each other.
 2 But you are not talking just to us. You are
 3 talking to a much wider group of people. There will
 4 be somewhere between 100 and 200, probably, judging by
 5 the attendances earlier this week, and let me describe
 6 to you where they are. They are at home or elsewhere
 7 following remotely either on Zoom or YouTube, and
 8 you're talking, therefore, to them as well as to us.
 9 I've described the scene. Let me hand matters
 10 over now to Ms Richards.
 11 **MS RICHARDS:** I think first Dr Shirley will need to be
 12 sworn in by Mary.
 13 **SIR BRIAN LANGSTAFF:** Yes.
 14 **DR JANET ANN SHIRLEY, affirmed**
 15 **Questions by MS RICHARDS**
 16 **MS RICHARDS:** Dr Shirley, can you see and hear me?
 17 **A.** Yes, I can.
 18 **Q.** Good.
 19 I'm going to start by asking you a little about
 20 your career. You qualified as a doctor at the
 21 Royal Free Hospital in 1971; is that right?
 22 **A.** That's correct.
 23 **Q.** And you worked for a period in a junior capacity on
 24 the liver unit under Dame Sheila Sherlock?
 25 **A.** Yes.

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1 **A.** Yes, I did.
 2 **Q.** What did that entail?
 3 **A.** I don't actually remember very much about it. It was
 4 a shorter time than it should have been as far as
 5 I can remember because there were problems with
 6 finding places for senior registrars in blood
 7 transfusion -- the blood transfusion centres.
 8 I would have spent time looking at how the
 9 orders for blood products came in and how they were
 10 issued to different hospitals and also I would have
 11 spent -- I spent some time at the donor centre seeing
 12 how donors were managed. That's really all I can
 13 remember about it, I'm afraid.
 14 **Q.** In what year had you taken your MRCPPath exam?
 15 **A.** In 1979.
 16 **Q.** You then, in February 1980, were appointed as
 17 a consultant haematologist at Frimley Park Hospital,
 18 and you remained in that post until May of 1997.
 19 **A.** That's correct.
 20 **Q.** Now, you've explained in your witness statement that
 21 you, in that capacity, were responsible for providing
 22 a clinical and laboratory haematology service to the
 23 population served by that hospital.
 24 So you were dealing with a range of haematology
 25 services; is that correct?

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

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

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

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

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1 Frimley Park, generally at least, under the auspices
 2 of the haemophilia centre, would ordinarily be
 3 registered with another centre as well? They would be
 4 registered with a reference centre or another main
 5 centre.
 6 **A.** That's correct. We were really set up to be able to
 7 manage routine out-patient follow ups so that they
 8 didn't have to travel long distances and also to
 9 manage them if they had a bleeding problem.
 10 **Q.** You explained in your statement that the reference
 11 centres with whom your patients were mostly registered
 12 would either have been Oxford, the Royal Free or
 13 St Thomas'?
 14 **A.** Yes, and also boys at the Lord Mayor Treloar College.
 15 **Q.** The expectation you explain in your statement was that
 16 such a patient would once or twice a year attend their
 17 reference centre but, if they needed supplies for
 18 their home treatment or if they had a bleed, they
 19 might then present to Frimley Park on the basis that
 20 it was closer, it was their most local facility; is
 21 that right?
 22 **A.** That's correct.
 23 **Q.** If we just look at your statement -- I'll ask for it
 24 to go up on screen as well, it's WITN3901019 and if we
 25 could go please, Soumik, to page 5, we can see in

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1 **Q.** We can take that down, thanks, Soumik.
 2 How did the relationship between the reference
 3 centre and you at Frimley Park generally work?
 4 **A.** Usually, the reference centre would refer a patient
 5 who lived in the area of Frimley Park Hospital to say
 6 would you take over this patient for day-to-day
 7 management, and would give me the details of the
 8 patient's diagnosis, the level of the clotting
 9 factors, what tests had been carried out, whether, for
 10 example, they were hepatitis B positive, and then
 11 I would see them in my out-patient clinic, check on
 12 their general health, you know, whether they'd
 13 experienced any problems since their last visit and
 14 I would then write to the director of their main
 15 centre telling what had happened at the out-patients.
 16 If I had carried out any blood tests, I would send
 17 those results and I would be relying on the main
 18 centre to see them at least once a year in order to
 19 direct me if there were any changes in patient
 20 management.
 21 **Q.** You said also in your statement if you were concerned
 22 about a patient you could contact the reference centre
 23 by phone to ask for advice.
 24 **A.** That's correct.
 25 **Q.** Although you had the reference centre to contact in

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1 paragraph 5 a description of Frimley Park as
 2 an associate centre:
 3 "Associate centres were small Haemophilia
 4 Centres which did not always have the medical and
 5 laboratory facilities for comprehensive full-time care
 6 but which provided treatment for most of their local
 7 patients most of the time. Patients attended for
 8 regular home treatment supplies or for treatment of
 9 minor bleeds but were also under the care of
 10 a Reference Centre or other designated Haemophilia
 11 Centre for regular tests and treatment of any major
 12 problem. Associate Haemophilia Centres had suitable
 13 medical staff to give the treatment, correct storage
 14 facilities for the concentrate and had to co-operate
 15 with the main Centre in record-keeping. Major
 16 haemorrhages and surgery were still managed at the
 17 main Centre where full laboratory backup was
 18 available."
 19 Then you go on to say a few lines further down:
 20 "Patients were asked to attend the main Centre
 21 once or twice a year, for routine tests, such as
 22 coagulation factor levels, hepatitis and the presence
 23 or absence of inhibitors."
 24 Is that all correct?
 25 **A.** Yes, it is.

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1 the way you described, would you agree nonetheless
 2 that as a matter of principle clinicians in associate
 3 centres giving treatment would still need to keep
 4 up-to-date with developments relating to bleeding
 5 disorders and treatments for bleeding disorders?
 6 **A.** We would need to keep up-to-date but you need to
 7 understand that we had to keep up-to-date with an
 8 awful lot of other haematological diseases. So our
 9 ability to be really up-to-date would not be as great
 10 as the clinicians at the main centres.
 11 **Q.** We'll perhaps come back to that in a little more
 12 detail later.
 13 You've again set out in your statement what
 14 your role was as consultant haematologist and director
 15 of the associate centre, and I just want to ask you
 16 a little more about some of the responsibilities
 17 you've described. You had to keep a register of
 18 patients seen at the centre. How was that register
 19 kept?
 20 **A.** We had a book in the blood transfusion department. So
 21 we would have the names of the patients, their
 22 diagnosis, their factor level, and then we would --
 23 and whether they were hepatitis B positive and
 24 obviously, later on, whether they were hepatitis C
 25 positive or HIV positive, and what blood products had

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1 been issued and used for them.

2 **Q.** Was that register shared with any other organisation,
3 the reference centre or the -- Oxford, for the
4 purposes of its database?

5 **A.** Not as far as I recollect.

6 **Q.** Then the second responsibility you describe in your
7 statement is prescribing and supervising the use of
8 blood products to haemophilia patients and patients
9 with other bleeding disorders.

10 **A.** Yes.

11 **Q.** And that would involve you taking a decision in
12 relation to an individual patient, having regard
13 potentially to what the reference centre had told you
14 about that patient, but you taking a decision as to
15 what products to use on any given occasion when you
16 were prescribing treatment?

17 **A.** That's correct.

18 **Q.** It was also part of your responsibility to submit
19 annual returns to Oxford?

20 **A.** Yes.

21 **Q.** And you've explained also in your statement that it
22 was part of your responsibility to review patients
23 regularly in the out-patient department and ensure
24 that they were reviewed on an at least annual basis at
25 their main centre?

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1 annual UKHCDO meeting, you attended in 1981 and again
2 in the autumn of 1983 and then some later ones.

3 Why was it that you didn't attend every single
4 year?

5 **A.** Well, 1982 I was pregnant, so I wouldn't have attended
6 because I would have been on maternity leave. I was
7 a single-handed haematologist for the first five years
8 I was at Frimley, so I had to manage all the
9 haematological problems and we didn't have pagers or
10 mobile telephones, so I couldn't be very far away from
11 the hospital for a long period of time, and also
12 because I had two small children at home I didn't want
13 to be away from home overnight because I had to look
14 after the children. So I only attended those meetings
15 that I could get there and back in a day.

16 **Q.** How then, more broadly, did you keep abreast of
17 developments?

18 **A.** I mean, I relied on, obviously, the meetings, the
19 minutes of the meetings, discussions with Haemophilia
20 Centre Directors about issues regarding patients.
21 I regularly took the BMJ and the haematology --
22 British Journal of Haematology. We had one copy of
23 each in the laboratory and I used to have a look at
24 that whenever I had time. But, to be honest, I didn't
25 have an awful lot of time with my job and my family.

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1 **A.** Yes.

2 **Q.** If you had a newly diagnosed patient you would refer
3 them to the reference centre for registration and
4 assessment. Was that a common occurrence?

5 **A.** Well, common because of new patients or common that
6 I referred them?

7 **Q.** Common to have a patient who was newly diagnosed.

8 **A.** I suppose we had one or two patients a year.
9 Obviously, there were children that developed
10 a bleeding problem and were diagnosed as potentially
11 having a coagulation disorder, and then there would
12 sometimes be milder haemophiliacs who hadn't had
13 a problem in the past but who presented with a bleed
14 after trauma or after surgery. And then there were
15 women with history of bleeding after or during
16 childbirth or with menorrhagia who were diagnosed as
17 von Willebrand's disease. So anybody who hadn't
18 previously been diagnosed that I suspected had
19 a bleeding disorder I would refer to a reference
20 centre for diagnosis.

21 **Q.** Then you've also said in your statement that your
22 responsibilities included attending meetings of
23 Haemophilia Centre Directors whenever possible to
24 liaise with other centre directors and to keep abreast
25 of developments. You didn't, I think, attend every

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1 **Q.** Were there any other haematologists at Frimley Park at
2 the time with whom you could confer?

3 **A.** Not until I appointed a second haematologist. There
4 was a consultant at the Royal Surrey that I used to
5 consult if I had problems with non-bleeding patients.
6 If I had problems with bleeding patients, then I used
7 to phone usually Dr Savidge at St Thomas' Hospital and
8 then when Dr Bevan went to St Thomas' Hospital I used
9 to phone him on a regular basis.

10 **Q.** On average, in the first part of the 1980s -- so 1980
11 up to around 1985 -- are you able to assist with how
12 many bleeding disorder patients you would typically
13 see in a year?

14 **A.** I really can't remember. Most of the patients I saw
15 were mild or moderate haemophilia patients and also
16 I did have a cohort of boys who were at Lord Mayor
17 Treloar College whom I saw on a regular basis. It's
18 very difficult to say but probably -- I mean, I'm
19 guessing here really, but probably about 20.

20 **Q.** If we look at the 1983 annual returns -- and I think
21 they are the only returns we have for the first half
22 of the 1980s -- if we go to HCDO0000208_004 please,
23 Soumik. So we can see these are annual returns for
24 1983. Centre 123, was the centre's number. You're
25 identified as the director. This is total number of

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1 haemophilia A patients treated during the year 4,
 2 total number of von Willebrand's disease patients
 3 treated during the year 1.
 4 So we'll come on to the haemophilia B in
 5 a moment but it looks like in terms of actual
 6 treatment you've got five patients with haemophilia A
 7 or von Willebrand's that year. Would there also be
 8 patients that you would see which wouldn't be
 9 reflected in the annual return because you weren't, in
 10 fact, providing them with treatment?
 11 **A.** Yes, that's correct, and also there might have been
 12 patients that I saw who were treated with DDAVP later
 13 on which weren't on the -- I don't think they were on
 14 the haemophilia returns because I think it was -- the
 15 returns were only regarding patients who had been
 16 given factor concentrates.
 17 **Q.** Or we can see cryoprecipitate. If we just look at
 18 what was being used here, there's a small amount of
 19 cryoprecipitate used for a von Willebrand patient in
 20 hospital, and then we can see NHS Factor VIII
 21 concentrate being used in hospital, the number of
 22 units given there 4,290, and then for home treatment
 23 a larger number, 110,670 units, and then we can see
 24 Armour Factor VIII concentrate a small amount used in
 25 hospital 1,225 units, and then 19,100 units used for

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1 commercial products were obtained by Tooting Regional
 2 Transfusion Centre and then you obtained your supplies
 3 from Tooting. Is that correct?
 4 **A.** It is.
 5 **Q.** Did the same apply in relation to cryoprecipitate?
 6 Did you obtain your supplies of that from Tooting or
 7 did the hospital have its own internal supplies?
 8 **A.** No, it came from Tooting.
 9 **Q.** Do you know how Tooting decided what products to keep
 10 in stock at the transfusion centre and then supply to
 11 you?
 12 **A.** No, I don't.
 13 **Q.** Did you ever make any representations to Tooting about
 14 wanting to have different products or particular
 15 products that you can recall?
 16 **A.** I don't remember doing so.
 17 **Q.** You said also in your statement that you would then
 18 order products from the Tooting Regional Transfusion
 19 Centre. Can you tell us how that worked? Was it on
 20 an individual patient basis or periodically?
 21 **A.** We did keep a supply of Factor VIII in the blood
 22 transfusion department so that if a bleeding -- sorry,
 23 and cryoprecipitate as well, so that if we had
 24 a bleeding patient we had some on site but we only
 25 kept a very small amount, enough for an initial dose,

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1 home treatment.
 2 I do not know whether you can answer this when
 3 we don't have the other returns but does anything
 4 about this strike you as unusual or does this look
 5 pretty typical, as far as you can recall?
 6 **A.** This looks pretty typical. I have since had some
 7 returns for, I think, in the 1990s and I think there
 8 were about six patients there. So it seems that this
 9 is fairly typical.
 10 **Q.** For the sake of completeness, the annual return for
 11 the same year, 1983, in terms of patients with
 12 antibodies recorded that you treated, none, and then
 13 we'll just look at the return for haemophilia B
 14 patients. So that's, Soumik, HCDO0000208_006.
 15 **A.** We didn't treat any inhibitor patients. They were
 16 always treated at their main centre.
 17 **Q.** Okay. Then this is haemophilia B for 1983, two
 18 patients treated during the year and the product used
 19 is NHS Factor IX concentrate for hospital treatment.
 20 I wanted to ask you next about the arrangements
 21 for acquiring cryoprecipitate and factor concentrates.
 22 We can take that down, Soumik, thank you.
 23 You have said in your statement that you had no
 24 input at all into decisions about the selection and
 25 purchase of blood products, and both NHS and

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1 and then if a patient had an ongoing bleeding problem
 2 we would order product from Tooting, saying the number
 3 of units that we required, and they would courier it
 4 down to us so we could get supplies on an emergency
 5 basis from Tooting that would be sent down
 6 immediately.
 7 **Q.** So if you wanted cryoprecipitate you would presumably
 8 simply say you wanted cryoprecipitate.
 9 **A.** Yes.
 10 **Q.** If you wanted Factor VIII concentrates, did you
 11 specify NHS or commercial or a particular type of
 12 commercial, or did you simply say we need some
 13 Factor VIII concentrates?
 14 **A.** We simply said we needed Factor VIII concentrate.
 15 **Q.** So whether a patient, an individual patient, received
 16 NHS concentrate manufactured by BPL, or a Scottish
 17 concentrate manufactured in Edinburgh, or a commercial
 18 concentrate, and if so which one, would ultimately
 19 depend simply on whatever it was that Tooting supplied
 20 to you?
 21 **A.** Yes.
 22 **Q.** Did you ever have any discussions, that you can
 23 recall, with Tooting about any shortages of NHS
 24 product and whether it would be possible to obtain
 25 more NHS product, rather than having to rely upon

24

1 commercial?

2 A. I don't remember any such discussions.

3 Q. If you had a patient who was on home treatment and, as

4 I understand it, the home treatment programmes were

5 not set up by you but by the reference centre; is that

6 right?

7 A. That's right.

8 Q. So if you had a patient, say, from Oxford, who was on

9 home treatment and who was ordinarily receiving NHS

10 concentrate, and Dr Richard would write to you saying

11 this is what the patient receives, how would you be

12 able to secure that that treatment continued with the

13 same concentrate?

14 A. I don't remember anybody at Oxford being on home

15 treatment. There were patients at St Thomas'

16 I remember being on home treatment, and St Thomas'

17 used to send down the supplies to us. So they

18 obtained the treatment and then sent it -- they either

19 sent it to us and patients picked it up from the

20 hospital blood bank or they sent it direct to the

21 patients' homes.

22 Q. Now, you've indicated most of your patients were mild

23 or moderate. On the occasions that you saw patients

24 with a severe bleeding disorder, if this arose at all,

25 what was your first line of treatment for them? I'm

25

1 was your product of choice in the first instance. Is

2 that right?

3 A. That's correct.

4 Q. Then if that didn't lead to a sufficient level, factor

5 level, you would then turn to concentrates?

6 A. Yes.

7 Q. What about DDAVP? When did you first start using

8 DDAVP?

9 A. I really can't remember. I would have started using

10 it as soon as it became a generally recognised

11 treatment for boosting Factor VIII levels in patients

12 with von Willebrand's disease and mild haemophilia.

13 But I can't remember when that was.

14 Q. Can you recall whether you had any experience of using

15 DDAVP at St Thomas'?

16 A. I don't.

17 Q. Was DDAVP something you also had to obtain from

18 Tooting or was that something that would be held in

19 stock at Frimley Park?

20 A. It would be held in the hospital pharmacy at

21 Frimley Park.

22 Q. Then, in terms of patients who were previously

23 untreated or minimally treated patients, was there any

24 particular policy or approach that you had in relation

25 to such patients who you were seeing for the first

27

1 talking here about 1980 through to 1985.

2 A. I don't remember a patient who was a severe

3 haemophiliac coming in with a bleeding disorder,

4 bleeding problem, because as far as I can remember --

5 no, sorry, we would have had some.

6 I'm just trying to think. Most -- those with

7 a severe bleeding disorder would have a programme for

8 treatment from their main centre. So we would have

9 some information saying what number of units of what

10 product were normally given for that patient if they

11 had a bleed and, therefore, we would endeavour to get

12 what was written down as the programme of treatment

13 for them.

14 Q. So is this right, in the case of a severe treatment

15 you wouldn't usually be taking a decision yourself as

16 to what treatment they required, you would be

17 following the treatment mapped out by the reference

18 centre?

19 A. Yes, as far as I can remember.

20 Q. So -- dealing here with haemophilia A for current

21 purposes -- those patients in respect of whom you were

22 taking a decision would ordinarily be mild or perhaps

23 moderate haemophilia A patients?

24 A. Yes.

25 Q. You have said in your statement that cryoprecipitate

26

1 time?

2 A. As far as I can remember, I would treat them with

3 cryoprecipitate. Obviously, if they were mild or

4 moderate, once I started using DDAVP I would use DDAVP

5 first.

6 Q. What was your understanding, in the first half of the

7 1980s, of the relative risks of commercial

8 concentrates and NHS concentrates?

9 A. My view was that NHS concentrates were safer to use

10 because they came from volunteer donors as opposed to

11 paid donors.

12 Q. And what was --

13 A. That was with respect really, to begin with, to

14 hepatitis, and it was only in about '83/'84 that I had

15 any knowledge of transmission of HIV through blood

16 products.

17 Q. What about your understanding of the relative risks of

18 cryoprecipitate versus concentrate?

19 A. Cryoprecipitate had fewer risks of transmitting

20 viruses because each pack was made from an individual

21 donor; so you weren't exposing a patient to a large

22 pool of donors.

23 Q. Now, if we come on specifically to the question of

24 hepatitis, you worked in a very junior capacity in

25 1971 under Dame Sheila Sherlock at the liver unit at

28

1 the Royal Free. What, if anything, can you recall
2 learning about hepatitis during that period?

3 **A.** There were patients whose chronic liver disease was
4 a result of hepatitis B, and you could diagnose that
5 because there were tests for hepatitis B. There were
6 other patients who had hepatitis, chronic active
7 hepatitis or cirrhosis, for which no causative agent
8 could be identified. Some of those were thought to be
9 autoimmune and some of them were thought to be
10 possibly due to a viral agent as yet unidentified.

11 **Q.** Do you recall knowing at that time or, indeed, at any
12 later stage in the 70s about the various outbreaks of
13 hepatitis that occurred at hospitals in which
14 significant numbers of patients became ill and indeed
15 some medical staff died? There was an outbreak in
16 Edinburgh, there was an outbreak in Guy's Hospital and
17 some elsewhere. Do you remember learning about those?

18 **A.** No, I don't.

19 **Q.** During the time you were at St Thomas' you worked
20 under Professor Ingram and Dr Savidge I think?

21 **A.** Yes.

22 **Q.** What can you recall, if anything, of them teaching you
23 about hepatitis, the risks of transmission and the
24 potential seriousness of hepatitis?

25 **A.** I can't remember having any specific teaching about

29

1 come from and how did your understanding of non-A,
2 non-B hepatitis develop?

3 **A.** I think it probably mainly came from attendance at the
4 Haemophilia Centre Directors' Organisation's meetings
5 and the minutes from those. And, I mean, I did attend
6 haematology conferences and I could have picked up
7 information there as well.

8 **Q.** Just dealing with hepatitis B for a moment, was
9 hepatitis B testing of patients with haemophilia or
10 other bleeding disorders undertaken at Frimley Park or
11 did you rely upon the reference centres for that?

12 **A.** I usually relied upon the reference centres for that.
13 But if there was no record of whether a patient had
14 been tested for hepatitis B, then I would arrange for
15 a blood test.

16 **Q.** Again, dealing specifically for present purposes with
17 hepatitis B, would you tell the patient that you were
18 testing them for hepatitis B?

19 **A.** Yes, I usually told my patients what I was taking
20 blood samples for.

21 **Q.** Would you tell patients the results of the hepatitis B
22 test?

23 **A.** Yes, I would definitely tell them the results.

24 **Q.** But then returning to non-A, non-B hepatitis, do you
25 think at the time you took up your post in 1980 that

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1 that. My recollection of working with them was mainly
2 learning about the different types of bleeding
3 disorders and how to manage haemophilia patients if
4 they presented with a bleeding problem.

5 **Q.** Did you, however, become aware during the period you
6 were working at St Thomas', if you weren't already
7 aware of it, of what was by now referred to as non-A,
8 non-B hepatitis?

9 **A.** I don't remember learning about that until when I took
10 up my consultant post, but I might have -- it's such
11 a long time ago I really can't remember.

12 **Q.** Was it something that was studied as part of the
13 MRCPPath qualification when you took the exam in 1979?

14 **A.** No, I don't remember us having to study anything about
15 hepatitis.

16 **Q.** The Inquiry has looked at and heard from clinicians
17 about the significance of research carried out under
18 Professor Preston in Sheffield, published in The
19 Lancet in 1978, liver biopsies undertaken and results
20 of those liver biopsies. Do you recall learning about
21 that at all?

22 **A.** No.

23 **Q.** You've said in your statement that you understood at
24 a point in time that non-A, non-B hepatitis was more
25 severe than hepatitis B. Where did that understanding

30

1 you at least knew that blood or blood products could
2 transmit a form of hepatitis, non-A, non-B or whatever
3 one might want to call it, as well as hepatitis B?

4 **A.** I don't know. I mean, I know I knew about it by 1984
5 but I don't know exactly when I gained that knowledge.

6 **Q.** Was it ever your understanding that non-A, non-B
7 hepatitis was something mild or harmless or
8 inconsequential, or whatever it was that you
9 understood existed did you always understand it to
10 have potentially severe consequences?

11 **A.** Yes, I understood that it could cause chronic liver
12 disease.

13 **Q.** Do you accept that, as a matter of principle, patients
14 receiving a form of treatment which could infect them
15 with a virus that could lead to chronic liver disease
16 should be informed about that in advance so that they
17 could decide for themselves if that was a risk they
18 wanted to take?

19 **A.** It's very difficult looking back to the early 1980s
20 when things were very different. Obviously nowadays
21 one would tell patients that. I do not -- as I said,
22 all my patients were registered at a main centre,
23 which had the support of haemophilia nurses and other
24 staff, and in my view it was their responsibility to
25 have those sorts of discussions with the patients that

32

1 they were looking after.

2 **Q.** Before I ask you a little more about that, can I just

3 go back to my earlier question. Whether it was the

4 responsibility of the reference centre or your

5 responsibility, do you accept that even in the first

6 half of the 1980s, as opposed to the 21st century,

7 patients should have been given some information about

8 the risks of their treatment, including the

9 possibility of developing hepatitis?

10 **A.** Yes, they should have done. I think most

11 haemophiliacs were aware of the problems associated

12 with hepatitis.

13 **Q.** Severe haemophiliacs might have some understanding.

14 It would perhaps depend upon what they were told,

15 whether they were a member of The Haemophilia Society.

16 Most of the patients you were seeing, you told us,

17 were mild or moderate haemophiliacs. What's the

18 factual basis for your view that they would have an

19 understanding of hepatitis if you never discussed that

20 with them?

21 **A.** I don't know whether they would have had knowledge of

22 it or not. I didn't -- I don't remember discussing

23 with a patient that my treatment might transmit

24 hepatitis. A lot of the patients I had, even if they

25 were mild or moderate haemophiliacs, were already

33

1 about the risks of non-A, non-B hepatitis.

2 Did you ever ask either the patient or the

3 reference centre what information they provided to the

4 patient so that you could know whether your assumption

5 was correct or not?

6 **A.** No, I didn't.

7 **Q.** Do you accept, at least with the benefit of hindsight,

8 that the practice you're describing ran the risk that

9 patients were receiving treatment in circumstances

10 where the potential risks of that treatment had not

11 been explained to them?

12 **A.** Yes, that is eminently possible. On the other side of

13 the coin, if it was a severe bleed that could lead to

14 disability or death, one would want to go ahead and

15 treat the patient.

16 **Q.** It's still the patient's decision, though. It may

17 well be that a patient facing very severe consequences

18 of the kind you describe would choose to go ahead with

19 the treatment, but it's still, as a matter of

20 principle, their decision as to what risks to run.

21 Would you accept that?

22 **A.** It is their decision and we would take that very

23 seriously nowadays but attitudes in the early 1980s

24 were considerably different from the attitudes today.

25 Medicine was a lot more paternalistic and patients

35

1 hepatitis B positive when I saw them for the first

2 time, as a result of having received treatment for

3 things like dental extractions in the past.

4 **Q.** You've said in your statement, and you told us a few

5 moments ago, that it was your view that it was the

6 responsibility of the patient's reference centre to

7 have had discussions with the patient about matters

8 such as risks of hepatitis. Why was that your view?

9 If you're the treating clinician, isn't it your

10 responsibility to ensure that your patient is giving

11 proper consent to the treatment, and that involves

12 them understanding the risks of that treatment?

13 **A.** A lot of the treatment -- well, yes, the treatment

14 that I was giving was usually in an emergency

15 situation. It was often administered by a senior

16 house officer. A lot of this would have been

17 out-of-hours and I would have been at home. I didn't

18 have the support of a haemophilia nurse who would, as

19 I understand it -- at the main centres would have

20 these sorts of discussions with patients before they

21 had treatment.

22 **Q.** You see, Dr Shirley, the evidence the Inquiry's heard

23 from patients treated at bigger centres, at reference

24 centres, much of it, not all but much of it, has been

25 to the effect that patients weren't given information

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1 were not given the amount of information that they

2 would be given nowadays.

3 **Q.** Do you recall whether there came a point in time in

4 the course of the 1980s or the 1990s, whenever it was,

5 where your approach changed and you did start

6 explaining to patients the risks of non-A, non-B

7 hepatitis?

8 **A.** By the time I was fully aware of the risks,

9 heat-treated Factor VIII was becoming available, and

10 where at all possible I was putting patients into the

11 8Y trial so that I could make sure that they were

12 getting heat-treated product.

13 **Q.** Does that mean that you didn't tell them of the risks

14 because you thought that the product, the heat-treated

15 8Y product, wouldn't give rise to a risk of hepatitis?

16 **A.** I would tell those patients that I was checking their

17 liver function tests on a regular basis to find out

18 whether the product was transmitting non-A, non-B

19 hepatitis.

20 **Q.** And did you tell them by this time, so we're talking

21 1985, 1986 --

22 **A.** 1985.

23 **Q.** Did you give them some information about what non-A,

24 non-B hepatitis was and that it could lead to,

25 potentially lead to chronic liver disease?

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1 A. I can't remember because I haven't had access to the
 2 trial protocol and what patient information was
 3 attached to that protocol. I would have followed the
 4 guidelines in the protocol.
 5 Q. Do you accept, as a matter of principle --
 6 I appreciate that I'm asking you about events a long
 7 time ago -- but do you accept that, as a matter of
 8 principle, whatever the protocol said, and it may
 9 indeed have said precisely this, patients receiving
 10 those heat-treated products 8Y should be told about
 11 non-A, non-B hepatitis and, if it was transmitted to
 12 them, what it could entail?
 13 A. It's very difficult because, as I said, things were
 14 very different in the early -- in the 1980s, compared
 15 to how they are today, and people's attitudes were
 16 different and we didn't tell patients nearly as much
 17 about the risks of treatment as we would nowadays.
 18 So, yes, nowadays I accept that, as a matter of
 19 principle, that is the correct thing to do but I can't
 20 say that in the 1980s it would have been considered
 21 the correct thing to do as a matter of principle then.
 22 SIR BRIAN LANGSTAFF: May I ask a question? You've said
 23 that when you spoke to patients about their
 24 participation in the 8Y trial, you said you were
 25 taking liver function tests to see if the 8Y gave them

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1 back to the protocol for the trial, would it?
 2 A. No, no.
 3 SIR BRIAN LANGSTAFF: Thank you.
 4 MS RICHARDS: Sir, I'm going to move on to HIV and AIDS.
 5 I know we started a little late but, bearing in mind
 6 people would have been online since 10, is this
 7 a convenient moment to break?
 8 SIR BRIAN LANGSTAFF: Yes, we normally have a break
 9 shortly after 11 for half-an-hour. It allows you to
 10 take some refreshment and have a break. So we'll do
 11 that and come back at 10 to 12.
 12 So 10 to 12, please, Dr Shirley.
 13 A. Okay, thank you.
 14 SIR BRIAN LANGSTAFF: The chances are you are not going to
 15 discuss it with anyone, certainly not with Luke, but
 16 you mustn't in any event discuss your evidence with
 17 anyone at all, either the questions you have been
 18 asked or those you might think you might later be
 19 asked to give -- anything else you like, but not your
 20 evidence. I'll see you at 11.50. Thank you very
 21 much.
 22 A. Thank you, Sir Brian.
 23 (11.20 am)
 24 (A short break)
 25 (11.50 am)

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1 non-A, non-B hepatitis.
 2 A. Yes.
 3 SIR BRIAN LANGSTAFF: Did you also tell them -- did anyone
 4 say, look, why are you giving me something that could
 5 give me hepatitis, anything of that sort, or did you
 6 head that off at the pass by saying: the treatment you
 7 have already been having carried that risk anyway?
 8 A. I can't remember what sort of discussions I had with
 9 patients about the 8Y protocol at the time. I'm
 10 sorry, but I can't remember.
 11 SIR BRIAN LANGSTAFF: Just for a moment, I pictured myself
 12 sitting there, as you are consulting with me and
 13 saying "I am going to take this test to see if what
 14 I'm giving you is giving you a disease", and the
 15 questions I think I might ask, and might always have
 16 felt inclined to ask, even in the 1980s, would be,
 17 "Well, what will that do to me if I get it" or "Why
 18 are you giving me something that will give me
 19 a disease?" Do you remember any conversation at all
 20 like that?
 21 A. I don't but, as a matter of principle, if patients ask
 22 me that sort of question I would answer as frankly as
 23 I could and give them as much information as I had
 24 available.
 25 SIR BRIAN LANGSTAFF: That wouldn't require your going

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1 SIR BRIAN LANGSTAFF: Yes.
 2 MS RICHARDS: Dr Shirley, as far as you can recall, how
 3 and when did you become aware that AIDS might be
 4 transmissible by blood or blood products?
 5 A. As far as I can remember, it would have been about
 6 1983.
 7 Q. Were you aware of or did you see the reports that came
 8 from the Centers for Disease Control in July and
 9 December 1982 reporting cases of AIDS in haemophiliacs
 10 and in transfused patients?
 11 A. No.
 12 Q. Now, if we could have up on screen, please,
 13 PRSE0002410, this is an article from the New England
 14 Journal of Medicine in January 1983. It's one I think
 15 of three articles in the course of that month on this
 16 issue. This particular one is 13 January. It's
 17 called "AIDS and preventative treatment in
 18 haemophilia".
 19 If we could go to the second page please,
 20 Soumik, and zoom in on the last paragraph on the
 21 left-hand column -- so the bottom of the left-hand
 22 column. You will see here the author says this:
 23 "The fact that haemophiliacs are at risk for
 24 AIDS is becoming clear. If the use of cryoprecipitate
 25 will minimise this risk, the current home-infusion

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1 programme needs to be revised."
 2 Then it talks about the data being consistent
 3 with a greater potential for AIDS in the population
 4 treated with concentrate.
 5 "Physicians involved in the care of
 6 haemophiliacs must now be alert to this risk.
 7 Preventing the complications of the present treatment
 8 may have to take precedence over preventing the
 9 complications of haemophilia itself."
 10 Do you recall whether you saw this at the time
 11 in January 1983 or later in the course of 1983?
 12 A. I wouldn't have done because I didn't read that
 13 journal.
 14 Q. There were various reports in the ordinary media,
 15 I think New Scientist in January and February 1983, of
 16 concerns about AIDS and possible risks to
 17 haemophiliacs. I won't take you to the details of
 18 them but do you recall whether you saw any of those in
 19 early '83?
 20 A. I don't remember.
 21 Q. Soumik, could we then go to HCDO0000517_001.
 22 Now, this is a letter sent out by UKHCDO. It's
 23 from Dr Craske, Dr Rizza and Dr Bloom, sent as far as
 24 we understand to all Haemophilia Centre Directors,
 25 dated 22 March 1983, about AIDS, and it refers -- it

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1 Do you recall receiving this letter with its
 2 enclosures in March of 1983, Dr Shirley?
 3 A. No, I don't.
 4 Q. If you did receive it, and, as I say, our
 5 understanding is the intention was it was sent to all
 6 directors, would you have read it at the time?
 7 A. Yes.
 8 Q. Is it possible that this was the basis for your
 9 developing understanding of the risks of AIDS from
 10 blood products in the course of 1983?
 11 A. Probably.
 12 Q. If we then go, please, Soumik, to HCDO0000270_004,
 13 you'll see, Dr Shirley, this is a letter dated
 14 24 June 1983. If we go to the second page, we can see
 15 it's authored by Professor Bloom and Dr Rizza.
 16 Go back to the first page, please.
 17 It's headed "[AIDS]". It refers to a meeting
 18 of Reference Centre Directors held on 13 May 1983 "to
 19 discuss this problem in haemophilia, its implications
 20 and our recommendations". It refers to one possible
 21 case having been reported. Then it says this:
 22 "At the above mentioned meeting on May 13th the
 23 following general recommendations were agreed.
 24 "1. For mildly affected patients with
 25 haemophilia A or von Willebrand's disease and minor

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1 circulates papers and refers to setting up of a system
 2 for the reporting of possible cases.
 3 If we go to HCDO0000517_002, please, Soumik,
 4 this is a report we understand to have been circulated
 5 with that letter, Dr Shirley. It's from Dr Craske
 6 dated 1 March 1983. And we can see it provides
 7 information about cases of AIDS.
 8 If we go to the second page, we can see towards
 9 the middle of the page it provides information about
 10 high mortality rates. And then, if we go to the third
 11 page, please, Soumik, we can see under the heading
 12 "Aetiology" there's a discussion about theories that
 13 have been advanced. The first is drugs, and that's
 14 discounted. The second is the immuno-suppressive
 15 effect of cytomegalovirus, and Dr Craske says that
 16 seems unlikely.
 17 Then if we go over the page reason 3 is "an
 18 infectious agent with a similar epidemiology to that
 19 of hepatitis B", and Dr Craske goes on to say in the
 20 following paragraph:
 21 "If (3) is the most likely cause, then it is
 22 possible that such an agent might be present in the
 23 plasma pools used to prepare commercial Factor VIII
 24 and IX concentrate manufactured from donor plasma
 25 collected in the USA."

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1 legions, treatment with DDAVP should be considered.
 2 Because of the increased risk of transmitting
 3 hepatitis by means of large pool concentrates in such
 4 patients, this is in any case the usual practice of
 5 many Directors.
 6 "2. For treatment of children and mildly
 7 affected patients or patients unexposed to imported
 8 concentrates many Directors already reserve supplies
 9 of NHS concentrates (cryoprecipitate or freeze-dried)
 10 and it would be circumspect to continue this policy.
 11 "It was agreed that there is as yet
 12 insufficient evidence to warrant restriction of the
 13 use of imported concentrates in other patients in view
 14 of the immense benefits of therapy but the situation
 15 will be constantly reviewed."
 16 Then it goes on to make some of further points.
 17 Now, again, our understanding is this was sent
 18 to all directors. Do you recall receiving it?
 19 A. I don't.
 20 Q. If it was received, would you have read it?
 21 A. Yes.
 22 Q. Now, if we look at paragraph 1, you'll see there that
 23 the recommendation is to consider DDAVP for mildly
 24 affected patients with haemophilia A or for patients
 25 with von Willebrand's disease.

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

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

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

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

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1 that directors might have had.
 2 Do you recall anything about any discussions
 3 you had in relation to AIDS at that meeting?
 4 **A.** No, I don't. It was such a long time ago and, as I've
 5 said before, the haemophilia side was a small
 6 proportion of my workload and to be able to remember
 7 what discussions I had at meetings 40 years ago is
 8 impossible, I'm afraid.
 9 **Q.** Did you take any proactive steps in the course of 1983
 10 or 1984 to keep up-to-date with developments about the
 11 risks of AIDS, for what may have been a very small
 12 number of your patients but was nonetheless the risk
 13 of a very serious, probably fatal, illness?
 14 **A.** I don't remember taking any proactive steps to keep
 15 up-to-date. Obviously, I would have had the
 16 information from the Haemophilia Centre Directors
 17 Organisation meetings and minutes and I'm sure, at
 18 that time, that at meetings of the Royal College of
 19 Pathologists or the British Society for Haematologists
 20 this is a subject that would have been discussed, and
 21 I attended those meetings whenever I could.
 22 **Q.** But you don't recall anything about any particular --
 23 the content of any particular discussions?
 24 **A.** No, I'm sorry, I don't.
 25 **Q.** If we then go to HCDO0000394_117, please, Soumik.

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1 Reference Centre Directors and not privy to the
 2 internal discussions going on within UKHCDO?
 3 **A.** Yes, it should have been. To be honest, until what
 4 you've just said, I didn't know that a whole cohort of
 5 patients had been infected from a Scottish blood
 6 product. This is the first I've heard of it.
 7 **Q.** Did Dr Savidge, Dr Rizza or Dr Kernoff, or any of
 8 their colleagues at the three reference centres with
 9 whom you had dealings, Oxford, St Thomas', Royal Free,
 10 did they at any time in December 1984 or early
 11 January 1985, after this meeting, make contact with
 12 you, who -- you were dealing with some of their
 13 patients, to pass on to you what had been discussed at
 14 this meeting?
 15 **A.** No, I don't think so.
 16 **Q.** If we look at HCDO0000270_007, this is the document
 17 that was produced following the meeting on
 18 10 December. It's called "AIDS Advisory Document"
 19 and, as you know, it's dated 14 December 1984. Do
 20 I understand correctly that this is a document which
 21 you did receive but you don't think you received it
 22 before Christmas 1984?
 23 **A.** I can't say definitely that I did receive this
 24 document but I can't imagine that I did not receive
 25 it. I think it very unlikely that I would have

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1 These are notes of a meeting of the Reference Centre
 2 Directors at Elstree on 10 December 1984, and we can
 3 see that those attending included Dr Kernoff from the
 4 Royal Free, Dr Rizza from Oxford, Dr Savidge from
 5 St Thomas'; so three of the reference centres that you
 6 had dealings with.
 7 Were you aware that such a meeting was taking
 8 place?
 9 **A.** No, I wouldn't have been aware, unless it had been
 10 mentioned in the previous minutes of the general
 11 meeting of the directors.
 12 **Q.** Were you aware that by this time, by 10 December 1984,
 13 it was known that patients in Edinburgh treated with
 14 NHS concentrate had been tested positive for HTLV-III?
 15 **A.** I think the only thing I was aware of at that time was
 16 that the vast majority of haemophilia patients who had
 17 become positive for HIV had received commercial
 18 factor, but that there were one or two patients in the
 19 country who had seroconverted after receiving NHS
 20 factor.
 21 **Q.** Do you consider that the fact that a whole cohort of
 22 patients in Scotland had been infected as a result of,
 23 or seemingly as a result of, treatment with Scottish
 24 NHS product, that that should have been immediately
 25 notified to directors such as yourself, who were not

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1 received it before January 1984, given the fact that
 2 it would have been put in the post and then we're
 3 looking at Christmas and New Year. So it's unlikely
 4 that I would have read it until January.
 5 **SIR BRIAN LANGSTAFF:** Just a point about dating, I think
 6 you mean January 1985.
 7 **A.** Yes, sorry, I do. It's January 1985.
 8 **SIR BRIAN LANGSTAFF:** While on dating, if I may just raise
 9 one point in case I've misunderstood, you mentioned
 10 the knowledge of the Edinburgh outbreak. It didn't
 11 break in the press until 20 December.
 12 **MS RICHARDS:** That's right.
 13 **SIR BRIAN LANGSTAFF:** Just so that I make sure I've got
 14 that right. There was no other way of knowing of it
 15 except by the internal grapevine presumably.
 16 **MS RICHARDS:** Presumably. We explored obviously with
 17 Professor Ludlam in his evidence in December when he
 18 became aware, late October/early November, the
 19 meetings and discussions that took place, and then we
 20 have the meeting on 10 December.
 21 **SIR BRIAN LANGSTAFF:** Yes, he knew.
 22 **MS RICHARDS:** Yes, and others knew.
 23 **SIR BRIAN LANGSTAFF:** Yes.
 24 **MS RICHARDS:** Precisely who knew is a matter that we may
 25 need to explore further but you're absolutely right,

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

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

6 **MS RICHARDS:** In Edinburgh, yes.

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

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

12 **A.** No.

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

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

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

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

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

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1 commercial."

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

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

10 **Q.** I think you mean 1985?

11 **A.** Oh, '85, yes. Sorry.

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

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

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

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

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

5 "2. Single donor cryo or FFP.

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

8 "4. Unheated UK concentrate.

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

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

15 "1. Concentrate still needed ...

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

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

19 "3. For Haemophilia A needing blood products

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

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

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

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

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

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

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

18 **A.** I don't recall telling patients that.

19 **Q.** Do you accept that was wrong?

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

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

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

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

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

15 **A.** Yes.

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

24 Can you recall whether at this time, in early
25 1985, you were only using heat-treated concentrate

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

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

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

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

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

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

25 **A.** Yes.

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

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

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

7 **SIR BRIAN LANGSTAFF:** Yes, of course.

8 **A.** Thank you. *(Pause)*

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

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

13 **A.** Thank you.

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

20 **A.** Yes, yes.

21 **SIR BRIAN LANGSTAFF:** Thank you.

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

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

3 **A.** Oh, yes, fine. Thank you.

4 **Q.** It's the second paragraph there:

5 "The physician should assess and record ..."

6 **A.** Right, okay, thank you.

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

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

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

17 **A.** Yes.

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

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

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1 I know, the 8Y trial we were only taking samples for
 2 liver function tests.
 3 **Q.** For the sake of completeness, I don't think it answers
 4 what you don't know, Dr Shirley, but we'll just look
 5 at BPLL0006186_002.
 6 So this is an internal memo dated
 7 10 March 1986. I'm not suggesting you would have seen
 8 it at the time, Dr Shirley, but it's recorded as an
 9 "Interim report on surveillance for [non A, non B
 10 hepatitis] after first infusions of 8Y and 9A into
 11 deficient patients", and it says in the first
 12 paragraph:
 13 "This is an interim collation of data kindly
 14 provided by Dr Rizza, Dr Colvin, Dr Kernoff, Dr Hill,
 15 Dr Daly [et cetera, et cetera] and Dr Shirley."
 16 So you did supply data about your patients and
 17 whether there was any indication that they were
 18 developing non-A, non-B hepatitis to Dr Snape as part
 19 of this study, I think?
 20 **A.** Yes, as part of the 8Y study. What I'm saying is that
 21 previous document you put up, where there were also
 22 bloods being taken for other hepatitis viruses and
 23 HTLV-III, I wasn't aware that the 8Y trial took those
 24 other blood samples, so I can't say whether that
 25 previous document referred to the 8Y trial or to

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1 you some questions about it, hopefully without going
 2 to too many of the underlying documents.
 3 If you need to see any of the underlying
 4 documents, Dr Shirley, please indicate, because we do
 5 have them available.
 6 This was a patient registered with Oxford
 7 Haemophilia Centre as their main reference centre; is
 8 that right?
 9 **A.** That's correct.
 10 **Q.** And it was a patient with mild haemophilia A who'd had
 11 treatment on only three occasions between 1968 and
 12 1971, so they were -- he was a patient who had been
 13 minimally treated?
 14 **A.** There was a question over what level of haemophilia he
 15 had because his Factor VIII levels, as measured in the
 16 laboratory, tended to be lower than one would expect
 17 from his clinical course. So he was actually thought
 18 to be a moderate haemophiliac, not a mild
 19 haemophiliac.
 20 **Q.** The --
 21 **A.** I would like to say at this point that I have always
 22 remembered this patient because I have always felt
 23 very sorry and guilty about the fact that he developed
 24 HIV as a result of the treatment that I gave him.
 25 **Q.** Thank you.

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1 something else.
 2 **Q.** I understand.
 3 We can take that down, thank you, Soumik.
 4 Now in your statement you say you recall only
 5 one patient at Frimley Park being infected with HIV
 6 but you say that there could have been others who were
 7 diagnosed at their reference centre. Just so that
 8 I understand that correctly, we'll come on to the one
 9 patient who you know was infected in a few moments,
 10 you can't, as I understand it, exclude the possibility
 11 that patients were infected with HIV as a result of
 12 their treatment at Frimley Park but whose diagnosis
 13 was picked up by their reference centre rather than by
 14 you. Is that correct?
 15 **A.** I only know of one patient that was infected by the
 16 treatment I gave at Frimley Park Hospital. There are
 17 other patients who were sent to me from their
 18 reference centres who had already been diagnosed
 19 with HIV.
 20 **Q.** I want to ask you about that one patient, who I'm
 21 going to refer to for reasons I know you understand as
 22 Mr AJ. I'm not going to go through every aspect of
 23 his care and treatment and you have provided a witness
 24 statement in response to Mrs AJ's statement which
 25 deals with a number of matters, but I do want to ask

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1 This was a patient who presented at
 2 Frimley Park on 17 December 1984 and the significance
 3 of that date is obvious. It's a week after the
 4 meeting at BPL we've been looking at. It post-dates
 5 at least the date of the draft of the AIDS advisory
 6 document. Is this right, he was treated, first of
 7 all, with cryoprecipitate and then over the following
 8 days treated with concentrates, not commercial
 9 concentrates, NHS concentrates, on several occasions?
 10 **A.** That's correct.
 11 **Q.** Is the fact that he was treated with NHS concentrates,
 12 rather than commercial concentrates, anything other
 13 than the luck of the draw of Tooting, so to speak, or
 14 the bad luck of the draw of Tooting, that's what
 15 Tooting sent, or was there a conscious decision on
 16 your part by December 1984 not to use commercial
 17 concentrates?
 18 **A.** I think I probably was trying to avoid using
 19 commercial concentrates because of the much higher
 20 number of patients that were infected with HIV as
 21 a result.
 22 **Q.** The records suggest that he was treated with more than
 23 one batch and that the batches included, as well as
 24 BPL products, a Scottish product. Do you know why
 25 that was the case? Was it common to receive Scottish

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1 products from Tooting?

2 A. I don't remember receiving Scottish products from

3 Tooting. As far as I remember, we generally got BPL

4 products. With regard to the batches, it was

5 a question of what we were sent from Tooting.

6 Q. Now, why was it that this patient was not treated in

7 the first instance with DDAVP, given that was the

8 recommendation from UKHCDO in June 1983?

9 A. Because for the type of bleed that he had, it was

10 known that DDAVP would not have increased his

11 Factor VIII level to what was the recommended

12 treatment level for the severe muscle bleed that he

13 had.

14 Q. When you say that was known, what's the basis for that

15 knowledge?

16 A. Well, DDAVP generally would increase the Factor VIII

17 level by a small amount. It increased the Factor VIII

18 level much better in von Willebrand patients than it

19 did in haemophilia patients and for somebody like this

20 patient, who had a Factor VIII level of somewhere

21 between 1 and 5 per cent, when you're needing to get

22 the Factor VIII level up to over 40 per cent, you're

23 not going to achieve that with DDAVP.

24 Q. Now, why having started with cryoprecipitate would you

25 not continue with cryoprecipitate for a longer period

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1 document that we looked at, the 14 December document,

2 by this time, do you think your treatment of him would

3 have been different?

4 A. Yes, I think I would have attempted to get hold of

5 heated product, heated concentrate.

6 Q. Do you agree that a system which led to you treating

7 this patient in late December 1984, in ignorance of

8 what the Reference Centre Directors had by now decided

9 was the right course, was a system in which something

10 had gone fundamentally wrong?

11 A. I think it was a system that reflected what was

12 available at the time. We didn't have the quick

13 communication possibilities that we have nowadays.

14 Q. You had -- and this is -- when I say "you", I'm not

15 talking about you specifically, Dr Shirley, but phones

16 existed.

17 A. Yes.

18 Q. Materials can be sent out speedily by post, they don't

19 have to wait around for days. There are means of

20 communicating albeit not with the same instantaneous

21 ability that we may have nowadays. Do you think that

22 the Reference Centre Directors should have done more

23 to ensure that directors such as yourself were better

24 informed as soon as they knew of the greater risk from

25 NHS concentrates?

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1 of time, given that it was safer product in terms of

2 the risks of viral transmission?

3 A. It was because the Factor VIII levels that were being

4 achieved with cryoprecipitate weren't reaching the

5 level recommended for the treatment of his severe

6 muscle bleed, and if the bleed wasn't stopped, then

7 there was a very high risk of permanent disability.

8 Q. Given that you knew by this time at least of the risk

9 of AIDS associated with concentrates, albeit that your

10 understanding was that the risk was more greatly

11 associated with commercial concentrates, did it not

12 occur to you to contact Dr Rizza, as the consultant at

13 the reference centre where the patient was registered,

14 to seek any kind of advice?

15 A. No, I didn't. I was going by the guidelines in the

16 Haemophilia Centre Directors Handbook, and my

17 understanding was that there was a very low risk of

18 contracting HIV from Factor VIII concentrates and NHS

19 Factor VIII concentrates.

20 Q. Did you tell this patient of the possible risk of AIDS

21 from the receipt of concentrates?

22 A. No, I didn't.

23 Q. Do you think you should have done?

24 A. In hindsight, yes, I think I should have done.

25 Q. If you had been in receipt of the AIDS advisory

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1 A. Yes, I think they should have. Obviously, they sent

2 round the AIDS advisory document. It was drafted on

3 14 December. Whether it went into the post that day,

4 I don't know. It was a Friday. The earliest I could

5 possibly have got it would have been the Monday, and

6 it might have been later because of Christmas post,

7 and then it would have to go through the hospital

8 postal system to get to my desk. So for most of --

9 most documents sent by post there would be a two or

10 three-day delay before I had them on my desk.

11 Q. Now as a result of that treatment this patient was

12 infected with HIV, and I'm going to ask you to look at

13 one document from his records. It's WITN3901013.

14 I think that's right, sorry.

15 We can see it's a letter dated 6 August 1985,

16 and if we look at the fourth paragraph, please,

17 Soumik:

18 "He has had no symptoms of a recent flu-like

19 illness and we are slightly concerned that this may be

20 in relation to some viral infection."

21 That refers to the findings set out earlier in

22 the letter:

23 "We must however, also keep in mind the

24 possibility of the HTLV-III virus being present in

25 this gentleman and causing this problem. We have

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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

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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:

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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

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"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

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1 a matter of principle, rather than relating to the
2 specifics of the case -- could have passed on
3 an infection to their partner?
4 **A.** I can't -- I suspect part of it may have been that
5 I didn't really know an awful lot about HIV because it
6 wasn't something that I came across very often. I had
7 a very busy out-patient clinic. It was difficult to
8 fit in patients at short notice. There wasn't
9 a specific haemophilia clinic. I saw the haemophilia
10 patients in the same clinic as I saw all the other
11 haematology patients.

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

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

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

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1 patients?
2 **A.** Yes. Sorry, can I just go back to the HIV?
3 **Q.** Yes, of course.
4 **A.** With regard to testing and counselling patients,
5 I worked closely with the consultant microbiologist,
6 and I was guided to quite a large extent by what she
7 recommended for the testing of patients who might have
8 HIV.
9 **Q.** Just to return then to hepatitis C, do we correctly
10 understand from these documents that in early 1991 you
11 were routinely testing your patients for hepatitis C,
12 a test now, by that time, being available?
13 **A.** Yes, I think the Haemophilia Centre Directors
14 Organisation was asking all the Haemophilia Centre
15 Directors to do this.
16 **Q.** As far as you can recall, were you arranging for all
17 of your patients to be tested, all of your haemophilia
18 bleeding disorder patients to be tested for
19 hepatitis C?
20 **A.** Those that had no record of having been tested.
21 **Q.** Was that undertaken with the advance knowledge and
22 consent of the patient?
23 **A.** I -- again, it's not something that I can remember
24 but, I mean, I usually told them at their
25 out-patient's attendance what we were taking -- what

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1 **Q.** When a test for hepatitis C became available, you
2 were, I think, involved in arranging for your patients
3 to be tested. We can see, if we look at a couple of
4 documents, HCDO0000119_051, this is a letter, it's
5 between the Public Health Laboratory Service and
6 Colindale and Ms Spooner at Oxford, but it says:
7 "I gather Dr Shirley is presently routinely
8 screening her haemophiliac patients for anti-HCV."
9 Then if we look at another document,
10 HCDO0000119_053, we can see this is what triggered the
11 letter. You have sent hepatitis survey reports for
12 patients who tested hepatitis C antibody positive to
13 Oxford, and if go over the page, just by way of
14 example -- we don't need to look at all the details --
15 we can see there a patient, if we look at the top of
16 the page, a few lines down:

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

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

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

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1 tests we were taking their blood samples for.
2 **Q.** Did you have any involvement thereafter with the
3 treatment of any of your patients for hepatitis C, for
4 example with interferon?
5 **A.** No, I didn't.
6 **Q.** Were there arrangements in place for referrals to
7 liver specialists for patients who were infected with
8 hepatitis C?
9 **A.** Not at Frimley Park, not for my haemophilia patients.
10 I would have told their main centre what the result
11 was, and I would have expected them to do the
12 referrals because they had the facilities in place.
13 **Q.** Do you recall anything of your involvement with the
14 hepatitis C look-back programme in the 1990s?
15 **A.** Yes.
16 **Q.** What can you tell us?
17 **A.** I remember we had to do a hepatitis C look-back and we
18 had to identify batches of product that had been used
19 for patients. So we had to go through the blood
20 transfusion records, the blood bank records, to see
21 whether any of the batches that had been identified
22 had been used for patients at Frimley Park Hospital.
23 **Q.** Do you recall whether there were many or any patients
24 identified through that process who were then tested
25 and tested positive for hepatitis C?

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1 A. I can't remember.

2 Q. Just going back to the question of risks of HTLV-III

3 AIDS and what was available by way of information and

4 guidance in 1984, you've said in your statement you

5 wish you'd been given more guidance from UKHCDO and

6 the Blood Transfusion Service about treatment and

7 products. What type of advice or guidance would you

8 as an Associate Director, with a practice ranging

9 across a wide range of haematology, as you've

10 described, what sort of advice or guidance would you

11 have found most beneficial, do you think?

12 A. I think, as far as I can remember, that December 1984

13 document was the first time that we were given any

14 guidance on what product we should use in what type of

15 patient, and I think if we had had that sort of

16 guidance issued through the 1980s, it would have

17 been -- it would have been easier for consultants to

18 know that they were giving the right treatment and

19 also, I think, it would have enabled consultants like

20 myself to put pressure on the regional Blood

21 Transfusion Services to give us certain types of

22 product.

23 MS RICHARDS: Sir, I note the time. I've pretty much come

24 to the end of my questions for Dr Shirley. If we

25 could take the lunch break now and invite recognised

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1 protocol by testing. The reason that you understood

2 the hospital was saying don't tell the patient,

3 because that's what you would normally want to do,

4 it's what you did in other cases -- you told us

5 earlier you told your patients what you were testing

6 them for.

7 A. Yes.

8 SIR BRIAN LANGSTAFF: So you want to tell the patient but

9 you don't because the hospital's view is it's going to

10 affect or might affect their insurance.

11 A. Yes.

12 SIR BRIAN LANGSTAFF: Did it ever occur to you, or, for

13 that matter, those who were in a similar position that

14 you spoke to, that insurers were very likely to know

15 that the general recommendation from the doctor's

16 organisation was that every haemophiliac should be

17 tested for HIV and, therefore, they would naturally

18 assume that, if you happen to have haemophilia, you

19 would be testing for that or tested for that

20 particular condition?

21 A. I don't think that ever crossed my mind. I didn't

22 think about what access insurers had to protocols

23 or -- it wasn't a protocol, as such, it was a request

24 that we test. It never entered my head that the

25 insurers would have had knowledge of the UK

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1 legal representatives of Core Participants to send

2 over the course of the lunch break to me and

3 Mr Boukraa any questions they would wish us to

4 consider arising out of Dr Shirley's evidence, that

5 would be useful.

6 SIR BRIAN LANGSTAFF: We will do that in a couple of

7 minutes, within which I want to ask you something

8 which arises out of the evidence you have given.

9 You were talking about being between a rock and

10 a hard place; do you remember that?

11 A. Yes.

12 SIR BRIAN LANGSTAFF: You were describing that the advice

13 that you had had from the UKHCDO was to test every

14 patient that you saw who had haemophilia and test them

15 for HIV, HTLV-III.

16 A. Yes.

17 SIR BRIAN LANGSTAFF: So this was advice that was widely

18 circulated and widely understood from the UKHCDO.

19 A. As far as I can remember.

20 Q. The policy that the hospital adopted, for anyone who

21 was given such a test was not to tell them that they

22 were being tested for HIV HTLV-III infection.

23 A. Yes.

24 SIR BRIAN LANGSTAFF: So you're following a recognised

25 protocol by not saying, you're following a recognised

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1 Haemophilia Centre Directors Organisation asking

2 Haemophilia Centre Directors to test their haemophilia

3 patients for HIV.

4 SIR BRIAN LANGSTAFF: Because there'd be no secret about

5 that advice to doctors from the UKHCDO, would there,

6 as far as you know?

7 A. As far as I know but, I mean, I don't know how many

8 people knew about the organisation.

9 SIR BRIAN LANGSTAFF: If it had occurred to you, you said,

10 right towards the end of your evidence, that in other

11 respects you might have been in a position to put

12 pressure on the local blood supply services to provide

13 different product, and you're describing the position

14 of a consultant occasionally being able to apply

15 pressure to improve services or question practices.

16 You would have been in a position, do you think, would

17 you, to have raised it with the hospital, saying,

18 "Well, surely everyone knows that if you happen to be

19 someone who suffers from haemophilia that you're

20 likely to be tested, can we have a different approach

21 here?" Something along those lines? It obviously

22 didn't occur to you but do you think it would have

23 done if you'd known, if you'd thought about it?

24 A. I did have discussions with the consultant

25 microbiologist about whether we should or should not

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

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

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

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

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

25 **SIR BRIAN LANGSTAFF:** I see. So this is really

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

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

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

13 **A.** No.

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

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

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1 a collegiate approach that you were taking?

2 **A.** I think so, yes.

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

6 **A.** Okay, thank you.

7 (1.04 pm)

8 (Luncheon Adjournment)

9 (2.05 pm)

10 **SIR BRIAN LANGSTAFF:** Yes.

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

14 **A.** Okay.

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

20 **A.** No, I don't.

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

25 **A.** No, he wasn't.

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

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

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

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

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

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1 department, to help keep up-to-date with developments,
 2 send them to conferences, send them in your place to
 3 the UKHCDO meetings you couldn't attend?
 4 **A.** I didn't have any junior staff. One SHO in general
 5 medicine was assigned to me part-time to help with the
 6 haematology clinics and haematology in-patients, but
 7 I didn't have any staff specifically assigned to me,
 8 so I couldn't have asked them to go to conferences in
 9 my stead.
 10 **Q.** Then in the course of the 1980s, was there any kind of
 11 either formal or informal auditing of associate
 12 centres such as yours by UKHCDO or by connected
 13 reference centres?
 14 **A.** No, I don't think so. And I don't remember anybody
 15 coming to audit the setup at Frimley Park Hospital.
 16 **Q.** Did any of the consultants at the reference centres
 17 that you were dealing with -- so Royal Free,
 18 St Thomas', Oxford -- did they ever actually visit
 19 Frimley Park in the 80s?
 20 **A.** No, they didn't.
 21 **Q.** Then in relation to the batches, which you would have
 22 understood by August 1985 one of those batches had led
 23 to the infection of the patient that we were
 24 discussing before lunch, Mr AJ, what, if any, steps
 25 were taken by you or, to your knowledge, others to

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1 I've got no firm proof about that.
 2 **Q.** Because you don't know what happened to any tracing
 3 exercise?
 4 **A.** Yes, that's right.
 5 **Q.** You said in your evidence before lunch that
 6 December 1984 and the AIDS advisory document was the
 7 first time you can remember guidance being given on
 8 product use. Would you accept that the June 1983
 9 letter that we looked at, which recommended directors
 10 continuing with a policy of DDAVP or reserving
 11 NHS products for certain categories of patients,
 12 was -- did you understand that to be some form of
 13 guidance on product use from UKHCDO?
 14 **A.** Yes, it was some form of guidance. And that may be
 15 why I used NHS product in Mr AJ. It may have been as
 16 a result of that that I used NHS product for him,
 17 because I knew that he hadn't had any product for
 18 a very long time.
 19 **Q.** Now, you referred at one point in your evidence to if
 20 you're giving emergency treatment that may impact upon
 21 the extent to which you would provide full and
 22 detailed information to patients about the risks of
 23 treatment. You referred also to bleeds that might
 24 lead to disability. Would you accept, first of all,
 25 that the kind of bleed that Mr AJ, the patient, was

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1 follow up those batches?
 2 **A.** I sent Dr Rizza a list of the batches of the
 3 Factor VIII concentrates that I had used in the
 4 patient, and asked for him to follow these up. And
 5 I also later -- I think I sent it to the blood
 6 transfusion authority, a list of the units of
 7 cryoprecipitate I had used on this patient, to see if
 8 any of those had been contaminated. But I was never
 9 given any information as to whether they had
 10 identified HIV contamination in any of the products
 11 I had used on this patient.
 12 **Q.** So the units of cryoprecipitate you contacted Tooting,
 13 the concentrates, Dr Rizza, and you never received an
 14 answer either from the Transfusion Service or from
 15 Oxford as to any particular batch?
 16 **A.** No, I didn't. To this day I have no idea whether what
 17 I gave the patient is what caused his HIV. I've
 18 assumed it was but I've got no proof.
 19 **Q.** Just in relation to that, you've no reason to think
 20 it's anything other than his treatment at Frimley Park
 21 that gave rise to the HTLV-III, have you?
 22 **A.** No, I haven't. I asked all the relevant lifestyle
 23 questions and the replies were negative, so the only
 24 way I can think of that he got his HIV was through the
 25 blood products that I gave him. But as I've said,

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1 experiencing, that wasn't an emergency or
 2 life-threatening situation, was it?
 3 **A.** It wasn't life-threatening but it was an emergency in
 4 as much as if he didn't receive prompt treatment it
 5 could have led to permanent disability.
 6 **Q.** But there was nothing about the circumstances in which
 7 his treatment was required that would have precluded
 8 a conversation about risks and giving the patient
 9 a choice?
 10 **A.** No, there wasn't.
 11 **Q.** To what extent were -- or what proportion of bleeds
 12 that you customarily treated in the first half of
 13 the 80s were life-threatening? Was that something
 14 that you ever came across?
 15 **A.** No, it wasn't.
 16 **Q.** You referred to the Haemophilia Centre Directors
 17 handbook in the course of your evidence, and I think
 18 there's been a request for clarification of what that
 19 is. I'm going to ask you to look at one of the
 20 documents you exhibited to your witness statement and
 21 see whether that's what you were referring to.
 22 Soumik, could we have WITN3901020. If we go to
 23 the next page, please, I'm looking -- I'm not sure
 24 what page it is but I am looking --
 25 **A.** I think you need to go back for the cover.

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

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

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

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1 UKHCDO or would you have had other sources?
2 A. No, it would have been information that I had received
3 through other sources and probably from the consultant
4 dealing with HIV at the hospital.
5 Q. Then, sorry, one additional question, Dr Shirley: when
6 communicating the HIV diagnosis to your patient, what
7 safety advice did you give, as far as you can recall,
8 if any, about reducing risks of transmission to
9 others?
10 A. I certainly talked about using a condom. I can't
11 remember what else, but I have actually noted that in
12 the patient's notes, and I gave them the booklet, the
13 DHSS booklet, on safer sex.
14 MS RICHARDS: Sir, those are the additional questions I'm
15 proposing to ask. Before I ask Dr Shirley if she has
16 anything to add, do you have further questions?
17 Questions by SIR BRIAN LANGSTAFF
18 SIR BRIAN LANGSTAFF: Yes, I do. In the light of your
19 answers about sexual transmission, I'm just looking at
20 some of my own notes because, whatever the consultant
21 in HIV knew, my understanding was that it was as early
22 as 1981/82 that the CDC became aware that there had
23 been instances of sexual transmission, including
24 marital sexual transmission between a man and a woman.
25 So that's just what surprised me, just so that you

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

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

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

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

16 **A.** Yes.

17 **SIR BRIAN LANGSTAFF:** Did your husband take a paper?

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

22 **SIR BRIAN LANGSTAFF:** Yes.

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

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1 transmission?

2 **A.** Yes.

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

7 **A.** That's correct.

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

11 **A.** That's correct.

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

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

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

21 **A.** Yes.

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

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

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

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

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

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

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

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

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

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

11 **A.** Yes.

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

17 **A.** That's correct.

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

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

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1 risk of contamination with other viruses in
 2 NHS concentrate than in commercial concentrates.
 3 **SIR BRIAN LANGSTAFF:** And sufficient, as you have told us,
 4 to make a difference in what you would actually use?
 5 **A.** Yes.
 6 **SIR BRIAN LANGSTAFF:** Or choose to use, if you had the
 7 choice.
 8 **A.** Yes.
 9 **SIR BRIAN LANGSTAFF:** Just looking --
 10 **A.** But at Frimley I often didn't have the choice.
 11 **SIR BRIAN LANGSTAFF:** No, you have said that very clearly.
 12 You relied upon what was available at Tooting.
 13 **A.** Yes.
 14 **SIR BRIAN LANGSTAFF:** Can I just ask you in relation to
 15 that, did you ever have visitors coming to the area
 16 who happened to be haemophiliacs who required product
 17 to manage their condition?
 18 **A.** We did very occasionally have a visitor who wasn't on
 19 home treatment and had a bleed and needed to have some
 20 treatment.
 21 **SIR BRIAN LANGSTAFF:** We have been told in the Inquiry
 22 that a number of people were warned by their regular
 23 doctor that if they needed to get any treatment while
 24 they were away from home on holiday, they should
 25 always make sure that they asked for and it would be

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1 haemophilia centres in London to find out if they had
 2 got that product because some of them would have got
 3 their product from other transfusion centres, such as
 4 Colindale, and so if Tooting didn't have something,
 5 they might have been able to access it from somewhere
 6 else.
 7 **SIR BRIAN LANGSTAFF:** You're not far away, I think, from
 8 the centre at Treloars.
 9 **A.** No, that's right. I mean, I don't know whether
 10 they -- I don't know what arrangements they had for
 11 having product available there. I mean, obviously,
 12 they must have had some way of storing blood product
 13 but I don't know anything about their facilities.
 14 **SIR BRIAN LANGSTAFF:** No. The reason I mention that, it's
 15 been the recollection of a couple of the witnesses who
 16 we have evidence from, who went to school at Treloars,
 17 that Dr Aronstam sometimes spoke about what was in the
 18 fridge and said, "Well, the best is the Scottish and
 19 the next best is", and so on. So, plainly, if that's
 20 right, he had a choice of what he might be able to
 21 offer the lads who were at his school or under his
 22 care.
 23 So it suggests that there was some
 24 availability, at any rate, in that location, albeit
 25 maybe supplied from Oxford, of those particular

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1 whatever concentrate they happened to be on. So if
 2 they were from Scotland, they might be advised
 3 "Whatever you do, don't have any English product have
 4 some Scottish product". We've heard examples of that.
 5 Did you have anything like that said to you do
 6 you remember?
 7 **A.** I don't remember that happening.
 8 **SIR BRIAN LANGSTAFF:** If it had been, do you think you
 9 would have been able to go to Tooting and say, "Look,
 10 I've got someone here who's been told he really ought
 11 to be on Scottish concentrate", or Armour, whatever it
 12 may be, "Can you get me some?" Do you think you could
 13 have done that?
 14 **A.** Yes, I think so. Whether Tooting would have been able
 15 to access it, I don't know, but there's no reason why
 16 I couldn't have gone to Tooting and said could they
 17 get this particular product.
 18 **SIR BRIAN LANGSTAFF:** So you wouldn't have felt it was
 19 a lost cause at the start to do that?
 20 **A.** No, no, I think I could have done that.
 21 **SIR BRIAN LANGSTAFF:** So your sense was that in particular
 22 cases they might have been able to get hold of the
 23 product you wanted.
 24 **A.** Yes. I think one of the ways they might have been
 25 able to get hold of it is to ring round some of the

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1 products. So it rather backs up what you're saying,
 2 that perhaps Tooting could have rung round and
 3 obtained what was necessary.
 4 Can I ask something slightly different: you
 5 were engaged in the study in respect of 8Y?
 6 **A.** Yes.
 7 **Q.** You did it, I suspect, because you thought it would be
 8 useful for such a study to be undertaken.
 9 **A.** That's correct. I mean, over my time as a consultant
 10 there were a few studies generally in haematology, not
 11 just in haemophilia patients, that I entered patients
 12 into because I thought it would be useful to gain the
 13 knowledge and I felt, in a way, it was my duty if
 14 I had suitable patients to enter them into trials.
 15 **SIR BRIAN LANGSTAFF:** What did you think might be the
 16 useful outcome of the 8Y study?
 17 **A.** That it didn't -- that the heat treatment prevented
 18 transmission of viruses in the 8Y product.
 19 **SIR BRIAN LANGSTAFF:** You put that in the plural: viruses.
 20 So it's not just a question of HTLV-III but a question
 21 of other viruses too?
 22 **A.** Yes. I mean, I was particularly thinking of hepatitis
 23 viruses and HIV, with respect to the heat treatment of
 24 the 8Y product.
 25 **SIR BRIAN LANGSTAFF:** Was it, do you think, more the

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

6 **A.** I think it was more the hepatitis because it was the
7 hepatitis side of things that I was asked to follow
8 up, with taking regular blood samples for liver
9 function tests from the patients who were part of the
10 8Y trial.

11 **SIR BRIAN LANGSTAFF:** So at that stage, at any rate in
12 1985, you saw it as a real benefit to the medical
13 fraternity and their patients to be able to eliminate,
14 if one possibly could, or significantly reduce the
15 amount of hepatitis non-A, non-B which was being
16 transmitted by blood and blood products?

17 **A.** Yes.

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

24 **A.** Yes.

25 **SIR BRIAN LANGSTAFF:** -- or cryoprecipitate.

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

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

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

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1 **A.** Yes.

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

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

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

24 **A.** Yes.

25 **SIR BRIAN LANGSTAFF:** Some of your evidence given earlier

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1 rather than commercial concentrate.

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

8 **A.** Yes.

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

15 **A.** Yes, it would be sensible.

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

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

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

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1 treatment, cryoprecipitate isn't working well enough,
 2 needs some concentrate, let's get enough in to cover
 3 him while he's here"; that wasn't the way it worked?
 4 **A.** Well, we didn't know how much he was going to use
 5 because he was being assessed on a daily basis as to
 6 how his symptoms were progressing and whether he
 7 needed any more concentrate, and then I felt and it
 8 was recommended that for a psoas bleed, for
 9 rehabilitation, that you should cover the first few
 10 physiotherapy sessions with Factor VIII, until you
 11 were quite certain that he wasn't going to bleed again
 12 as a result of the physiotherapy.

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

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

17 **A.** No. I mean, the cryoprecipitate didn't give him
 18 a high enough Factor VIII level in the blood so I then
 19 gave him a dose of Factor VIII, which raised the level
 20 quite substantially. I think I was giving him
 21 800 units. And then I reduced that to 500 units and
 22 that was giving an adequate response. So those were
 23 response-related, and it would have been difficult to
 24 ascertain how much overall the patient was likely to
 25 need.

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

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

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

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

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

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

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

18 **A.** Yes.

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

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

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

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

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

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

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

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

17 **A.** Mmm.

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

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

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

5 **SIR BRIAN LANGSTAFF:** Do you think you did?

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

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

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

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

25 **Further questions by MS RICHARDS**

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1 out in your witness statement, Dr Shirley:
2 "So far no patients who have only received NHS
3 concentrates had shown [HTLV-III positive] results."
4 Then he goes on to say:
5 "HTLV-III testing had only been available since
6 August 1984 and he would only give Directors reports
7 on the results when he was sure of the information."
8 Now, in terms of that sentence, or part of
9 a sentence, "So far no patients who have only received
10 NHS concentrates have shown [HTLV-III plus] results",
11 you point to it in your statement, I think, please
12 correct me if I've misunderstood, as an indication
13 reinforcing your view that NHS concentrates were safer
14 than commercial concentrates. Was that what you were
15 trying to convey in your statement?

16 **A.** Yes.

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

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1 **MS RICHARDS:** Sir, there is just one further matter
2 I wanted to ask Dr Shirley about in light of the
3 questions and answers.
4 Could we have up on screen, please,
5 BART0002269. I should say this is a document that
6 Dr Shirley herself refers to in her witness statement.
7 We can see these are the minutes of the
8 Haemophilia Centre Directors meeting from the autumn
9 of 1984, 27 September 1984. We can see the location
10 was Cardiff and you're not down as attending. Is that
11 because it would have been too far away for you to
12 attend and get back the same day?

13 **A.** Yes, that's correct.

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

16 **A.** Yes, yes.

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

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1 **A.** Yes, but it would suggest that it would be better to
2 give patients NHS concentrates than commercial
3 concentrates.
4 **Q.** But it wouldn't provide, would it, a basis for being
5 confident that NHS concentrates themselves were free
6 of risk?

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

10 **Q.** Thank you. That was the document I wanted to ask you
11 about, as you had referred to it in your statement.
12 Dr Shirley, do you have anything further that
13 you wanted to add?

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

15 **MS RICHARDS:** Sir.

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

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1 who had haemophilia in the period between 1980 and, in
 2 particular, the evidence you've given, 1986.
 3 Can I thank you for the insights you've given
 4 us into what it was like and the way in which your
 5 information and product choice was affected by others
 6 in the field, although you did have, as you accept,
 7 some responsibility yourself. It's been very valuable
 8 to listen to that and can I thank you for that and
 9 your attempting as best you can to remember back and
 10 to ask what may have seemed to you at times to be
 11 rather searching and probing questions. But thank
 12 you.
 13 **A.** Thank you. Well, I'm glad I've been of help.
 14 **SIR BRIAN LANGSTAFF:** You have.
 15 **MS RICHARDS:** Sir, that's the evidence for today and
 16 tomorrow we have Professor Collins.
 17 **SIR BRIAN LANGSTAFF:** Yes. So tomorrow at ten o'clock
 18 Professor Collins.
 19 **MS RICHARDS:** Yes.
 20 **SIR BRIAN LANGSTAFF:** Thank you very much.
 21 (2.57 pm)
 22 (Adjourned until 10.00 am the following day)
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 24
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I N D E X

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(45) treatment... - whether

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