

Wednesday, 4 November 2020

(10.05 am)

**SIR BRIAN LANGSTAFF:** Good morning, Professor Hay. Can you hear me?

**THE WITNESS:** Yes, I can, thanks.

**SIR BRIAN LANGSTAFF:** I'm sorry we're just a few minutes late starting this morning, but can I tell you what will happen? You're here. You're on a number of screens in this room, in London. You're being seen by a small audience here, and you will be followed by a much larger one out there virtually, following you, just as you are virtually connected with us. We had a couple of problems with sound yesterday on our transmission. I hope they've been sorted, but if you have any difficulties, please let us know as we go along and we'll try and resolve it as soon as we possibly can.

First of all, you'll take the oath. Mary will ask you to do that, and then you will see Ms Richards who will be asking you the questions, and occasionally you might see me if I have one to ask as well. Thank you.

**CHARLES RICHARD MORRIS HAY (affirmed)**

**Examined by MS RICHARDS**

**MS RICHARDS:** Professor Hay, can you see and hear me okay?

1

I think, the Sheffield University hospitals as they became, but you essentially rotated between Sheffield Royal Infirmary, or the Royal Hallamshire Hospital by then, and the Sheffield Children's Hospital for several years?

**A.** Effectively, with a six-month stint right at the beginning at the Blood Transfusion Centre.

**Q.** That was August 1982 to April 1983 at the Blood Transfusion Centre. Was that the centre in Sheffield?

**A.** Yes. At Longley Lane.

**Q.** And the director, was that Dr Wagstaff at that time?

**A.** Yes, it was.

**Q.** What did your role for those six months entail?

**A.** Well, this was largely a training course. I was there with another senior registrar, Dr Katie Foreman, and the pair of us spent most of our time doing laboratory practicals and rotating around the different departments of the Transfusion Centre, but we also fielded telephone enquiries with a clinical element from clinicians and labs around the region.

**Q.** Did you encounter during that period any practice of taking blood from prisons?

**A.** I think I know what you're referring to, because I mentioned in my statement that I had been told that there had been donations from prisons. By that stage,

3

**A.** Yes, I can.

**Q.** I am just going to start by asking you a handful of questions about your career. Picking it up from 1977, you were for a period of months a house physician in haematology at Sheffield Royal Infirmary. Was this your introduction to haematology?

**A.** Yes, it was.

**Q.** And then 1977, August '77 to August '78, you were a senior house physician, the Royal Hospital Sheffield. You then worked --

**A.** Yes.

**Q.** -- I think for a year as a junior medical registrar in general medicine at St Mary's in London; is that right?

**A.** Yes, correct.

**Q.** And then August '79 to August 1982, you were a junior registrar in haematology at the Northern General Hospital in Sheffield?

**A.** Yes, I was.

**Q.** That work, I think, was general haematology work, rather than specifically concerned with patients with bleeding disorders?

**A.** That's correct.

**Q.** And then you took up a post in August 1982 as a senior registrar in haematology at the -- you described,

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it had stopped. I'm not sure exactly when it had stopped. I was told this by the head of the virology department. We rotated through their virology department at one point. And he told me that they had stopped taking donations from prisons when they introduced testing for hepatitis B, and they realised that the vast majority of their positive tests were coming from the prisons, and so they recognised that prisoners were a high risk group, and they stopped taking donations from them.

Now, I was there in '82. The practice of taking donations from prisons had stopped some time before, and I can't tell you exactly when.

**Q.** But that was in relation to the local area, the Sheffield area?

**A.** Well, that region, it's quite a big region.

**Q.** Yes. And then between April 1983 and August 1984, you were in your capacity as senior registrar at the Royal Hallamshire Hospital, and your statement says you were given day-to-day responsibility for the haemophilia service under Professor Preston there.

**A.** Yes.

**Q.** Could you explain a little more in -- what in practice that day-to-day responsibility entailed?

**A.** Well, if patients with a bleeding disorder came in

4

1 with an acute bleed, I would be their first port of  
 2 call, and I also ran the follow-up clinics under  
 3 supervision from Professor Preston and consequently  
 4 Dr Mike Greaves.

5 **Q.** And did you have any involvement with the home  
 6 treatment programme during that 18-month stint?

7 **A.** Well, I guess I must have done. The patients at that  
 8 time used to come in to the hospital for -- to pick up  
 9 their home treatment and take it home. We  
 10 subsequently arranged a system whereby the Transfusion  
 11 Service would deliver it to their nearest blood bank  
 12 so that it was easier for them to pick up and they  
 13 didn't have to come all this way, because some of the  
 14 patients lived a long way from the centre. But home  
 15 delivery is a much more recent innovation.

16 **Q.** From August 1984 to April 1985, you were at the  
 17 Sheffield Children's Hospital. Was that under  
 18 Dr John Lilleyman?

19 **A.** Yes, it was.

20 **Q.** And, broadly speaking, what did that entail?

21 **A.** That -- well, that was -- it involved some thrombosis  
 22 and haemostasis, because he looked after the children  
 23 with bleeding disorders, but also involved the  
 24 management of childhood leukaemia and, at that time,  
 25 childhood solid tumours.

5

1 equally between the three of us. So I was clearly the  
 2 busiest of the three.

3 **Q.** And then December 1994, you moved from Liverpool to  
 4 Manchester as a consultant haematologist and director  
 5 of the Manchester Haemophilia Centre at the Royal  
 6 Infirmary?

7 **A.** Yes, the Manchester Adult Centre.

8 **Q.** And that's a post that you continue to occupy?

9 **A.** Yes.

10 **Q.** Then in terms of membership of relevant organisations,  
 11 you've been a member of UKHCDO since 1987, I think?

12 **A.** That's correct.

13 **Q.** And then within that, and leaving aside various  
 14 working parties which we may come on to at a later  
 15 stage, you were treasurer from 1992 to 1997, vice  
 16 chair 1997 to 2005, and chair of UKHCDO 2005 to 2011?

17 **A.** Correct.

18 **Q.** And you have been closely involved with the National  
 19 Haemophilia Database. Again, we'll come back to the  
 20 detail of that, but I understand from your statement  
 21 you've been director of that database since 2002, and  
 22 you continue to hold that post?

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

24 **Q.** And then amongst other matters, you have given written  
 25 and oral evidence to the Penrose Inquiry, and you

7

1 **Q.** Then April of 1985 to August 1986, you were back at  
 2 the Royal Hallamshire Hospital under  
 3 Professor Preston, carrying out similar duties as you  
 4 had previously; is that correct?

5 **A.** Yes.

6 **Q.** Then you returned for a further six months to  
 7 Sheffield Children's Hospital between August 1986 and  
 8 April 1987; is that right?

9 **A.** It is.

10 **Q.** And then you had a very brief stint at the Northern  
 11 General Hospital, undertaking general haematology.  
 12 I think your statement suggests that might have been  
 13 just for a few weeks --

14 **A.** Yes.

15 **Q.** -- before taking up your post in Liverpool?

16 **A.** That's correct.

17 **Q.** So May 1987, you became a consultant haematologist in  
 18 Liverpool and director of the Liverpool Haemophilia  
 19 Centre, or I think it may have become known as the  
 20 Mersey Region Haemophilia Centre; is that right?

21 **A.** Yes, it is.

22 **Q.** And you were to start with a sole consultant there?

23 **A.** Well, I was the sole consultant with responsibility  
 24 for haemophilia management. There were two other  
 25 consultants, and we shared the malignant haematology

6

1 acted as an expert witness for the defence in the  
 2 hepatitis C class litigation?

3 **A.** I did.

4 **Q.** So I'm going to ask you now some more detailed  
 5 questions about Sheffield and the Royal Hallamshire  
 6 Hospital, in particular for that first 18-month period  
 7 you were there, April '83 to August '84; an important  
 8 period for the Inquiry's terms of reference. I know,  
 9 of course, that it's a long time ago, professor, but  
 10 if you can do your best to assist us.

11 Can you describe in broad terms what the  
 12 facilities were at the Haemophilia Centre at the Royal  
 13 Hallamshire when you arrived?

14 **A.** Well, they had a world-class laboratory and were very  
 15 active in coagulation research. The facilities for  
 16 the patients were less good. Haematology was based on  
 17 ward P2. There was a clinical room on ward P2 which  
 18 was designated the Haemophilia Centre. When  
 19 I arrived, there was a weekly follow-up clinic for  
 20 patients with haemophilia, which I did. And at that  
 21 point, there were no haemophilia nurses. There was  
 22 only irregular physio input, and there was no joint  
 23 orthopaedic clinic.

24 But with the passage of time, we acquired  
 25 a haemophilia nurse specialist, and we organised joint

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1 orthopaedic clinics. And on a grace and favour basis,  
 2 we got regular physiotherapy input, so things improved  
 3 from that perspective. There was very good  
 4 secretarial support throughout that time.  
 5 **Q.** And the clinical nurse specialist, was that  
 6 Sister Joy Farnsworth?  
 7 **A.** It was.  
 8 **Q.** And she joined, I think, in around 1985?  
 9 **A.** I can't remember exactly, but that's probably right.  
 10 **Q.** You mentioned the weekly clinic. Your statement  
 11 refers to there being a weekly discussion that would  
 12 take this --  
 13 **A.** Well, I mean, if I came across a problem that was  
 14 either above my pay grade or outside my previous  
 15 experience, I'd go to either Professor Preston or  
 16 Dr Greaves for advice. But apart from that, we had  
 17 a multi-disciplinary meeting once a week before the  
 18 main ward round of the week. And that would take half  
 19 the morning, during which we would discuss difficult  
 20 cases and any policy changes. Eric would give us some  
 21 feedback from committees he might have attended, and  
 22 we would discuss the literature. It was a separate  
 23 meeting actually called the Journal Club where we went  
 24 through recent papers of interest.  
 25 **Q.** How often did the Journal Club meeting take place?

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1 a clinical overlap. The frequency of bleeding doesn't  
 2 correlate as closely with the baseline Factor VIII or  
 3 IX level as you might expect.  
 4 **Q.** And there was, at that stage, no programme of  
 5 prophylactic treatment?  
 6 **A.** No, none.  
 7 **Q.** Can I just ask you about the products that were used  
 8 for treatment at that time. We've looked at the 1983  
 9 return with Professor Preston. You've exhibited to  
 10 your statement a document -- Henry, could we have  
 11 WITN3289040.  
 12 So this is an exhibit to your statement and it  
 13 sets out products used. Is this material that you  
 14 have picked up from the National Haemophilia Database?  
 15 **A.** Yes, it is. I certainly couldn't remember all these  
 16 details.  
 17 **Q.** Okay. And we can see from it, and from, as I say, the  
 18 return that we went through with Professor Preston,  
 19 that DDAVP was in use, Professor Preston told us that  
 20 would be used routinely for mild haemophiliacs; was  
 21 that your experience?  
 22 **A.** Yes, I think -- this is one of the things I actually  
 23 remember from being a houseman because I think  
 24 I actually administered the very first dose of DDAVP  
 25 that was ever used in that department, because I can

11

1 Was that regular or ad hoc?  
 2 **A.** No, that was regular. That was once a week.  
 3 **Q.** In terms of the number of patients with the Sheffield  
 4 Haemophilia Centre, your statement tells us that --  
 5 and you, I think, ascertained this from looking at the  
 6 National Haemophilia Database -- that in 1983 there  
 7 were 166 patients who were registered with the Centre.  
 8 **A.** Yes.  
 9 **Q.** We've already touched on the Home Treatment Programme.  
 10 Was that well established and well under way by the  
 11 time you arrived in April 1983?  
 12 **A.** My impression is that Sheffield was at the forefront  
 13 of adopting home therapy. I had assumed that all the  
 14 other centres were the same. It was only as  
 15 I recently read through various minutes I realised  
 16 that some centres had been far slower to establish  
 17 home therapy. But, to be honest, most of the patients  
 18 were on home therapy even when I was a houseman in  
 19 1977. And certainly by 1983 it was more or less  
 20 universal, except for the odd patient that never took  
 21 to self-injection.  
 22 **Q.** And the patients who would have been on home therapy  
 23 were typically patients with severe haemophilia A?  
 24 **A.** Yeah, either severe haemophilia A or B, or moderate  
 25 severity with the severe phenotype. There is

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1 remember, as a houseman, the letter being published  
 2 from Mannucci, and, because of his interest in liver  
 3 disease, Eric was very keen to try this.  
 4 And he told me to administer it but he didn't  
 5 tell me how. So I just gave it as a bolus injection,  
 6 which is something you'd never do now, and the patient  
 7 went bright red and complained of a headache. It has  
 8 to be administered slowly.  
 9 So it was established in Sheffield, probably  
 10 earlier than in most haemophilia centres. Because it  
 11 unlicensed, apart from anything else.  
 12 **Q.** We can see from this list that there were --  
 13 NHS Factor VIII was used?  
 14 **A.** Yes.  
 15 **Q.** Then a range of commercial concentrates. So for 1983,  
 16 by way of example, we can see it's the Armour  
 17 Factor VIII, Hemofil and Kryobulin, and then FEIBA  
 18 presumably for those with inhibitors?  
 19 **A.** Correct.  
 20 **Q.** Was the porcine Factor VIII used solely for inhibitor  
 21 patients as well?  
 22 **A.** Yes.  
 23 **Q.** Then NHS Factor IX for patients with haemophilia B?  
 24 **A.** Correct.  
 25 **Q.** There's also reference to Autoplex. What was that

12



1 used for?

2 **A.** Autoplex was another activated prothrombin complex

3 concentrate similar to FEIBA, manufactured by

4 a different manufacturer, thought to be a little bit

5 more activated than FEIBA but used similarly for

6 inhibitor patients.

7 **Q.** Then we can see reference to cryoprecipitate, and

8 Professor Preston has already told us that

9 cryoprecipitate was only used, by that time, to

10 a limited extent.

11 For what categories of patients can you recall

12 cryoprecipitate being used in '83, '84?

13 **A.** Well, predominantly patients with von Willebrand's

14 disease. And I would also expect it might have been

15 used in people that needed very infrequent treatment.

16 **Q.** Did you have any role in deciding what products should

17 be used at the Centre?

18 **A.** No, not really.

19 **Q.** In terms of arrangements for the supply of products,

20 do you know whether the NHS concentrate was obtained

21 from the Transfusion Centre or from BPL?

22 **A.** To be honest, I can't remember.

23 **Q.** In terms of arrangements for the supply of commercial

24 concentrates, did you have any involvement in those

25 arrangements or do you know what they were?

13

1 hepatitis.

2 Now, you know, these are sort of case

3 presentations. I think it is accepted that some

4 patients certainly did, and we didn't know really

5 whether that was because they'd received concentrate

6 from a different geographical origin or just been

7 unlucky and exposed to another strain. As I'm sure

8 you know at this stage in the Inquiry, there are

9 a number of different hepatitis C genotypes but we

10 didn't know that at the time.

11 So it was felt that if you kept the patients to

12 a single brand and took some care to make sure that

13 that was the case, they might be less likely to be

14 infected for a second time. And the principle behind

15 not putting all your eggs in one basket is because all

16 of these manufacturers have interruptions of supply

17 from time to time; and if you only had one supplier,

18 you might suddenly find yourself very short of

19 Factor VIII.

20 **Q.** Do you know how it was decided which patients would

21 get NHS concentrate and which patients would receive

22 a commercial concentrate?

23 **A.** If I did know, I can't remember, to be perfectly

24 honest.

25 **Q.** Do you recall whether there were any particular

15

1 **A.** No, to both questions.

2 **Q.** And in terms of cryoprecipitate, to the extent it was

3 used, was that obtained from the Regional Transfusion

4 Centre or elsewhere?

5 **A.** It was obtained from the Regional Transfusion Centre,

6 and I would imagine that that would have been the case

7 everywhere.

8 **Q.** Now Professor Preston has told us and Professor Makris

9 has told us in a written statement that two of

10 Professor Preston's guiding principles, in terms of

11 his approach to treatment, were not to put all your

12 eggs in one basket, so to have more than one source of

13 commercial product?

14 **A.** Yeah.

15 **Q.** And to keep patients on the same treatment and same

16 batch as far as possible?

17 **A.** Yes.

18 **Q.** Does that accord with your collection?

19 **A.** Absolutely, and I think I've written exactly the same

20 thing in my statement. And to be frank, I've followed

21 that principle ever since.

22 **Q.** What did you understand, in 1983, the rationale for

23 that principle to be?

24 **A.** There was some weak epidemiological evidence that some

25 patients had had more than one episode of non-A, non-B

14

1 difficulties in terms of the supply of NHS

2 concentrate? Was there enough?

3 **A.** Well, there wasn't enough. There wasn't enough

4 nationally. And that's why, as you go through the

5 returns and the minutes of various UKHCDO committees,

6 which I've done recently, but was unaware of way back

7 then, you discover that the proportion of commercial

8 concentrate used in the late seventies and early

9 eighties was going up and up and up, because BPL could

10 not supply enough.

11 And I can remember that when I was a senior

12 registrar there, they were distributing product on

13 a pro rata basis, depending on how much plasma was

14 sent for fractionation by the local transfusion

15 centre. And I think we got about 40% -- that's my

16 recollection, anyway -- of our requirement, as BPL

17 product, on that basis.

18 And that actually, was a reflection of the fact

19 that our local Transfusion Centre sent more than

20 average to be fractionated. So that was considered

21 a good proportion. But the problem just got worse and

22 worse because if you look at the amount of Factor VIII

23 that is consumed by the patients, over the years you

24 see that over a 40, 50-year period, the amount used

25 goes up by 7% or 8% every single year until very

16



1 recently.

2 **Q.** And you've exhibited a graph taken from the 1986

3 annual report of UKHCDO.

4 Henry, it's WITN3289045.

5 We can see from this that the top line, which

6 has the circles, gives us the total amount of

7 Factor VIII concentrates used in the period that this

8 figure covers, roughly 1970 until a little bit beyond

9 1985. And then, as I understand it, the line broken

10 up by triangles shows us the amount of commercial

11 Factor VIII usage, the line which is broken up by

12 crosses shows us the NHS Factor VIII usage. And then

13 the line which has the dark squares shows us the usage

14 of cryoprecipitate. And we can see the use of

15 cryoprecipitate declining whilst the use of the

16 concentrates goes up.

17 Have I correctly understood this document --

18 **A.** Yes.

19 **Q.** -- that you have shared with us?

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

21 **Q.** We saw with Professor Preston copies of a handwritten

22 ledger which ran from 1976 to 1981. We haven't

23 burdened you with it, Professor Hay, because it's

24 before you arrived, but it's a handwritten book in

25 which patient details for every attendance are

17

1 into that ledger.

2 **Q.** And in terms of home treatment, I know the programme

3 was already well established by the time you took up

4 your post in 1983 --

5 **A.** Yes.

6 **Q.** -- but were patients on home treatment generally

7 required to keep detailed records of their usage of

8 product?

9 **A.** Um, well, they were supposed to. Compliance with that

10 was variable. There's something called Factor VIII

11 returns. They'd have to fill out a line lease on

12 a form to give details of what they'd used the product

13 for, whether they'd responded, whether there were any

14 side effects, and what they'd used, and they were

15 supposed to return those by post or bring them in when

16 they came in. And that provided useful clinical

17 information because when you're assessing the patient,

18 you'd know how often they were bleeding, which joint

19 they were bleeding into, and you could assess whether

20 they were treating themselves adequately or not,

21 because some patients were very stingy with the

22 treatment. And the actual doses that were used to

23 treat bleeds increased progressively, with an evidence

24 base. Because when we were using cryo, six bags of

25 cryo would be equivalent to, I think, one tiny little

19

1 recorded, the nature of the bleed, the particular

2 product given, and the batch number. Can you recall,

3 by the time you arrived in 1983, what, if any, system

4 there was for recording treatments and batch numbers.

5 Presumably you needed to record batch numbers because

6 you had your policy of trying to keep patients on the

7 same batch.

8 **A.** We recorded batch numbers partly for that reason, and

9 partly because if there was a specific problem with

10 a given batch, you could trace who'd had it.

11 It was very common to get allergic reactions,

12 particularly to plasma or cryoprecipitate but also, to

13 a lesser extent, to the relatively crude concentrates

14 that were being used at that time. And some batches

15 were much worse, and occasional batches were actually

16 withdrawn. And you have presented me with some

17 correspondence with Armour, that I'd long since

18 forgotten, that details how we actually withdrew the

19 small number of bottles of their product that we had

20 at one point.

21 You know, people still use ledgers like that.

22 I have a ledger like that in my Haemophilia Centre.

23 So if we send product out to a patient, we record all

24 those details in the ledger. If a patient comes in or

25 is having surgery, every dose that they get is put

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1 250-unit bottle of concentrate, which is now regarded

2 as a paediatric dose. And that's what the patients

3 were treating themselves with, and they weren't

4 getting a very good response. By the time I came

5 along in '83, the standard dose was about 500 units

6 and it crept up; today it would be 2,000 units.

7 **Q.** Now how frequent were the regular appointments at the

8 Haemophilia Centre in Royal Hallamshire? So not those

9 who were attending to outpatients with a particular

10 bleed but those patients you were seeing regularly.

11 **A.** Well, to start with, and assuming those specific

12 problems, they would be reviewed every six months.

13 When HIV came along, we reviewed the patients that we

14 knew to have HIV more frequently, particularly once

15 treatment came along, every three months. The

16 patients had open access to the service. This is

17 a universal arrangement with any Haemophilia Centre,

18 that the patients can bypass the switchboard, in

19 a sense, and phone up and speak to a doctor for

20 advice, or pop into the Haemophilia Centre when they

21 feel the need to do so.

22 **Q.** So at a typical six-month routine appointment with the

23 patient, an existing patient with severe

24 haemophilia A, could you just talk us through, to the

25 extent that you're able to, from 1983 and 1984, what

20

1 that typical appointment would entail? What kind of  
 2 discussions, what kind of tests?  
 3 **A.** Well, you would ask them about any bleeds that they'd  
 4 had, and you'd ask them how they'd treated themselves.  
 5 If they had returns, you would examine these, because  
 6 they would give, hopefully, a more accurate view of  
 7 how often they were bleeding. If you thought that  
 8 they had non-A, non-B hepatitis, you'd examine their  
 9 abdomen as well as their joints. You might discuss  
 10 that, you might arrange an ultrasound if they hadn't  
 11 had one for a while. And as time wore on, we talked  
 12 more about HIV.  
 13 **Q.** In terms of decisions about the products they would  
 14 receive by way of treatment, would your role have been  
 15 essentially just to continue the status quo or were  
 16 there occasions when you would be recommending  
 17 a change of -- or wanting to consider a change of  
 18 treatment?  
 19 **A.** Well, during that period, we -- following the  
 20 principles I've already discussed, we more or less  
 21 maintained the status quo, to be frank, until virally  
 22 attenuated products came along. There wasn't a great  
 23 deal to pick and choose between the products that we  
 24 had available to us.  
 25 We did participate in one or two studies of

21

1 supply. Sometimes companies had some technical  
 2 problem that caused supply issues, and then the  
 3 patients treated with that product had to change.  
 4 **Q.** And then, in terms of the liver function tests that  
 5 you would undertake at the routine outpatient  
 6 six-monthly appointment, '83, '84, what tests, broadly  
 7 speaking, would you undertake and what discussions  
 8 would you hold with patients about them?  
 9 **A.** Well, all of the patients were tested for the markers  
 10 of hepatitis B, and from 1982 they were all  
 11 vaccinated. We obviously didn't have a test for  
 12 non-A, non-B hepatitis at the time but we checked the  
 13 liver function tests, and these would be plainly  
 14 transaminases but basically a liver function profile,  
 15 and we checked their blood count, and probably their  
 16 electrolytes, and not a lot else. They would have an  
 17 abdominal ultrasound every couple of years.  
 18 **Q.** And if the outcome of the liver function tests gave  
 19 rise to any cause for concern, how and when would that  
 20 be communicated to the patient? Would it be at the  
 21 next six monthly appointment?  
 22 **A.** Yes, it would be at the next six-month appointment.  
 23 **Q.** And was it your routine practice to tell patients  
 24 the -- what their test results showed?  
 25 **A.** Well, as far as I recall, yes.

23

1 virally attenuated products during that time, as you  
 2 know from the publications. We tested an Armour  
 3 product, for example, and you'll have remembered the  
 4 letter to The Lancet about two patients, both of whom  
 5 became quite ill with quite severe non-A, non-B  
 6 hepatitis after administration of that product.  
 7 And then the unit also participated in the  
 8 multi-centre study of Alphanate, and I was very  
 9 peripherally involved in that, which you might guess  
 10 from the absence of my name in the list of authors.  
 11 A lot of it -- that trial actually took place when  
 12 I was out of the department, at the Children's  
 13 Hospital, but I was aware of it at the time.  
 14 **Q.** So if there needed to be a decision to change  
 15 treatment, whether it's changing to a different  
 16 concentrate or use of a heat-treated concentrate,  
 17 would that be something that you would then discuss  
 18 with Professor Preston or --  
 19 **A.** Well, to be honest, my recollection is that if there  
 20 were any changes of treatment, he would make the  
 21 decision. I mean, the decision about Alphanate, which  
 22 I expect we're coming to at some point, was entirely  
 23 his, and -- apart from that, there were very few  
 24 changes of treatment, and where they occurred, they  
 25 probably would have related to difficulties with

22

1 **Q.** We understand from other evidence -- again,  
 2 Professor Makris, Professor Preston -- that at  
 3 Sheffield there were stored blood samples, a system  
 4 which I think predated your arrival there. What, if  
 5 anything, can you tell us about that?  
 6 **A.** Well, these were plasma samples stored in the lab.  
 7 There would probably also have been samples stored  
 8 routinely in virology, because they retained samples  
 9 for three years.  
 10 **Q.** Were those samples taken at every routine appointment,  
 11 to your knowledge?  
 12 **A.** I don't think so.  
 13 **Q.** Were you, as far as you can remember, ever involved in  
 14 taking those samples for storage?  
 15 **A.** I presume I must have been.  
 16 **Q.** Can you recall what, if anything, was said to patients  
 17 about that?  
 18 **A.** No, I can't.  
 19 **Q.** In terms of providing patients with information about  
 20 non-A, non-B hepatitis, we take first of all the case  
 21 of a patient who you don't currently suspect has  
 22 non-A, non-B. What, if any, information would you  
 23 give a patient in this 1983/1984 period about the  
 24 risks of non-A, non-B from treatment with factor  
 25 concentrates?

24

1 A. Are we talking about a patient with severe  
2 haemophilia?  
3 Q. Yes.  
4 A. Well, by that stage, they'd all been treated with  
5 concentrate, and I think we would have understood  
6 that, although we couldn't quantify the risk, there  
7 was a very high risk that they'd been exposed to  
8 hepatitis C. But what we didn't know was how many of  
9 those patients would clear the virus. We now know  
10 it's about a third. So we really didn't know whether  
11 patients with normal liver function tests were viremic  
12 or not. But, you know, we would have said to them  
13 that it was a possible risk.  
14 Q. And would you have told them, and if you can remember,  
15 would you have told them, do you think, that there was  
16 a possible risk of non-A, non-B hepatitis, or would  
17 you have also told them there was a possible risk of  
18 them developing chronic or serious liver disease?  
19 A. Well, when I first went there, although there were  
20 papers in the literature that showed very high  
21 incidence of abnormal liver function tests in patients  
22 with haemophilia, all the liver biopsy studies up to  
23 that point, including Professor Preston's study of  
24 1978, tended to show very mild liver disease, and it  
25 was the consensus of opinion at that time that non-A,

25

1 assumed a much higher profile in that centre than  
2 I believed to be the case in many others.  
3 Q. Then for patients who were not severe haemophiliacs,  
4 so patients who were infrequently treated, or mild  
5 haemophiliacs, would there be any different  
6 conversation that you might have with those patients  
7 about non-A, non-B hepatitis and its risks?  
8 A. Well, however mild or not non-A, non-B hepatitis was,  
9 one didn't want to transmit it. For most of the  
10 patients with severe haemophilia, it was probably too  
11 late at that point, but patients with mild bleeding  
12 disorders required treatment infrequently, and so  
13 those patients would have been much less likely to  
14 have been already exposed to non-A, non-B hepatitis.  
15 And it was the unit policy to try to minimise any  
16 further exposure. And so those patients would have  
17 been treated with DDAVP if the patient was known to  
18 have an adequate response to it, or cryoprecipitate,  
19 or they would have had a discussion about the relative  
20 risks of non-A, non-B hepatitis.  
21 A lot of the patients who were treated for the  
22 first time with some of these agents, and particularly  
23 the trials of virally attenuated products, would have  
24 had that conversation because one of the problems of  
25 DDAVP is tachyphylaxis. That's particularly a problem

27

1 non-B hepatitis was by and large benign and  
2 non-progressive.  
3 Now, we know that that's a very poor  
4 generalisation now, but back then, that would have  
5 been the consensus. So I think the patients would  
6 have been generally reassured. But as you know from  
7 my statement, I made a clinical observation that drew  
8 that into question, and we started to biopsy our  
9 patients more extensively to find out what was  
10 happening.  
11 Q. I'll come back to possibly the consensus and the  
12 medical literature in a little while, Professor Hay,  
13 but just sticking with the information given to  
14 patients, because of the -- as I understand your  
15 evidence -- please correct me if I'm wrong -- because  
16 of your understanding that it was perceived as  
17 a relatively mild and non-progressive condition,  
18 patients, is this right, might have been told of the  
19 risk of non-A, non-B hepatitis but would have been  
20 given reassuring information that it wasn't something  
21 for them particularly to worry about?  
22 A. Well, that's right. I mean, I can't speak for other  
23 centres. One of the things I think you should  
24 recognise about the Sheffield Centre is that because  
25 of the longstanding interest in liver disease, it

26

1 with haemophilia so that each dose has 40% less  
2 response than the dose before. So the response may be  
3 adequate for a minor procedure such as a dental  
4 extraction, but if the patients are to undergo more  
5 invasive surgery, the effective DDAVP would wear off,  
6 and the patient would be exposed to an excessive  
7 bleeding risk. So they may have no alternative but to  
8 have concentrate or possibly cryo.  
9 Cryo is quite difficult for surgery because you  
10 need such huge doses. You might be giving a patient  
11 24 bags a day or more, and very soon you get into the  
12 sort of territory where they're exposed to  
13 a significant hepatitis risk anyway.  
14 Q. Now, you've mentioned already the use of heat-treated  
15 products.  
16 A. Mm-hm.  
17 Q. What more, if anything, are you able to tell us about  
18 the Centre's involvement in 1984 in those early uses  
19 of heat-treated products? Do you know how it came  
20 about, for example?  
21 A. I'm not entirely sure how it came about, but we had  
22 previously tried heat-treated Armour products, and  
23 clearly the heat treatment was inadequate to exclude  
24 non-A, non-B hepatitis. And then Alpha came along  
25 with Alpha Profile, and that needed to be tested in

28



1 a PUP study, a Previously Untreated Patient study.  
2 And that trial was conducted between Sheffield, the  
3 Royal Free and St Thomas', I believe, and they put 27  
4 patients into it, of whom 24 did not develop non-A,  
5 non-B hepatitis, and 3 did.

6 So, clearly, that was a big step in the right  
7 direction, but when they ultimately came to market  
8 this product, and indeed a number of others, they were  
9 marketed as hepatitis-reduced products. Now, people  
10 used them partly because of HIV and because it was  
11 obviously a step in the right direction, but they  
12 didn't think it was the full answer.

13 Q. As far as you can recall, was the Centre's involvement  
14 in the use of these -- the two heat-treated products  
15 on a trial basis, was that a response to the risk of  
16 hepatitis in 1984, or was it a conscious response to  
17 the risk of AIDS?

18 A. No. Well, the AIDS virus hadn't been isolated. It  
19 was very much a response to hepatitis. And there were  
20 various commercial companies that were looking into  
21 viral reduction, mostly abroad, and these products  
22 were not necessarily available to us. But, you know,  
23 Behring were conducting clinical trials from 1979, but  
24 unfortunately their trial of Humate-P took years and  
25 years and years to complete. It's quite difficult to

29

1 1983 for Sheffield Children's Hospital: total number  
2 of haemophilia A patients treated during the year, 17;  
3 no von Willebrand's patients; no carriers. Then we  
4 can see cryoprecipitate being used, 1,135 bags in  
5 hospital, none for home treatment ... NHS Factor VIII  
6 being used, 26,185 units in hospital, 147,622 units  
7 for home treatment. And then a small amount of  
8 commercial concentrate, Factor VIII, 5,266 units in  
9 hospital, 8,500 for home treatment, and then the other  
10 material that we see there is Autoplex.

11 Actually, we'll just go to the next page,  
12 please, Henry, for the sake of completeness, as we  
13 don't currently have much information about the  
14 Children's Hospital. This is -- then for the  
15 haemophilia A patients with inhibitors, we can see  
16 that they received predominantly cryoprecipitate,  
17 a very small amount of NHS Factor VIII concentrate,  
18 and down the bottom of the page, Autoplex. And then  
19 if we go to the third page, please, Henry, we see one  
20 child patient with haemophilia B treated during that  
21 year, and treated solely with NHS Factor IX  
22 concentrate. And then there's a handwritten note  
23 which tells us that some Factor IX concentrate was  
24 used for a Factor X deficiency patient on home  
25 treatment.

31

1 recruit patients, and it wasn't available to us at  
2 that time.

3 Q. Do you know, you may not, but do you know whether, for  
4 the purpose of these heat-treated trials,  
5 Professor Preston approached the pharmaceutical  
6 companies to ask to enroll some of his patients in  
7 them, or the pharmaceutical companies approached  
8 Professor Preston?  
9 A. I really don't know. But I would imagine it was the  
10 pharmaceutical company approaching him. That is  
11 usually the way round it comes. And they may have  
12 approached him and the Royal Free because both of  
13 those centres had a historical interest in liver  
14 disease and had indeed published on the use of virally  
15 attenuated products.

16 Q. I just want to ask you a little about the Children's  
17 Hospital. I know you were there for a shorter period  
18 of time, from August '84 to April '85 first of all,  
19 and then you went back for a further six months,  
20 August '86 to April '87.

21 Just going to put on screen the 1983 return  
22 from Sheffield Children's Hospital just so we can see  
23 as a matter of fact what products were being used.

24 Henry, it should be HCDO0000139\_004. So we can  
25 see here, Professor Hay, it's the annual return for

30

1 Professor, that paints a picture, at least for  
2 1983, and I'm afraid we don't have the returns for '84  
3 or '85 at the moment, of a -- predominantly NHS  
4 concentrate, a more substantial use of cryoprecipitate  
5 than at the Royal Hallamshire, and a very modest role  
6 for commercial concentrates.

7 Does that assist in triggering your  
8 recollection of the products that were used at the  
9 Children's Hospital at all?

10 A. Well, I think they had a very small number of patients  
11 with haemophilia, and they were able to use NHS  
12 products to a greater degree. Most of the patients  
13 with haemophilia B throughout the country were managed  
14 with UK Factor IX concentrate because there were far  
15 fewer of them. So we were, essentially,  
16 self-sufficient in Factor IX concentrate.

17 Q. And, broadly speaking, what was the role that you  
18 undertook at the Children's Centre during those two  
19 6-month placements there?

20 A. Well, I worked closely with the junior registrar in  
21 paediatrics, and we worked as a team. And he was not  
22 a haematologist, or she, and we managed mainly  
23 patients with childhood leukaemia, childhood solid  
24 tumours, and occasionally saw patients with bleeding  
25 disorders and outpatients, but it was a much smaller

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1 Haemophilia Centre than the adult one.  
 2 **Q.** And were the decisions as to what products to use,  
 3 therefore, down to Dr Lilleyman?  
 4 **A.** Yes, definitely.  
 5 **Q.** Do you happen to know if the policy or system of  
 6 keeping a patient on the same treatment and same batch  
 7 was in use at the Sheffield Children's Hospital?  
 8 **A.** I don't recall.  
 9 **Q.** And do you recall whether you had any involvement in  
 10 talking to the patients' parents about risks of non-A,  
 11 non-B hepatitis whilst you were there?  
 12 **A.** I honestly don't remember.  
 13 **Q.** As far as you can recall, did the Children's Hospital  
 14 have any involvement in or access to the early use of  
 15 the heat-treated products?  
 16 **A.** Well, I don't think so. You know, when we switched  
 17 over to Alphanate, my recollection is that the supply  
 18 was extremely limited and that there was some special  
 19 negotiation whereby they agreed to supply those  
 20 centres that had participated in the clinical trials.  
 21 I think Dr Mark Winter may have been able to  
 22 switch his patients because of his close association  
 23 with St Thomas' because I don't think he participated  
 24 in a clinical trial. But to start with, there  
 25 certainly wasn't enough of the stuff to supply the

33

1 **A.** No.  
 2 **Q.** So your knowledge of what was being said by UKHCDO to  
 3 the extent that you -- it was disseminated to you,  
 4 would it have been by Professor Preston at, for  
 5 example, the weekly meetings you've described?  
 6 **A.** Yes.  
 7 **Q.** On the question of what information to provide to  
 8 patients about risks, was that something that was  
 9 covered in your training, either your general medical  
 10 training or your specialist haematology training?  
 11 **A.** In my specialist haematology training.  
 12 **Q.** So would you have picked up what -- that advice, or --  
 13 essentially from Professor Preston, or from others --  
 14 **A.** Yes.  
 15 **Q.** You've described what you referred to as there being  
 16 a consensus, or an international consensus, in the  
 17 early 1980s that non-A, non-B hepatitis was relatively  
 18 benign and non-progressive. Can you assist us with  
 19 what material you're there referring to to support the  
 20 existence of this international consensus?  
 21 **A.** Well, there were a number of patients showing  
 22 incidence of abnormal liver function tests. Some  
 23 focused on the use of cryoprecipitate, for example,  
 24 the paper of Kevin Rickard from Australia, others on  
 25 the incidence after the introduction of concentrate.

35

1 whole of the UK.  
 2 **Q.** Now, can I just ask you more generally about how you  
 3 would keep up to date with literature publications in  
 4 the early '80s. You've already told us about the  
 5 Journal Club.  
 6 What magazines, as in medical journals and  
 7 publications, would you read in the early '80s?  
 8 **A.** Well, I got The Lancet, The New England Journal of  
 9 Medicine. I was a member of the British Society of  
 10 Haematology and therefore got the British Journal of  
 11 Haematology. I was not yet an ASH member, so I'd have  
 12 to go to the library for the -- for blood. And, oh,  
 13 yes, I was a member of ISTH, so I got Thrombosis and  
 14 Haemostasis which was the journal of the International  
 15 Society of Thrombosis and Haemostasis.  
 16 And those would be the journals I would read  
 17 regularly, but if someone pointed me at an article or  
 18 it came up in discussion in another journal, one might  
 19 go to the library and take it out.  
 20 **Q.** Prior to 1987 when you became a member of UKHCDO as  
 21 a director at Liverpool, do you -- did you have access  
 22 to the reports that were produced for UKHCDO meetings  
 23 by, for example, Dr Craske or the Hepatitis Working  
 24 Party, or access to the minutes of the annual meetings  
 25 or the Reference Centre Director meetings?

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1 It was clear that both agents transmitted whatever the  
 2 agent was that caused it.  
 3 There are a whole series of liver function --  
 4 sorry, liver biopsy papers. One from, actually, the  
 5 Children's Hospital, from Professor Lilleyman. Then  
 6 there was Eric Preston's in 1978 and, more recently,  
 7 the Stevens paper from Manchester, which we parodied  
 8 in the title of my own paper. And Mannucci and  
 9 Colombo also did liver biopsy studies and they all  
 10 showed mainly low grade of inflammation or no  
 11 inflammation at all. So, you know, Mannucci in  
 12 particular at that time was particularly going around  
 13 saying that this was non-progressive.  
 14 That title, of the Stevens paper -- or Dick  
 15 Stevens, actually, I think in the British Journal of  
 16 Haematology 1981, was "Non-A, non-B hepatitis in  
 17 haemophilia: an overstated problem?"  
 18 **Q.** Professor Hay, we're currently losing the visual sight  
 19 of you. We can currently see your tie and nothing  
 20 else. Given the time, it's five past 11, I'm going to  
 21 suggest we take a break there, and try to sort that  
 22 out in any event. But it's probably about the right  
 23 time for a break anyway.  
 24 **SIR BRIAN LANGSTAFF:** Yes, it is. I think you're probably  
 25 ahead of us in having had a restorative drink during

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1 the course of the morning, but we take half an hour  
 2 now, professor.  
 3 **A.** Okay.  
 4 **SIR BRIAN LANGSTAFF:** So we'll come back at 25 to 12.  
 5 By then, I hope we can see more of you than  
 6 your tie, nice though it is to look at.  
 7 **MS RICHARDS:** Sir, if Professor Hay can be given the usual  
 8 warning.  
 9 **SIR BRIAN LANGSTAFF:** Yes, what I say to all witnesses,  
 10 you may be accustomed to this from previous  
 11 experience, but is this: you're giving evidence you're  
 12 on oath, you must not discuss what you have said in  
 13 evidence or what you think -- whatever you think you  
 14 might be asked about to come in evidence. You can  
 15 discuss anything else you like with anyone, but you  
 16 can't discuss your evidence, past or to come, with  
 17 anyone at all, whoever they are.  
 18 Thank you very much.  
 19 (11.06 am)  
 20 (A short break)  
 21 (11.36 am)  
 22 **SIR BRIAN LANGSTAFF:** Professor, we're back in session.  
 23 I gather that you may have problems perhaps seeing  
 24 some of the documents. If you need them enlarged  
 25 just, please say.

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1 suggest you would have seen this at the time. It's  
 2 a letter dated 27 April 1979, and it's from  
 3 Dr Kernoff, who, as you've already referred to, had  
 4 a particular longstanding interest in hepatitis, to  
 5 Dr Colvin.  
 6 Henry, can we go to the second page, please.  
 7 Could you zoom in on -- can we have the whole of that  
 8 second paragraph, thank you.  
 9 You'll see there's a paragraph, professor,  
 10 beginning "Types of therapeutic material available".  
 11 Then if we go about two-thirds of the way  
 12 through that paragraph, there's a sentence beginning  
 13 "The clinical reason ..." Actually, I'll pick it up  
 14 just before that to make sense of it.  
 15 "Not only is commercial concentrate expensive,  
 16 but there are both clinical and moral reasons for  
 17 preferring the NHS material. The clinical reason is  
 18 the growing awareness of the probability that  
 19 commercial concentrates have a higher risk of  
 20 transmitting non-A, non-B hepatitis than NHS material.  
 21 This is a serious disease with long-term consequences  
 22 which, as far as is known, is at present much less  
 23 common in the UK than in those parts of the world --  
 24 particularly the USA -- where donor blood for  
 25 commercial concentrates is collected."

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1 **THE WITNESS:** I will.  
 2 **MS RICHARDS:** Professor Hay, I've been asking you about  
 3 what you described as an international consensus as to  
 4 the nature of non-A, non-B hepatitis. You had  
 5 referred to a number of papers, Mannucci and the  
 6 Stevens paper, which I understand.  
 7 You referred also to the paper co-authored by  
 8 Dr Lilleyman, and I'm just going to ask for that to go  
 9 on screen so we could have a look at that.  
 10 Henry, it's OXUH0001751\_003. And can we just  
 11 zoom in a bit closer, please, to the top half of the  
 12 page.  
 13 Is this the paper to which you were referring,  
 14 Professor Hay?  
 15 **A.** No. I was referring to one from 1975, actually.  
 16 **Q.** We don't, I think, have that. In relation to this  
 17 paper, was this a paper that you were aware of at the  
 18 time?  
 19 **A.** I don't remember it.  
 20 **Q.** Don't worry. In that case, I won't ask you anything  
 21 further about this particular paper.  
 22 Could we then have on screen, Henry,  
 23 BART0002487. Again, if we could zoom in to the top  
 24 half of the letter so we can see what it is.  
 25 Professor Hay, this is a letter -- I don't

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1 Now, I'm not asking you, professor, about  
 2 the -- whether there was a different risk from NHS and  
 3 commercial concentrates. But just in terms of  
 4 Dr Kernoff's characterisation of non-A, non-B  
 5 hepatitis, he describes it as a serious disease with  
 6 long-term consequences. Was that your understanding  
 7 in the early 1980s and that characterisation of non-A,  
 8 non-B hepatitis?  
 9 **A.** No.  
 10 **Q.** So you would not have characterised it as -- would you  
 11 disagree with serious or long-term consequences or  
 12 both?  
 13 **A.** Well, I think the long-term consequences were unknown.  
 14 And, I mean, it clearly is a correct statement, as we  
 15 now know it, but at that time, the long-term  
 16 consequences were not known. I think that was part of  
 17 the problem. The liver biopsy studies that had been  
 18 published were all looking at the early stages of the  
 19 disease. And there was a consensus forming around  
 20 that time that this was not a serious problem.  
 21 **Q.** Other than the papers to which you've referred, so  
 22 I think you've told us about Mannucci in '82, the  
 23 Richard Stevens paper in '81, and you referred to a  
 24 Lilleyman paper, 1975, which I'm afraid we don't have  
 25 available at the moment --

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1 **SIR BRIAN LANGSTAFF:** There's also the Australian paper  
 2 from Rickard.  
 3 **MS RICHARDS:** Oh, yes. And an Australian paper.  
 4 Are those the sources of your understanding  
 5 that there was an international consensus, or was it  
 6 your training, or discussions, or something else?  
 7 **A.** Well, it was partly my training, but I just  
 8 highlighted some of the papers. I mean, I think there  
 9 are about 300 references in my antithesis, but those  
 10 are perhaps the most important.  
 11 **Q.** And what about Professor Preston's own 1978 work?  
 12 What was your understanding in 1983 of what that paper  
 13 showed?  
 14 **A.** Well, it showed a variety of different types of  
 15 hepatitis, histologically, which included mostly  
 16 relatively low grades in inflammation.  
 17 **Q.** Sorry. Included relatively ...?  
 18 **A.** Mostly relatively low grades of inflammation.  
 19 **Q.** Can we just have a look at that?  
 20 Henry, it's PRSE0003622. If we could zoom in  
 21 on the top half of the right-hand column, please,  
 22 Henry.  
 23 So we've got the paper there; I know you're  
 24 familiar with it. Professor Preston, September 16,  
 25 1978. We have the title of it there, "Percutaneous

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1 Stevens et al.  
 2 **Q.** What we also see from this table, as well as the two  
 3 cases of cirrhosis, are two cases of chronic  
 4 aggressive hepatitis, which was characterised for us  
 5 by Professor Preston as being more serious and  
 6 significant than chronic persistent hepatitis was then  
 7 understood to be.  
 8 Do you disagree with that characterisation?  
 9 **A.** No. It's now known as chronic active hepatitis. In  
 10 non-A, non-B hepatitis, or rather hepatitis C, it can  
 11 progress to cirrhosis, though there are also instances  
 12 of it going back to chronic persistent hepatitis.  
 13 **Q.** Professor Hay, the paper by Mannucci may be said to  
 14 lend some support for your view of how non-A, non-B  
 15 hepatitis was understood at least by some.  
 16 Do you maintain your view, however, that that  
 17 was the consensus view, as opposed to there being  
 18 potentially a range of different views emerging in the  
 19 literature?  
 20 **A.** Well, there's always a range of views, but I think the  
 21 consensus view was that it was relatively benign and  
 22 non-progressive.  
 23 **Q.** You referred in your statement to one professor using  
 24 the term "a biochemical curiosity" about non-A, non-B  
 25 hepatitis, or about the liver function abnormalities.

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1 liver biopsy and chronic liver disease in  
 2 haemophiliacs". Then the summary refers to:  
 3 "Liver biopsies being carried out on eight  
 4 symptom-free patients under Factor VIII cover. A wide  
 5 spectrum of chronic liver disease was demonstrated,  
 6 including chronic aggressive hepatitis and cirrhosis."  
 7 Then if we go to the second page, please, just  
 8 the table at the bottom of the page. I'm not  
 9 proposing to go through the detail of it with you,  
 10 professor, but we looked at it with Professor Preston,  
 11 and he set out what he was referring to by reference  
 12 to the term -- the various terms there set out.  
 13 Is it -- do you say that this paper supports  
 14 a consensus that non-A, non-B hepatitis was mild and  
 15 non-progressive?  
 16 **A.** Well, it's certainly less supportive than some of the  
 17 others because there are two cases of cirrhosis there.  
 18 But apart from that -- you know, and I'm not sure  
 19 exactly how these patients were selected either,  
 20 because the two cases of cirrhosis may have had  
 21 physical signs that led to their liver biopsies.  
 22 But the papers of Mannucci showed only one case  
 23 of cirrhosis, and he referred to it as the  
 24 non-progressive course of non-A, non-B hepatitis, and  
 25 I think that similar findings from the paper of

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1 Who was that, professor, and when was that, roughly?  
 2 **A.** That was Professor Sam Machin. That would have been  
 3 about 1983, '84, when I was chatting with him about  
 4 our findings. And he expressed surprise that we were  
 5 still interested in this liver disease because he said  
 6 it was a biochemical curiosity. Naturally, by that  
 7 stage, I would have violently disagreed with that  
 8 view.  
 9 **Q.** By 1983, 1984, you would have disagreed with that  
 10 view?  
 11 **A.** Yes.  
 12 **Q.** And what was it that led to your own personal  
 13 realisation that non-A, non-B hepatitis was not benign  
 14 and non-progressive?  
 15 **A.** Well, I observed a patient in clinic who came along  
 16 and told me he'd been admitted to the local hospital,  
 17 having sort of gone to sleep. And he gave a very  
 18 vague story. His wife was with him. But I examined  
 19 him, and he had clear physical signs of cirrhosis of  
 20 the liver. But he was one of the patients with  
 21 chronic persistent hepatitis previously reported by  
 22 Professor Preston. And our understanding was that  
 23 that particular histological appearance, which is a  
 24 very mild inflammation, not chronic active hepatitis,  
 25 was thought to be benign and non-progressive. So this

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1 was clearly a very odd thing. He was relatively  
2 elderly, but he progressed from chronic persistent  
3 hepatitis in the late '70s to full-blown cirrhosis  
4 with hepatic encephalopathy, which implies a degree of  
5 hepatic failure in the space of only six years.

6 So I brought this to the attention of  
7 Professor Preston and Dr Triger, who was the  
8 hepatologist, and they agreed that this was a  
9 remarkable observation, and they agreed that we should  
10 be monitoring our patients more closely with liver  
11 biopsy.

12 Q. Doing the best you can, was that 1983 or 1984?

13 A. I think it may have been late 1983.

14 Q. If we just look at the paper that was then published  
15 in The Lancet in June of '85. Henry, it's  
16 PRSE0004229. And if we zoom in on the bottom half of  
17 the page, Henry.

18 This is the paper co-authored between yourself,  
19 Professor Preston, Dr Triger and Dr Underwood.  
20 "Progressive liver disease in haemophilia: an  
21 understated problem?"

22 I'm just going to read the summary for the  
23 benefit of those following:

24 "In an eight-year study of 79 unselected  
25 patients with haemophilia who had received clotting

45

1 A. Yes.

2 Q. This tells us that the eight-year study of patients  
3 was of 79 unselected patients. How were patients  
4 identified or selected for biopsy; can you recall?

5 A. Well, the patients who had been biopsied before -- who  
6 did not have cirrhosis, or at least hadn't had  
7 cirrhosis before -- were approached to -- for consent  
8 to (inaudible) biopsy again to see if their liver  
9 disease had changed. And it was explained to them  
10 that we had some doubts about the current view about  
11 the natural history of non-A, non-B hepatitis, and we  
12 couldn't make any assumptions, and we wanted to know  
13 what was happening with their liver disease, and the  
14 only way to find out was to do a liver biopsy. And  
15 further patients who had abnormal liver function tests  
16 were approached, and a similar conversation took  
17 place.

18 Q. And if we go to the second page, please, Henry, if we  
19 look at the bottom half of the page under the  
20 left-hand column under the heading "Results", please,  
21 Henry.

22 We can see this is what is recorded:

23 "Initial biopsy in 34 patients showed chronic  
24 persistent hepatitis in 20; chronic lobular hepatitis  
25 in one."

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1 factor concentrates, there was evidence of chronic  
2 progressive liver disease in at least 17 (21%). Eight  
3 patients had chronic active hepatitis, and nine had  
4 cirrhosis, five with oesophageal varices.  
5 Histological evidence suggested that non-A, non-B  
6 hepatitis was mainly responsible, although the  
7 influence of other viruses could not be excluded.  
8 Serial liver biopsies showed progression from chronic  
9 persistent hepatitis to chronic active hepatitis and  
10 cirrhosis within six years, suggesting that chronic  
11 persistent hepatitis in haemophiliacs is not as benign  
12 as hitherto supposed."

13 And then the last sentence of the summary:

14 "It's anticipated that liver disease in  
15 haemophiliacs will become an increasing clinical  
16 problem in the future."

17 So this was the result of work that had in fact  
18 been undertaken over an eight-year period, so prior to  
19 your joining.

20 A. Well, yes, it's an eight-year period because it  
21 includes all the data from Professor Preston's earlier  
22 study.

23 Q. And then in terms of the process of undertaking  
24 further biopsies, the serial liver biopsies referred  
25 to, were you directly involved in that process?

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1 Pausing there. Could you just explain for us  
2 "chronic lobular hepatitis" as distinct from "chronic  
3 persistent" and "chronic active"?

4 A. I think chronic lobular hepatitis is a similar low  
5 grade of inflammation.

6 Q. Then:

7 "Chronic active hepatitis in 9, established  
8 micronodular cirrhosis in 4."

9 And then the next paragraph refers to 9  
10 patients having a second biopsy. And we can then see  
11 that you set out various matters relating to that, and  
12 you say:

13 "Cirrhosis was present in at least 9 of the 34  
14 patients."

15 And then we can see the table with the results  
16 of the serial liver biopsies. The first biopsy,  
17 having shown chronic persistent hepatitis in 6, and  
18 then there's 4 in chronic -- showing chronic active  
19 hepatitis.

20 And then the second biopsy showing, as I  
21 understand it, that in patients 3 and 4, the chronic  
22 progressive hepatitis was now showing to be chronic  
23 active hepatitis. Patients 5 and 6 had progressed to  
24 cirrhosis. Likewise, patients 8 and 9. Patient 7,  
25 perhaps somewhat curiously, had gone from chronic

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1 active hepatitis to chronic persistent hepatitis.  
 2 Is that a correct reading of that part of the  
 3 results?  
 4 **A.** Yes, it is.  
 5 **Q.** So is it fair to say that the significance of this  
 6 paper was the further light it shone on chronic  
 7 persistent hepatitis and its potential to progress to  
 8 serious liver damage?  
 9 **A.** Yes.  
 10 **Q.** And then, Professor Hay, for the sake of completeness,  
 11 we'll just look at the two other applications from the  
 12 Lancet in 1985 to which you contributed.  
 13 Henry, could we have PRSE0004594, please.  
 14 If we could just zoom in on the bottom half of  
 15 the page, please, Henry.  
 16 So this is July 1985 in The Lancet, professor,  
 17 and we can see it's a letter co-authored by  
 18 Professor Preston, you, Dr Dewar, Dr Greaves,  
 19 Dr Triger:  
 20 "Non-A, non-B hepatitis and heat-treated  
 21 Factor VIII concentrates."  
 22 Is this the letter that you were referring to  
 23 earlier which talked about the problems experienced  
 24 with the trials of the Armour heat-treated products in  
 25 1984?

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1 **A.** Yes, I guess so.  
 2 **Q.** Before we leave this, is there anything further you  
 3 wanted to say about this letter?  
 4 **A.** No, not particularly. I think the significance is  
 5 that it was not immediately accepted by everybody.  
 6 And Mannucci argued back, in defence of his own  
 7 earlier assessment.  
 8 **Q.** I'm going to move on to ask you about the developing  
 9 knowledge of the risk of AIDS.  
 10 **SIR BRIAN LANGSTAFF:** Well, before you do that, can I just  
 11 ask you one further question about the consensus.  
 12 The title of your article in The Lancet was  
 13 "... an understated problem?"  
 14 **A.** Yes.  
 15 **SIR BRIAN LANGSTAFF:** And you said that was a parody of  
 16 Stevens' article in 1982 --  
 17 **A.** No, it was 1981's.  
 18 **SIR BRIAN LANGSTAFF:** '81, I'm sorry. Where he said,  
 19 effectively: is it an overstated problem?  
 20 **A.** Yes.  
 21 **SIR BRIAN LANGSTAFF:** Why would he think that it was an  
 22 overstated problem if the consensus was that it  
 23 wasn't?  
 24 **A.** Well, he published that before Mannucci came along and  
 25 published his paper in 1982. So there clearly was

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1 **A.** It is.  
 2 **Q.** And the two patients who developed significant non-A,  
 3 non-B hepatitis within a fairly rapid period of time?  
 4 **A.** Yes. Quite short incubation, unusually severe.  
 5 **Q.** And then the third article in The Lancet from 1985 is  
 6 WITN3289051, please, Henry.  
 7 And if you go to the next page. In fact if you  
 8 move to -- if you go down the page, please. Next  
 9 page, sorry, Henry.  
 10 There are two letters entitled "Liver disease  
 11 in haemophilia". If we zoom in on this one. So this  
 12 is the second letter, entitled "Liver Disease in  
 13 Haemophilia", is the one authored by you, Dr Preston,  
 14 Dr Triger and Dr Underwood.  
 15 **A.** Yes.  
 16 **Q.** And I think you refer to this in your statement. This  
 17 is the disagreement that emerged, through the pages of  
 18 The Lancet, between those undertaking the work at  
 19 Sheffield that we've just looked at, and  
 20 Professor Mannucci and Dr Colombo.  
 21 **A.** Indeed.  
 22 **Q.** And this letter identifies two possible reasons for  
 23 difference: the age of the cohort being biopsied and  
 24 studied; and patient selection.  
 25 Is that a fair summary?

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1 some diversity of opinion. But by the early eighties  
 2 I think the consensus was, oh, well, it's not so much  
 3 to worry about. And in the seventies people sort of  
 4 became aware of the problem, and would naturally have  
 5 been worried about it. We know that hepatitis B can  
 6 progress to cirrhosis and hepatocellular carcinoma in  
 7 chronic carriers, for example, so there would  
 8 certainly have been concerns about the progress of  
 9 non-A, non-B hepatitis based on theoretical  
 10 considerations alone. But various live biopsies had  
 11 been done, and as time went by, they appeared, or at  
 12 least were interpreted to suggest that, well, maybe  
 13 this isn't as big a problem as we thought it was.  
 14 And, you know, I think it's against that context.  
 15 So you've got the Stevens paper and then  
 16 another liver biopsy series from Mannucci which also,  
 17 in its title, talked about it being non-progressive.  
 18 But the interesting thing is, a lot of this is  
 19 about interpretation, because even the Mannucci paper,  
 20 it was about 11 patients, quite a small series to base  
 21 any sort of conclusion on, and one of those patients  
 22 had cirrhosis.  
 23 So looking at the same data, and I think in our  
 24 correspondence we point out that to him, you could  
 25 argue that, well, ten per cent of your patients have

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(13) Pages 49 - 52



1 got cirrhosis. And we're showing 15 per cent. So why  
2 are you arguing the toss?

3 **SIR BRIAN LANGSTAFF:** Yes, I see.

4 So the one thing that seems to be clear, tell  
5 me if this is fair, is that there was a significant  
6 risk -- sorry, a risk that serious hepatitis might  
7 result, but people were at odds over time, views  
8 differing, as to quite how serious the risk was. Is  
9 that fair?

10 **A.** Particularly in the seventies there was probably  
11 greater dichotomy of opinion. But by the early  
12 eighties I think that they'd settled around thinking,  
13 oh, well, it wasn't such a big problem after all.  
14 That was my perception, talking to colleagues from  
15 around the country, and reading the literature. And  
16 I think it was Professor Preston's perception too, to  
17 be honest. But then we started to see more people  
18 with more serious liver disease, and the closer we  
19 looked, the more we found.

20 Not everyone with cirrhosis will have physical  
21 signs of cirrhosis. They often don't. So it's only  
22 if you do a liver biopsy -- or, more recently, we  
23 would, of course, do a fibroscan, we have non-invasive  
24 methods now, but back then the only way to find out  
25 was to do a liver biopsy.

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1 at the Blood Transfusion Service?

2 **A.** Yes.

3 **Q.** Would the MMWR have been a publication that you saw or  
4 had access to at that time?

5 **A.** No.

6 **Q.** Can you recall what, if any, discussion there was in  
7 the six months you were at the Blood Transfusion  
8 Centre, so from August '82 to April '83, about the  
9 risk of AIDS and AIDS as a potential blood-borne  
10 virus?

11 **A.** I don't remember anything about that.

12 **Q.** Do you recall reading the article in the New England  
13 Journal of Medicine January 1983 by Jane Desforges  
14 about AIDS and haemophilia? We can put it up on  
15 screen.

16 Sorry, it's a slightly unfair question without  
17 showing you the document.

18 It's PRSE0002410. It's New England Journal of  
19 Medicine, January 1983, "AIDS and preventive treatment  
20 in haemophilia".

21 And if we go to the bottom paragraph, please,  
22 Henry, we can see there it refers, third line down:

23 "Reports from the Centers for Disease Control  
24 include three haemophiliacs among cases of ... AIDS."

25 And then there's further discussion about the

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1 **SIR BRIAN LANGSTAFF:** Thank you very much.

2 **MS RICHARDS:** Professor Preston [sic], can you recall when  
3 and how you first became aware of reports of AIDS in  
4 haemophiliacs in the States?

5 **A.** Well, the very early 1980s, when there was a run on  
6 pentamidine, CDC recognised that they were issuing far  
7 more pentamidine, which is a treatment for  
8 pneumocystis pneumonia, than they expected.

9 Now, pneumocystis pneumonia is a type of  
10 pneumonia that haematologists are very familiar with  
11 because we see it in our immunosuppressed patients  
12 with lymphoma or leukaemia. But it's not common.  
13 It's caused by an opportunist pathogen. And the CDC  
14 in the United States realised that this was -- this  
15 sudden increase was being used in a different risk  
16 group, and it was predominantly being used for  
17 homosexual men who were presenting with pneumocystis  
18 pneumonia. And it was at that point, I think 1981,  
19 maybe '82, that they really began to realise that  
20 there was a new disease out there.

21 **Q.** We know there were reports in July 1982 in the MMWR  
22 publication produced by CDC of PCP observed in  
23 haemophiliacs?

24 **A.** Yes.

25 **Q.** This was shortly before you'd be taking up your post

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1 presentation of AIDS. And then if we go over the page  
2 the last paragraph, please, left-hand column, Henry,  
3 it says:

4 "The fact that haemophiliacs are at risk for  
5 AIDS is becoming clear. The use of cryoprecipitate  
6 will minimise this risk, the current home infusion  
7 programme needs to be revised."

8 And then the last two sentences:

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

14 Leave aside for a moment, professor, the  
15 reference to use of cryoprecipitate. Was this is an  
16 article, as far as you can recall, that you saw at the  
17 time?

18 **A.** I can't remember. I don't remember the specific  
19 article. I think I was aware of the three cases in  
20 the US, one way or the other, during 19 -- certainly  
21 by 1983.

22 I can't remember exactly when I started to take  
23 the New England Journal. I started to --

24 **Q.** Now, we also --

25 **A.** -- take the Lancet, however. I don't think I was

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1 taking the New England Journal at that point.  
 2 **Q.** Now we know that in around December of 1982 there were  
 3 reports of a baby, a San Franciscan baby, 20-month old  
 4 baby transfused with platelets developing the AIDS  
 5 syndrome, and we know that that is something that, as  
 6 a matter of fact, came to the attention of  
 7 Professor Preston, along with an update of what the  
 8 current position was in terms of AIDS and  
 9 haemophiliacs at a meeting in late January 1983.  
 10 Now that, of course, is whilst you're still at  
 11 the Regional Transfusion Centre and three months  
 12 before you joined the Royal Hallamshire.  
 13 When you joined the Royal Hallamshire in  
 14 April 1983, can you recall what discussions there were  
 15 about AIDS and the risk of AIDS being transmissible by  
 16 blood or blood products?  
 17 **A.** I can remember that it was recognised that it was  
 18 beginning to appear in patients with haemophilia. And  
 19 that we assumed that it was caused probably by  
 20 a virus. There were some contrary hypotheses, but  
 21 they never gained much traction. So I think we  
 22 assumed it was caused by an unknown virus, and we  
 23 didn't know what the risk was.  
 24 We assumed that all blood products might carry  
 25 it, I think, because it was beginning to appear in the

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1 says at (1):  
 2 "For mildly affected patients with  
 3 haemophilia A or von Willebrand's disease and minor  
 4 lesions, treatment with DDAVP should be considered.  
 5 Because of the increased risk of transmitting  
 6 hepatitis by means of large pool concentrates in such  
 7 patients, this is in any case the usual practice of  
 8 any Directors."  
 9 Was that the usual practice at the Sheffield  
 10 Centre at that time?  
 11 **A.** It was already the usual practice because of non-A,  
 12 non-B hepatitis.  
 13 **Q.** And then in (2), it says:  
 14 "For the treatment of children [and we can  
 15 leave that aside] and mildly affected patients or  
 16 patients unexposed to imported concentrates many  
 17 Directors already reserve supplies of NHS concentrates  
 18 (cryoprecipitate or freeze-dried) and it would be  
 19 circumspect to continue this policy."  
 20 So taking, first of all, mildly affected  
 21 patients, this is a suggestion that if you have an  
 22 existing policy of treating them with cryo or NHS  
 23 concentrates, continue. Did this lead to any change  
 24 of approach for your mildly affected patients? Or  
 25 were you already predominantly using DDAVP?

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1 UK population as well. By "UK population" I mean the  
 2 general population.  
 3 **Q.** We also know that in around March 1983 Haemophilia  
 4 Centre Directors were asked to look out for symptoms  
 5 or signs of AIDS in their patients and report back to  
 6 Dr Craske if they detected any such signs.  
 7 **A.** They did.  
 8 **Q.** Do you recall whether -- is that something you were  
 9 asked to undertake as part of your routine care of  
 10 patients, to look out for signs of AIDS, and if so,  
 11 alert Professor Preston?  
 12 **A.** Yes.  
 13 **Q.** And then did you, as a matter of fact, identify, as  
 14 far as you can recall, in any of the patients at the  
 15 Sheffield Centre at that time, any such signs?  
 16 **A.** I don't remember.  
 17 **Q.** Then you've produced a document from June 1983.  
 18 Henry, could we have WITN3289041. If we just  
 19 zoom in on that.  
 20 This the letter of 24th June 1983 sent to  
 21 Centre Directors by Professor Bloom and Dr Rizza,  
 22 following a special meeting of Reference Centre  
 23 Directors, and it sets out in the two numbered  
 24 paragraphs there two general recommendations.  
 25 If we just look at those recommendations, it

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1 **A.** I think we were already doing that. And as you've  
 2 already pointed out to me, at the Children's Hospital  
 3 they were using predominantly cryoprecipitate or NHS  
 4 concentrate at that time.  
 5 **Q.** And then in terms of patients unexposed to imported  
 6 concentrates, was there any particular approach or  
 7 policy agreed at the Sheffield Centre in relation to  
 8 that category of patients in light of this letter?  
 9 **A.** Well, I don't think it changed very much, because we  
 10 already had a policy of keeping people to the brand  
 11 that they were on. So, you know, if people had been  
 12 treated exclusively with British products, that would  
 13 continue.  
 14 **Q.** But if it was a patient who was a new patient,  
 15 maybe -- I don't know that you didn't come across any  
 16 in your time there -- a new patient who hadn't  
 17 previously been treated with imported concentrates,  
 18 would they have been started on NHS concentrates or  
 19 would it have depended on availability?  
 20 **A.** It would have depended on availability, I think.  
 21 **Q.** And then other than the continuation of the existing  
 22 policies you have described and the early use of  
 23 heat-treated products, which you've already referred  
 24 to, were there, as far as you know, any other changes  
 25 to the approach to treatment at the Sheffield Centre

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1 in '83, '84 in response to the risk of AIDS?  
 2 A. I can't think of any. I think we deferred some  
 3 surgery.  
 4 Q. Do you know whether that would have been 1983 or '84  
 5 or indeed later?  
 6 A. I'm not sure, to be honest. But I seem to remember  
 7 that some surgery was deferred. That happened in  
 8 quite a few places.  
 9 Q. Was any consideration given to a suspension, at least  
 10 on a temporary basis, of the Home Treatment Programme?  
 11 A. Well, I think this was discussed. I can't say exactly  
 12 when because, as you've pointed out, the suggestion  
 13 did come up in the literature occasionally, so it  
 14 wasn't something that was completely ignored. But it  
 15 was certainly Professor Preston's view, and I think  
 16 that this was commonly the case, that this would be  
 17 resisted by the patients, was not recommended by the  
 18 Haemophilia Society or the World Federation of  
 19 Haemophilia.  
 20 And I think what people were trying to do --  
 21 this comes across in some of the minutes involved with  
 22 Professor Bloom -- was to try to balance out the  
 23 risks. Now, on the one hand, if you go back to cryo,  
 24 you have an immediate supply problem because cryo  
 25 wasn't being very much produced, and the requirement

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1 hand against an unknown effect of AIDS. And I think  
 2 at the time they were doing that in 1983, there was  
 3 one patient reported with AIDS, and by the following  
 4 year it had gone up to about three, as far as I can  
 5 recall.  
 6 So, you know, numerically, the problem didn't  
 7 appear big, but there clearly was an enormous degree  
 8 of uncertainty. Because the natural history of HIV  
 9 had not yet unfolded, and we had no idea how many  
 10 patients were affected.  
 11 Q. Can I try and unpick some of that with you, professor?  
 12 A. Yes.  
 13 Q. First of all, as far as Sheffield is concerned, can  
 14 you recall whether there was -- whether positive  
 15 consideration was given, whether at the weekly  
 16 meetings you've described or otherwise, to reverting  
 17 to cryoprecipitate, either in whole or in part? Was  
 18 there actual discussion about that in Sheffield?  
 19 A. Yes, there was.  
 20 Q. And what was the forum for that? Was that on  
 21 a regional basis, or was it in the weekly meetings  
 22 you've described?  
 23 A. Well, we certainly discussed it in the weekly  
 24 meetings. Whether it was more widely discussed,  
 25 I don't know. But Professor Preston rejected it. As

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1 for Factor VIII had tripled during for the previous  
 2 decade.  
 3 So I'm not sure there would have been enough  
 4 cryo. Certainly, you would have had to turn the  
 5 Transfusion Service on its head to suddenly produce  
 6 a whole lot of cryo, which would not have happened  
 7 overnight. Then you would have reverted to the life  
 8 expectancy that had pertained before that event of  
 9 concentrate.  
 10 Now, the introduction of cryo improved life  
 11 expectancy enormously, because in the pre-treatment  
 12 era, it was 10 to 15 years, and it increased to about  
 13 40. Actuarial methods published by Charlie Rizza  
 14 et al suggested that we'd nearly normalised life  
 15 expectancy.  
 16 So changing back to cryo would have been  
 17 expected to have reduced life expectancy, maybe not  
 18 dramatically, but to some extent. And they were  
 19 trying to balance this up, because this was all  
 20 knowledge that was known at the time. Trying to  
 21 balance this up against the big unknown.  
 22 Now, of course, if we'd known then what we know  
 23 now, the argument for switching to cryo would have  
 24 been very much stronger. But they were trying to  
 25 balance a known change in life expectancy on the one

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1 far as I'm aware, John Lilleyman rejected the idea as  
 2 well. And they quoted other colleagues' consensus  
 3 documents. You know, I think it was considered fairly  
 4 widely.  
 5 Q. You've raised one possible practical impediment, that  
 6 of supply.  
 7 A. Yeah.  
 8 Q. Now, we've seen evidence, for example, from -- and I'm  
 9 not suggesting you would necessarily have been aware  
 10 of this at the time -- from an October 1983 UKHCDO  
 11 meeting, where Dr Chisholm in Southampton said that  
 12 she had unlimited supplies of cryoprecipitate -- her  
 13 problem was getting commercial concentrates -- and  
 14 some other directors agreed. So in --  
 15 A. I think it would have varied from region to region  
 16 because this is a product that's produced by the local  
 17 Transfusion Centre, and it's not just used for  
 18 haemophiliacs. It was also used for the treatment of  
 19 disseminated intra-vascular coagulation and other  
 20 acquired bleeding problems. But, you know, it varied  
 21 from centre to centre.  
 22 When I got to Manchester, for example,  
 23 admittedly much later than this, they'd stopped  
 24 manufacturing cryoprecipitate altogether, and I had to  
 25 actually ask them to start making it again.

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1 Q. Do you know whether Professor Preston or indeed  
2 Dr Lilleyman approached the Sheffield Regional  
3 Transfusion Centre, or Dr Wagstaff, to explore with  
4 them the possibility of increasing production of  
5 cryoprecipitate?  
6 A. If he did, I don't know about it.  
7 Q. Then in your statement, you've set out a number of  
8 concerns about possible reversion to cryoprecipitate,  
9 some of which you've touched on in your oral evidence.  
10 You'd said in your statement that cryoprecipitate was  
11 incompatible with home therapy. We've heard evidence  
12 that -- of a number of haemophiliacs in the course of  
13 the 1970s receiving home treatment through the use of  
14 cryoprecipitate.

15 Would you accept that incompatible is perhaps  
16 an overstatement?

17 A. Well, I wasn't aware of that at the time. I am aware  
18 of it now. But what I would say about that is that it  
19 was a minority of centres that had some pilot -- what  
20 I'd describe as pilot projects of home therapy with  
21 cryo, because logistically it was quite challenging.  
22 You'd need a minus 40 to minus 60 freezer. A domestic  
23 freezer would not do. These are sort of great big  
24 bulky things. They're quite expensive. Not everyone  
25 would have room for it. Many of the patients actually

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1 therapy with cryoprecipitate because by the time 1983  
2 came along, it was all concentrates?

3 A. Well, it isn't just that. When I was a houseman,  
4 there were still patients switching from cryo to  
5 concentrate and going on to home therapy, so I did  
6 have some experience of routine treatments. I also  
7 came across it as a medical student when I did my  
8 paediatrics, but they never had a home therapy  
9 programme with cryo in Sheffield.

10 Q. And then you've said in your statement and again in  
11 your oral evidence this: that changing to  
12 cryoprecipitate or no treatment would dramatically  
13 increase the risk of haemorrhagic death, decrease life  
14 expectancy dramatically, and lead to more rapid  
15 deterioration of haemophilic arthropathy.

16 Now, if we take out the reference to no  
17 treatment, professor, what's the evidential basis for  
18 your assertion that changing to cryoprecipitate in  
19 1983 would have dramatically increased the risk of  
20 death as a result of haemorrhage?

21 A. Well, haemorrhage at that time was the commonest cause  
22 of death in severe haemophilia, and the life  
23 expectancy estimate, before the introduction of  
24 concentrates, was about 40 years, whereas I think  
25 Rizza et al, based on the early returns to Oxford, the

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1 complained about the amount of space their Factor VIII  
2 concentrate took up in their fridge. Some patients  
3 had to have more than one domestic fridge. But at  
4 least the concentrate you could keep in a domestic  
5 fridge, whereas with cryo, it has to be delivered from  
6 the Transfusion Centre, without breaking the cold  
7 chain, to the patient's home and then stored in  
8 a minus 40 freezer. And even as home therapy, there  
9 would be a delay in being able to treat yourself  
10 because you've got to defrost it and draw it all up.  
11 It's much more difficult drawing up, you know, 6 or 12  
12 bags of gloopy stuff than it is having concentrate.

13 So, yes, there was limited use of cryo for home  
14 therapy, but it depended on a number of factors, and  
15 it was never widespread.

16 Q. Yes, well, I mean, we've heard a range of evidence in  
17 relation to that, so I'm not sure the evidence we've  
18 heard would support the characterisation of it as  
19 pilot in terms of its usage in the '70s.

20 A. Well, I honestly don't think there were large numbers  
21 of patients on home therapy with cryo, and most  
22 centres weren't doing it at all.

23 Q. In terms of your own direct experience, is this right:  
24 that you would have had no experience or little  
25 experience of patients in Sheffield on the home

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1 National Haemophilia Database, calculated that life  
2 expectancy was about 67, 68.

3 Q. Is the answer to my question that the factual or  
4 evidential basis for that assertion is Dr Rizza's  
5 paper?

6 A. Yes.

7 Q. If a return to cryoprecipitate had been not for  
8 haemophiliacs for the rest of their natural lives but  
9 for a period of time -- a year, 18 months -- in the  
10 knowledge that work was being done on heat-treated  
11 products, that work was being done to identify what  
12 the virus was, that there might be a test for the  
13 virus, what basis is there for believing that a change  
14 to cryoprecipitate for a year or 18 months would  
15 dramatically increase the risk of death or decrease  
16 life expectancy dramatically?

17 A. Well, I mean, it would have -- for that period of  
18 time, they would have been more at risk of dying from  
19 haemorrhage. Now, okay, yes, it's a limited period of  
20 time, and that would reduce the danger, but for most  
21 patients it would have meant reverting to  
22 hospital-based treatment.

23 Now, this was one of the great advantages of  
24 concentrate because we knew that with haemophilic  
25 bleeding, the earlier you treated it, the less damage

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1 is done. So when the patients had the treatment at  
2 home, they were told: if you think you've got a bleed,  
3 treat yourself immediately. It may not be a bleed,  
4 but, you know, you have a lot of personal experience,  
5 and they would be able to do so.

6 Now, if they had to come into hospital and have  
7 cryo, it affected the way that they behaved so that,  
8 you know, if they lived a long way away, they'd think  
9 twice about coming in to hospital. They would make  
10 sure they were certain it was a bleed before they  
11 considered treatment, so by the time they arrived in  
12 the hospital, they often had an advanced  
13 haemarthrosis. And then someone would assess them,  
14 decide they needed cryo, send to the blood bank. The  
15 blood bank would send the cryo. Then they'd defrost  
16 it. Then they'd draw it up, and then they'd  
17 administer it. So by the time you'd finished, there's  
18 been a delay of a number of hours.

19 Now, with a haemarthrosis, the result of that  
20 is that there is far more joint damage and the  
21 haemarthrosis takes a lot longer to resolve, but  
22 I think you can probably argue that doesn't make  
23 a difference to life expectancy.

24 If, on the other hand, they develop a headache,  
25 which may just be a headache or it could be the early

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1 considered and what difference they might --  
2 A. Okay.  
3 Q. What the practical impediments might have been. Do  
4 you --  
5 A. I think in most centres, they considered that it was  
6 not a suitable product for home therapy, for logistic  
7 reasons.  
8 Q. Do you accept or agree that the question of whether to  
9 take that risk of possibly delayed treatment in the  
10 event of a headache, or to take the risk of having  
11 less than ideal treatment for other bleeds and  
12 possible risks of joint damage was a decision for the  
13 patient to take, rather than for the physician to take  
14 for the patient?  
15 A. That's an interesting philosophical question, because  
16 the big problem is that these decisions were being  
17 made on the basis of very little information. And,  
18 you know, even the guidelines that came out were not  
19 as evidence based as we like our guidelines to be  
20 because they were based on opinion, and that opinion  
21 was very poorly informed because there were so many  
22 reasonable questions about AIDS, and subsequently HIV,  
23 that just were not known. A lot became clearer once  
24 the tests became available.  
25 Q. Were patients, as a matter of fact, at the Sheffield

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1 signs of an intracranial bleed, then a delay can be  
2 really life-threatening. So if somebody with  
3 haemophilia phones up the Haemophilia Centre and says,  
4 "I've got this headache and it won't go away," you'd  
5 say to them, "Give yourself some Factor VIII and come  
6 in to the hospital." Or maybe you'd organise  
7 transport. But they would have treatment before they  
8 left their house, in that instance, and that could be  
9 a matter of life and death.

10 Q. On this hypothetical scenario, the delay that you're  
11 describing could have been dramatically reduced by the  
12 provision of cryoprecipitate as a home therapy, to be  
13 used --

14 A. Yes.

15 Q. -- perhaps not on a regular basis but in the event of  
16 an emergency such as that which you describe?

17 A. Yes, but I would suggest that -- well, you know, home  
18 therapy with cryo happened in a few centres,  
19 a relatively small number of patients. Setting it up  
20 on a national basis, with the purchase of all those  
21 refrigerators, some patients wouldn't have had any  
22 room for it, would have been a major undertaking that  
23 couldn't have happened very quickly, I would imagine.

24 When do you suggest that they should have done that?

25 Q. Professor, I'm exploring with you what options were

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1 centre [audio disruption] --  
2 A. -- questions --  
3 Q. -- told --  
4 A. And I think it would have been an order of magnitude  
5 more difficult for the patients, because, you know,  
6 the conversations were to be relatively uninformed.  
7 Q. Sorry, professor, we had a slight problem with the  
8 Internet connection then but I think we got your  
9 answer.  
10 A. Okay.  
11 Q. Were patients, as a matter of fact, from -- in the  
12 time you were at Sheffield, so from April 1983  
13 onwards, told of the possible risk of AIDS from the  
14 continuing use of factor concentrates?  
15 A. I do recall having conversations with the patients  
16 about AIDS. It was widely reported, patients did ask  
17 about it. And to be honest, we weren't able to  
18 quantify the risks.  
19 Q. Were patients routinely given that information, such  
20 information as you had, or was it only discussed with  
21 them if they raised it with you?  
22 A. They were routinely given that.  
23 Q. And what kind of information in 1983, '84, do you  
24 think they were given?  
25 A. I think they would have been told that there was some

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1 evidence that recipients of blood or blood products  
 2 were developing AIDS but that there were very few  
 3 cases, and they were probably told that, as far as we  
 4 could see, the risk was relatively small at that time.  
 5 I think that was the general view.  
 6 **Q.** Was any patient, as a matter of fact, given the choice  
 7 to revert to cryoprecipitate?  
 8 **A.** I don't recall that.  
 9 **Q.** Were there any attempts made in '83/'84, to acquire  
 10 more NHS concentrate in view of what was thought to be  
 11 the increased risk of AIDS associated with commercial  
 12 concentrates?  
 13 **A.** Er ... there may well have been, but I don't recall.  
 14 There was always a supplier problem with  
 15 NHS concentrates. We could never get enough of them.  
 16 **Q.** Was any consideration given, as far as you can recall  
 17 in this '83/'84 period, to using porcine products for  
 18 non-inhibitor patients in response to the risk of  
 19 AIDS?  
 20 **A.** Very little. There's several things you need to know  
 21 about porcine. I mean, in actual fact, the one  
 22 clinician who used porcine Factor VIII for  
 23 non-inhibitor patients during this period was my  
 24 predecessor in Manchester, who actually published  
 25 a paper on this. And he had used it for surgery in

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1 **Q.** You've referred in your statement, and indeed  
 2 Professor Preston made reference to them, to there  
 3 being a meeting or meetings involving a number of  
 4 patients at the centre to discuss the risk of AIDS or  
 5 to discuss AIDS. Can you recall anything further  
 6 about those meetings and how they were set up, and  
 7 what kind of matters were discussed?  
 8 **A.** Sorry, you broke up a little bit there.  
 9 Are we talking about the Journal Club or the  
 10 multi-disciplinary meetings?  
 11 **Q.** No, I'm sorry, neither. My apologies, Professor Hay.  
 12 Professor Preston told us about there having  
 13 been a meeting with patients, and your statement  
 14 I think also reflects that: a larger meeting, not  
 15 a one-to-one patient meeting, a larger meeting or  
 16 meetings to which patients were invited to discuss  
 17 AIDS.  
 18 **A.** Yes.  
 19 **Q.** What, if anything, can you recall about those?  
 20 **A.** I didn't -- I can't remember actually attending these.  
 21 They were meetings between Eric and any patients who  
 22 wanted to come along and I believe he discussed with  
 23 them what was known about the issue at the time. And  
 24 he had a number of them as the state of knowledge  
 25 progressed, particularly once we had a test. Because

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1 little-treated patients to avoid the risk of  
 2 non-A, non-B and, possibly, whatever the AIDS virus  
 3 was.  
 4 But the product that was available at that time  
 5 was, by modern standards, an intermediate purity  
 6 product. It's essentially a concentrate of porcine  
 7 Factor VIII. If you use it in a non-inhibitor  
 8 patient, a significant portion of patients will  
 9 develop antibodies which are specific anti-porcine  
 10 antibodies, and then you won't be able to use it  
 11 again. And some will develop transfusion reactions  
 12 with the product. And it intended to make your  
 13 platelet count fall in a very predictable way, because  
 14 it also included quite a lot of porcine von Willebrand  
 15 factor which causes human platelets to aggregate.  
 16 **Q.** Was the predecessor at Manchester who used that, are  
 17 you referring to Dr Wensley?  
 18 **A.** I am.  
 19 **Q.** And do you recall the use of porcine product in the  
 20 way that I've just discussed being actively considered  
 21 at Sheffield by Professor Preston or is it that it  
 22 wasn't considered and you're suggesting reasons why it  
 23 might not have been considered?  
 24 **A.** I can't remember it being discussed or considered.  
 25 I only found out about Dr Wensley much, much later.

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1 the state of knowledge progressed very rapidly after  
 2 that.  
 3 **Q.** In terms of the Children's Hospital, and you  
 4 returned -- you were at the Children's Hospital for  
 5 your first 6-month period, August '84 to April of  
 6 1985, can you recall what, if any, discussion there  
 7 was with the parents of patients at that hospital  
 8 about the risks of AIDS?  
 9 **A.** I can't recall. I'm sure we will have discussed it  
 10 with them. But I can't remember the nature of those  
 11 discussions. I'm sure it would, amongst other things,  
 12 have come up during the regular reviews.  
 13 **Q.** Do you or would you agree that the parents of children  
 14 who were receiving factor concentrates that might  
 15 expose them to a risk of AIDS were entitled to be told  
 16 of that risk?  
 17 **A.** Yes, of course.  
 18 **Q.** Now you'd then returned to the Royal Hallamshire  
 19 Hospital in I think April 1985. By that time, what  
 20 was the position in terms of the use of heat-treated  
 21 products?  
 22 **A.** Well, I think Eric had switched over -- in, I think,  
 23 December of the previous year -- as many patients as  
 24 he could to Alpha Profiletate, on the basis that there  
 25 was some evidence of a model virus, which they thought

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1 would be similar to what turned out to be the  
 2 causative agent of AIDS, being heat labile.  
 3 So it was quite a leap, to be perfectly honest,  
 4 but, you know, I was giving the patients the benefit  
 5 of the doubt. This was the safest product we had  
 6 available to them. And there was no direct evidence  
 7 that it was safe from the HIV point of view, but he  
 8 thought that it might be.  
 9 It clearly wasn't completely safe, but from the  
 10 point of view of non-A, non-B hepatitis. But we  
 11 didn't know at that time that the HIV virus was more  
 12 heat labile than the hepatitis viruses, so it was  
 13 actually easier to eradicate it using heat treatment  
 14 methods that might be inadequate for hepatitis.  
 15 **Q.** We know that in December 1984, and you've exhibited  
 16 the statement to the relevant document, UKHCDO  
 17 produced a set of recommendations which included the  
 18 recommendation to use heat-treated product.  
 19 Your statement says, at paragraph 48.4, that  
 20 most Haemophilia Centres were obliged to continue to  
 21 use some untreated concentrates until sometime in  
 22 1985. Was that because of insufficient supplies of  
 23 the heat-treated products?  
 24 **A.** Yes, and some centres still had a preference for  
 25 British products, which was impossible to satisfy,

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1 I think at Sheffield consistently been treated with  
 2 NHS Factor IX concentrate --  
 3 **A.** Yes.  
 4 **Q.** -- do you have any recollection as to the point in  
 5 time at which heat-treated Factor IX concentrate was  
 6 available for the Sheffield patients?  
 7 **A.** Well, I think that they had to use AlphaNine, if my  
 8 memory serves me correctly, which was commercial.  
 9 Because it was later in '85, I think, that 9A  
 10 heat-treated UK Factor IX became available, and in the  
 11 interim the only heat-treated Factor IX available  
 12 would have been commercial.  
 13 **SIR BRIAN LANGSTAFF:** If it helps, it was  
 14 2nd October 1985, that all the Factor IX issued by BPL  
 15 was heat treated. That's my note.  
 16 **A.** Thank you.  
 17 **MS RICHARDS:** I wanted to ask you about the process of  
 18 testing patients for HIV, HTLV-III, at the Royal  
 19 Hallamshire and then, to the extent that you can  
 20 recall, at the Children's Hospital.  
 21 The testing at the Royal Hallamshire, from  
 22 material that we've seen, probably began in late 1984,  
 23 and you'd have been at the Children's Hospital at that  
 24 stage. But we understand from Professor Makris that  
 25 the testing was on the basis of the stored samples.

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1 because BPL had been so slow to even begin to address  
 2 the issue of heat treatment. And what they did, as  
 3 I recall, was to withdraw their unheated products and  
 4 stick them in an oven and heat-treat them, and send  
 5 them back.  
 6 And the first heat-treated product that they  
 7 produced in that way was essentially insoluble, and we  
 8 couldn't use it. So there was, in effect, quite an  
 9 interruption in supply of British products, and it  
 10 took a while to sort out.  
 11 And people were scratching around for any  
 12 heat-treated product they could find. A lot of it was  
 13 unlicensed. And there wasn't enough of it.  
 14 **Q.** Do you know how long it took into 1985 for Sheffield  
 15 to no longer be using untreated concentrates and to  
 16 have exclusively heat-treated concentrates?  
 17 **A.** I can't remember exactly. I have actually looked at  
 18 the annual returns for that year, from the database,  
 19 in anticipation of this question. I couldn't get  
 20 a clear view from that either, because it was quite  
 21 clear that a variety of products were used during the  
 22 course of that year. And that is despite the fact  
 23 that Alpha was supplying preferentially those Centres  
 24 that had participated in their clinical trial.  
 25 **Q.** Then in relation to those with haemophilia B who had

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1 Do you have any knowledge yourself of the  
 2 arrangements that were made for testing patients at  
 3 the Royal Hallamshire for HTLV-III in late '84, or  
 4 early '85?  
 5 **A.** Well, I wasn't there when it all started. I didn't  
 6 remember it being from stored samples. I'm sure that  
 7 stored samples were tested because that gives you  
 8 historical background and a basis on which -- from  
 9 which to tell the patient not only whether they've got  
 10 HIV but when they contracted the infection. It's  
 11 useful to know.  
 12 But my recollection is of patients coming up,  
 13 having a chat, and then having a blood sample taken.  
 14 **Q.** So is your recollection that patients were told in  
 15 advance that they were going to be tested for HIV,  
 16 HTLV-III?  
 17 **A.** Yeah. I mean, it may well be that Professor Preston  
 18 sent stored samples off to Professor Tedder in London  
 19 at a point when the test was very experimental. And  
 20 the difficulty with that sort of thing -- I mean, it  
 21 was difficult enough once the test had been validated  
 22 because when you sit down with the patient and you  
 23 discuss the result, the implications of the test are  
 24 not fully known. So it's quite a difficult  
 25 conversation.

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1 Q. When you returned to the Royal Hallamshire in April of  
2 1985, as far as you can recall, had all the patients  
3 been tested and informed of their diagnosis by then,  
4 or was that an ongoing process in which you were  
5 involved?

6 A. I was never very much involved in that. I think it  
7 was an ongoing process. I don't think they had stored  
8 samples on everybody, but it was undertaken as fast as  
9 they could, I think. And Professor Preston spoke to  
10 the patients in his room, I think, before and after  
11 testing.

12 Q. Your statement suggests, in terms of the numbers who  
13 were found to be infected with HIV, that 24 had HIV,  
14 of which one was under the age of 18. We have  
15 slightly different figures from Professor Makris. Not  
16 radically different, but slightly different. Can  
17 I ask, where has your information come from to --

18 A. Well, my information -- you can imagine, I couldn't  
19 remember those numbers, so I went to the National  
20 Haemophilia Database. He may have a different source.

21 Q. And you're not in a position, from the information you  
22 had, to break it down by reference to whether it was  
23 haemophilia A or B, von Willebrand's and  
24 -- (overspeaking) --

25 A. No.

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1 Sheffield.

2 Q. You were asked in your statement whether work was  
3 undertaken at Sheffield to establish the time period  
4 during which patients seroconverted, and you said in  
5 your answer:

6 "Some stored samples were available in  
7 Sheffield from some but not all patients which enabled  
8 the approximate date of the initial infection to be  
9 determined. I recall that most had been infected in  
10 1982 to 1984."

11 Do you know when that exercise of trying to  
12 establish the dates of seroconversion was undertaken?

13 A. It would have been undertaken very early on, at the  
14 time of initial testing, possibly before the test was  
15 fully validated.

16 Q. And do you have any further information about that  
17 process and what it showed?

18 A. No.

19 Q. Then in relation to the Children's Hospital, so you  
20 were at the Children's Hospital during that last part  
21 of '84 and first part of '85 when testing was becoming  
22 widespread.

23 What, if anything, can you recall about the  
24 process of testing the children at the Children's  
25 Hospital for HTLV-III?

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1 Q. Did you have any involvement in the testing of family  
2 members for HIV at the Royal Hallamshire?

3 A. I honestly don't remember. Family members would have  
4 been offered a test, particularly since it was  
5 recognised from a very early stage that the causative  
6 agent could be sexually transmitted.

7 Q. The process of giving information to patients about  
8 their diagnosis and its significance, that was  
9 undertaken, was it, by Professor Preston, rather than  
10 by you?

11 A. Largely. Though, you know, obviously, I would have  
12 come across these people in clinics, and naturally  
13 they would have wished to discuss it there too. And  
14 as far as partners are concerned, we were all  
15 encouraging patients to bring their partners with  
16 them, to follow-up visits, and certainly to any  
17 discussions about testing.

18 Q. And what, if any, knowledge do you have about  
19 seroconversions from heat-treated products for  
20 patients at the Royal Hallamshire?

21 A. I don't think there were any. Though I am aware that  
22 there was an Armour product used in other centres that  
23 was withdrawn because some patients contracted HIV  
24 from those products, and I think that was the subject  
25 of litigation, but I don't think that involved

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1 A. I don't think they had any stored samples.

2 Professor Lilleyman would have seen all of the parents  
3 individually and arranged testing.

4 Q. So did you have any involvement in the process of  
5 informing parents that their children had tested  
6 positive?

7 A. It's the sort of thing that I think John Lilleyman  
8 would have wanted to do himself.

9 Q. Can I move on, then, to Liverpool, where you took up  
10 your post in 1987.

11 Who was it that you succeeded as director at  
12 the centre?

13 A. Dr BA McVerry.

14 Q. Can you give us an outline of the facilities that the  
15 Liverpool centre offered in 1987?

16 A. Well, the patients came along to the laboratory, which  
17 was in the Duncan Building, which is annexed to the  
18 main Royal Liverpool Hospital building, on the third  
19 floor, and there was a large clinical room in the  
20 middle of that laboratory, and that was the  
21 Haemophilia Centre.

22 We had secretarial support, and I had a junior  
23 member of staff that rotated through thrombosis and  
24 haemostasis as part of the internal hospital rotation.  
25 But there were no other staff. And there was no

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1 haemophilia nurse, no counsellor, no physiotherapy,  
2 and there were no joint clinics.  
3 **Q.** Was it a Reference Centre by 1987?  
4 **A.** No, there weren't any Reference Centres. Well, there  
5 were, but Liverpool was never a Reference Centre.  
6 That was one of the designations from the earlier  
7 days. It did subsequently become a Comprehensive Care  
8 Centre when those were -- that title was designated.  
9 **Q.** And your statement tells us, and again I think you've  
10 taken this from the National Haemophilia Database,  
11 that in 1987 there were 162 patients registered at the  
12 centre.  
13 **A.** Yes.  
14 **Q.** What was your understanding of the approach to  
15 treatment at the centre that had prevailed in the  
16 early part of the 1980s? What products typically had  
17 been used? Do you know?  
18 **A.** I think I've listed some of them. But basically  
19 a mixture of BPL and commercial products.  
20 **Q.** Had there been much use of cryoprecipitate at  
21 Liverpool?  
22 **A.** I don't think so.  
23 **Q.** Do you know whether it had been a user of DDAVP for  
24 mild haemophiliacs and others?  
25 **A.** I think latterly, yes.

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1 proportion of patients had not been registered with  
2 Oxford prior to your arrival in '87?  
3 **A.** Well, in the Liverpool centre I got the impression it  
4 was over 50%.  
5 **Q.** Over 50%?  
6 **A.** Yes.  
7 **Q.** And when you then completed I think you called them  
8 notification forms or something like that in your  
9 correspondence with Ms Spooner --  
10 **A.** Yes.  
11 **Q.** -- were those providing -- or what kind of information  
12 was then provided about the patient to Oxford in those  
13 notification forms?  
14 **A.** Well, the basic notification form just reported the  
15 patient's identifiers and their diagnosis and the  
16 severity of the diagnosis.  
17 **Q.** Did you report, either in relation to that cohort of  
18 patients or more generally, to Oxford, the HTLV-III or  
19 HIV positive status of your patients?  
20 **A.** Yes, you'll come across all of this when you read my  
21 still not completely written report that goes at the  
22 end of this statistical report, but there was -- there  
23 were separate forms for reporting the details of HIV.  
24 And as you've already observed, Dr Craske initiated  
25 that process, and it continued for a number of years.

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1 **Q.** What, if any -- sorry, by the time you got there in  
2 1987, were all the concentrates that were being used  
3 heat treated?  
4 **A.** Yes.  
5 **Q.** Do you know whether any of the Liverpool patients had  
6 seroconverted from heat-treated products?  
7 **A.** Not as far as I'm aware.  
8 **Q.** I think you raised a concern shortly after you arrived  
9 at Liverpool, with Ms Spooner, I think, at Oxford,  
10 that you discovered that there were quite a few  
11 patients who were not registered with Oxford. Is that  
12 right?  
13 **A.** That's correct.  
14 **Q.** Do you know how that had come about?  
15 **A.** Well, I think they were just not very conscientious  
16 about reporting patients. I think it was a voluntary  
17 database, and I think patients commonly weren't  
18 reported. When I took over the database in 2002,  
19 there were only 16,000 registrants, and we now have  
20 well over 30,000. And I don't think that that is  
21 reflecting the birth of new patients; I think it's  
22 reflecting previous historic under-reporting,  
23 particularly of the patients with mild bleeding  
24 disorders.  
25 **Q.** Do you have any recollection of what kind of

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1 So yes, I filled those forms out as well.  
2 **Q.** And did you tell your patients that you were providing  
3 that information about them to Oxford?  
4 **A.** I think that I did.  
5 **Q.** What did you learn at Liverpool about how patients had  
6 been told that they were HTLV-III positive?  
7 **A.** Well, the patients told me. I had very little  
8 information from Dr McVerry himself. They told me  
9 that they had been informed by post.  
10 **Q.** So they learnt they were HTLV-III positive by a letter  
11 from the centre?  
12 **A.** That's right.  
13 **Q.** And in terms of the numbers of patients at Liverpool  
14 who were found to be HTLV-III positive -- I've just  
15 lost the reference to the numbers -- I think you've  
16 said in your statement, in Liverpool 43 patients had  
17 HIV, of whom four were children.  
18 **A.** Yes.  
19 **Q.** And you've taken that from the National Haemophilia  
20 Database rather than any Liverpool records?  
21 **A.** I have.  
22 **Q.** Okay.  
23 **MS RICHARDS:** Sir, I note the time. Is that a convenient  
24 point at which to stop?  
25 **SIR BRIAN LANGSTAFF:** Yes, it is.

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1 We take a break for lunch. Two o'clock, if you  
2 please, professor. Two o'clock, everyone. I'll see  
3 you then.

4 **THE WITNESS:** Thank you. Thank you.

5 (1.01 pm)

6 (Luncheon Adjournment)

7 (2.00 pm)

8 **MS RICHARDS:** Professor Hay, I was asking you about  
9 Liverpool and your work there from 1987 onwards.

10 You were now, as director, responsible for  
11 decisions as to what products to use. What were the  
12 existing contractual arrangements, can you recall?  
13 Was it something that the previous director had done  
14 directly, or was it done regionally?

15 **A.** Well, it was what the previous director had done. It  
16 was done originally because it was a regional  
17 Haemophilia Centre. It covered Mersey Region and  
18 parts of North Wales.

19 He contracted on -- well, through the hospital  
20 purchasing manager, to purchase Factor VIII, and that  
21 would have to be agreed -- or Factor IX -- and that  
22 would have to be agreed with the commissioners.

23 **Q.** And was that then an arrangement that you took over?  
24 So for the years that you were director at Liverpool,  
25 did you undertake the decision-making process and the

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1 **Q.** Were you able to ascertain, either from the patient's  
2 records or from your own discussions with patients,  
3 what kind of information they'd been given in the  
4 preceding years about the risks of non-A, non-B  
5 hepatitis?

6 **A.** The medical records before I arrived appeared poor and  
7 were uninformative, so the short answer is no.

8 **Q.** So did you then discuss non-A, non-B hepatitis from  
9 '87 onwards with your patients when you saw them?

10 **A.** Yes, because we were monitoring for it, and, yes, we  
11 would.

12 **Q.** In relation to risks of AIDS, HTLV-III, HIV, were you  
13 able to ascertain, again either from records or from  
14 your discussions with patients, what information  
15 they'd received before they were tested about the risk  
16 of AIDS?

17 **A.** That was never very clear to me. I obviously spoke to  
18 the patients. They maintained that they didn't know  
19 very much about it and that when they had been  
20 informed of the result, they were not given very much  
21 support because there were very few staff. But  
22 nonetheless.

23 **Q.** And you told us already that they had been informed of  
24 their result by letter.

25 Did you ascertain or become aware of whether

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1 arrangements for the acquisition of commercial  
2 products?

3 **A.** Well, I agreed which products we should use, subject  
4 to the approval of the commissioners who paid for it.

5 **Q.** And by "commissioners" you mean the hospital  
6 authorities, effectively; the fund holders?

7 **A.** Yeah, the fund holders. We had a manager, and we  
8 would negotiate with each of the district health  
9 authorities what they would pay.

10 **Q.** Your statement says you continued with the policy that  
11 had been operated at Sheffield, of using a single  
12 brand of concentrate per patient, if you could?

13 **A.** Yes.

14 **Q.** And what was the basis for the continuation of that  
15 policy?

16 **A.** Well, it just seemed generally good practice. It made  
17 it easier to trace back if there was a problem with  
18 a specific batch of a product. It made it easier to  
19 handle any product recalls that might occur and also  
20 made it much easier to discuss with patients if there  
21 needed to be a change.

22 **Q.** Were you --

23 **A.** And we had to make changes from time to time, as  
24 newer, better products came along, or old products  
25 were withdrawn.

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1 they'd even been told they were being tested for HIV?

2 **A.** I can't remember.

3 **Q.** Was there any system of stored samples at Liverpool?

4 **A.** Before I arrived, there had been, apparently. And  
5 I made specific enquiries about that with Dr McVerry  
6 without any result. I suspect that some of the  
7 patients were tested from stored samples, but I was  
8 never able to obtain the results of those tests.

9 **Q.** So it would follow, I think, from that that you don't  
10 have any information about the periods of time during  
11 which Liverpool patients seroconverted?

12 **A.** That's right. I mean, that's why I made those  
13 specific enquiries. There was nothing left for me,  
14 and he didn't answer my letters.

15 **Q.** Do you have any recollection as to how many, if any,  
16 family members, partners, wives and so on of patients  
17 were HTLV-III positive?

18 **A.** I can't remember, but we certainly offered testing to  
19 all partners, and we encouraged partners to attend  
20 follow-up clinics with their husbands.

21 **Q.** Now, how was the care and treatment of the patients at  
22 Liverpool with HIV, how was it organised from 1987  
23 onwards through to 1994 when you left?

24 **A.** Well, I managed them largely myself, although,  
25 increasingly, I consulted with my STD colleague,

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1 Dr Carey, and occasionally with infectious diseases  
 2 consultants, but they were based at Fazakerley  
 3 Hospital, which was the other side of Liverpool.  
 4 **Q.** What kind of support in terms of counselling or social  
 5 work support was available?  
 6 **A.** Well, when I first arrived, there was nobody but me,  
 7 so I had a lot of -- initially quite difficult  
 8 consultations with these patients who, as you might  
 9 imagine, had many, many questions and required a great  
 10 deal of support. It was a pretty awful time, and  
 11 there was a great deal of uncertainty, and we all had  
 12 a great deal to learn about HIV still.  
 13 From 1988, AIDS money came along, and you'll  
 14 have seen the article in the Haemophilia Bulletin  
 15 about the team that they managed to put together, so  
 16 we then had a counsellor, a social worker and  
 17 a haemophilia nurse specialist, who was quite a senior  
 18 nurse, and they also provided a great deal of pastoral  
 19 support which was most certainly needed.  
 20 **Q.** And in terms of the AIDS money, can you just tell us  
 21 what that was and where it came from?  
 22 **A.** Well, I think it was recognised by the Department of  
 23 Health that a lot of Haemophilia Centres, particularly  
 24 those north of Watford, did not have the wherewithal,  
 25 in terms of staff and specialisation, to deal with

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1 you would always find that the regional Health  
 2 Authority or the local health authorities didn't have  
 3 the money, so there was often a delay. But HIV had  
 4 such a high profile that I don't remember having  
 5 inordinate difficulty getting the funding for that in  
 6 particular.  
 7 **Q.** Now, HCV testing became available whilst you were  
 8 still at Liverpool.  
 9 As far as you can recall, when did the process  
 10 of testing for hepatitis C start and for how long did  
 11 it go on?  
 12 **A.** It started when the second generation of hepatitis C  
 13 antibody tests became widely available, which would  
 14 have been during the course of 1991. Since the  
 15 testing was not clinically urgent -- and so the  
 16 patients weren't all brought in in a big wave but  
 17 tested at the next follow-up clinic, and then they  
 18 would be informed of their result at the follow-up  
 19 clinic following that, unless, of course, they wanted  
 20 to know the result more quickly.  
 21 **Q.** Had there been any use of the first generation of  
 22 tests by you at Liverpool?  
 23 **A.** No.  
 24 **Q.** When the second generation tests became available and  
 25 you started the process of testing, did you tell

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1 this new problem adequately.  
 2 You know, I only learned about the existence of  
 3 haemophilia nurses when the Haemophilia Society sent  
 4 me to one of their weekend annual residential  
 5 seminars. I'd never even met a haemophilia nurse  
 6 until I went along to one of those. So many  
 7 Haemophilia Centres didn't have haemophilia nurses or  
 8 the sort of full infrastructure that we now take for  
 9 granted.  
 10 So the Department of Health made some money  
 11 available which was distributed at a regional level  
 12 for that sort of infrastructure.  
 13 **Q.** And was that money made available on an annual and  
 14 continuing basis, or was it time limited?  
 15 **A.** My understanding was that it would be continuing.  
 16 **Q.** Do you know how the allocation was calculated?  
 17 **A.** I don't -- I can't remember. I do remember having  
 18 conversations with the regional Health Authority where  
 19 they said that they had received an allocation; what  
 20 was my shopping list? So I gave them a shopping list,  
 21 and they agreed to pay for it.  
 22 **Q.** Did you experience difficulties in obtaining funding  
 23 for treatments for HIV and AIDS as those treatments  
 24 became available at Liverpool?  
 25 **A.** Not unduly. Whenever any new treatments came along,

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1 patients that you were going to test them for  
 2 hepatitis C and seek their consent?  
 3 **A.** Well, I think I did tell them, because the context of  
 4 testing them was in the clinic, and this was a new  
 5 test. And, you know, they would also have had  
 6 conversations before then about non-A, non-B  
 7 hepatitis. So those that had abnormal liver function  
 8 tests, or who had been treated with concentrate in the  
 9 past, we would have expected to have a positive test.  
 10 Because this is an antibody test, it doesn't  
 11 tell you whether you've got hepatitis C, only that  
 12 you've been exposed to the virus at some stage in the  
 13 past. So, you know, you'd say to them that you wanted  
 14 to test them for hepatitis C, and you would say to  
 15 a lot of them that you would expect the result to be  
 16 positive.  
 17 There were some where you didn't know whether  
 18 it would be positive or not, and those were the  
 19 patients who had been very infrequently treated in the  
 20 past.  
 21 **Q.** You described that as being a process that was  
 22 undertaken at the regular outpatients appointment. So  
 23 a patient would come in for a scheduled appointment,  
 24 you'd arrange the hepatitis C test, and then you'd  
 25 tell them the results at their next appointment.

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1 What about those who were not attending for  
2 regular appointments because, for example, they were  
3 infrequent bleeders?

4 A. Well, they were brought up to clinic once a year at  
5 that time. Of course, now we follow more and more of  
6 them by telephone. But they were brought up once  
7 a year, and so it would take longer to test them. But  
8 over a 12-month period, you would have picked all of  
9 those up.

10 Q. Can you recall whether there was a cohort of patients  
11 who you were unable to trace who were effectively lost  
12 to follow-up and untested?

13 A. You find that in every centre, and we would chase  
14 those up very actively, particularly when we were  
15 wanting to test them for hepatitis C or any new agent  
16 for that matter.

17 Q. And then when patients were given their results, those  
18 who were tested positive, what information at that  
19 stage, 1991/1992, did you provide to them about the  
20 significance of the positive diagnosis?

21 A. Well, you would have already made some sort of  
22 assessment of their liver disease. These are -- if  
23 they had chronic transaminitis, indicating chronic  
24 liver disease, they would have had things like liver  
25 ultrasound and so on, and so you would be in

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1 of what was understood to be its prospects of success  
2 and in terms of side effects?

3 A. Well, that varied with time. We had already got  
4 experience of using interferon for some haematological  
5 malignancies. So, you know, when we started to use  
6 it, it wasn't without any experience. And interferon  
7 on its own was often not too badly tolerated.  
8 I should emphasise the "not too badly" because most  
9 people got flu-like symptoms and fatigue.

10 When you started to combine it with other drugs  
11 such as ribavirin, and then when you moved on to peg  
12 interferon, the side effects were generally much  
13 worse. And I would have a consultation with the  
14 patients, often several, and I would strongly  
15 encourage them to bring their wife along to the  
16 consultation so that they would hear about the side  
17 effects straight from the horse's mouth. And I would  
18 warn them that depression was an extremely common side  
19 effect and sometimes persisted for weeks or months  
20 after the treatment finished; that most patients  
21 suffered serious fatigue during the course of the  
22 treatment; some lost weight, and that it was extremely  
23 common, for the patient, however sweet natured they  
24 might have been before they went on to treatment to  
25 become extremely tetchy and get into arguments for no

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1 a position to say whether they had probably or not got  
2 severe liver disease or not. And you would have  
3 indicated to them that a proportion of patients can go  
4 on to develop cirrhosis or hepatic carcinoma, but it  
5 was still the minority of patients; that other  
6 patients go for a very long time without progressing  
7 and that, in general, the rate of progression is  
8 relatively slow (some people don't progress) and that  
9 we would have to monitor their liver disease, but they  
10 might need to see a hepatologist and that we were  
11 beginning to experiment with treatment to eradicate  
12 the virus.

13 Q. The first treatment that was available was interferon.

14 Were you using interferon for your patients at  
15 Liverpool, so prior to 1994 when you moved on to  
16 Manchester?

17 A. Yes. Once it was licensed.

18 Q. So it wasn't used on any kind of named patient basis;  
19 only when it was licensed.

20 Were you involved in any clinical trials of  
21 interferon?

22 A. No, I didn't participate in any of the trials. I only  
23 used it when it was licensed.

24 Q. Can you recall what information you gave to your  
25 patients at Liverpool about interferon, both in terms

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1 good reason.

2 It's particularly important to have the wife  
3 present for those sort of discussions so that they  
4 understood that that really was the case and that the  
5 husband wasn't spinning them a line, because these  
6 psychological side effects were very serious. Some  
7 patients committed suicide with the depression. The  
8 number of patients who expressed suicidal ideation to  
9 me ... and the family had to endure this as much as  
10 the patient. There are families whose marriages have  
11 broken up because of those side effects.

12 And then there were the haematological  
13 side effects, in that some patients became  
14 neutropenic, that's a low white cell count, or  
15 anaemic. Some required transfusions or the  
16 administration of growth factors to support their  
17 white cell count. So that you could optimise the  
18 dosage, because it became apparent that if you started  
19 to compromise with the dosage because of  
20 haematological side effects, that reduced the response  
21 rate.

22 And of course, you would discuss the response  
23 rate, which -- really depending on the regime that  
24 you're using and the patient's genotype. And of  
25 course we started with interferon alone for six

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(25) Pages 97 - 100



1 months. And that was successful in some. We were  
2 doing that before we were able to genotype the  
3 patients, but it had a very low success rate.

4 They then moved to interferon alone for about  
5 12 months, and then it was combined with ribavirin.

6 The combination with ribavirin for 12 months  
7 was much more successful, particularly, it turned out,  
8 in people who did not have genotype 1. With  
9 genotype 1, that regime had no better than a 40%  
10 response. And for patients that -- that sort of  
11 information is really important, because you'd  
12 describe the side effects and many patients would say,  
13 "Well, I'm going to hang on and wait for something  
14 better"; which I think, to be honest with you, wasn't  
15 unreasonable. And you wouldn't twist their arm. And  
16 these consultations would often be multiple. Because  
17 of the slow rate of progression of the hepatitis C,  
18 there was no clinical urgency for most of them to  
19 start treatment.

20 If they were developing serious liver disease,  
21 that might be another matter and then you would  
22 involve a hepatologist, a hepatologist might well  
23 already be involved, and their arm would be twisted  
24 a bit more. But ideally, you wanted to treat them  
25 before they developed serious liver disease, to

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1 had now been diagnosed by you with hepatitis C at  
2 Liverpool, what were the varying arrangements for them  
3 to be seen? How frequently were they seen? Would it  
4 depend on their liver disease?

5 **A.** It depended on their liver disease but, as a broad  
6 generalisation, they were seen every six months.

7 **Q.** Did you experience difficulties in Liverpool in  
8 obtaining funding for treatment for hepatitis C?

9 **A.** There were usually delays in getting funding. We  
10 couldn't really apply for funding until the product  
11 was licensed. I had developed a contractual structure  
12 for my patients with haemophilia, which was  
13 a cost-per-case contract, so I charged for each  
14 individual patient, and that contract specifically  
15 excluded certain extras such as interferon, because if  
16 you didn't exclude it, they might expect you to pay  
17 for it out of the allocation that they'd already given  
18 you, even though there wouldn't be enough money to do  
19 that. So you would have to make a separate  
20 application for funding for interferon.

21 And what usually happened was, when this came  
22 along it would be viewed by the health authority as  
23 a financial pressure, they would not have planned for  
24 it in advance, and there was usually a delay of a few  
25 months whilst they found the money for it. But once

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1 prevent serious liver disease from developing. And  
2 also because the response rate was better in people  
3 that didn't have cirrhosis.

4 **Q.** For those patients who were already HIV positive, how  
5 often between 1987 and 1991, 1992, would you be seeing  
6 the HIV positive patients in clinics?

7 **A.** At least every three months.

8 **Q.** Those who then also tested positive for HCV, so those  
9 who were co-infected, were there additional  
10 arrangements put in place for them to be seen, or  
11 hepatology inputs sought at Liverpool?

12 **A.** Well, Professor Gilmore, our only hepatologist at the  
13 time, had his clinic immediately next to mine, and was  
14 always an extremely available, helpful colleague. And  
15 so we had a lot of joint consultations. And if  
16 I was -- if I was concerned that a patient was  
17 developing more serious liver disease, I would ask him  
18 to manage the patient jointly. I would also consult  
19 with him about the changing indications for treatment  
20 during that time, and follow his protocol for  
21 selecting people for treatment, because there were  
22 national protocols for selecting people for treatment  
23 that the hepatologists developed, and he would pass on  
24 to me.

25 **Q.** And for those patients who were not HIV positive but

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1 there was a process in place, you would make an  
2 application and you would get the funding for  
3 treatment usually quite quickly. That was the  
4 process.

5 **Q.** You left Liverpool in 1994. Do you know who took over  
6 as centre director at that point, in Liverpool?

7 **A.** It was Professor Cheng-Hock Toh.

8 **Q.** And then you moved to Manchester. You've given an  
9 indication in your statement of the number of  
10 registered patients in Manchester in 1994, and the  
11 number there was 525. Is it fair to say that  
12 Manchester was one of the largest Haemophilia Centres  
13 in the UK by 1994?

14 **A.** Yes. Again, I think there was probably  
15 under-reporting, or under-registration of the  
16 patients, but I think it was probably about the third  
17 largest Centre in the country.

18 **Q.** Now you mentioned your predecessor there, Dr Wensley.  
19 Is it right that I think there had been a period after  
20 Dr Wensley's departure, before you took up your post,  
21 when Dr Lucas was director?

22 **A.** That's right. A period of about two years.

23 **Q.** Again, could you give an outline of the facilities  
24 that you found at Manchester when you arrived in 1994?

25 **A.** There was a small Haemophilia Centre attached to the

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1 laboratories, which included a storeroom, an office,  
 2 two consulting rooms, and a waiting area. And in  
 3 terms of staff, there was a nurse counsellor, two  
 4 other haemophilia nurse specialists, and that was it.  
 5 Oh yes, a clinical assistant.  
 6 Q. Do you have any knowledge of what the approach to  
 7 treatment had been at Manchester prior to the  
 8 universal availability of heat-treated concentrates in  
 9 the mid-eighties?  
 10 A. I think in Manchester they had been particularly slow  
 11 to switch people to home therapy. I had patients who  
 12 say that they hadn't had concentrate until 1982, and  
 13 they had had a strong preference for BPL products.  
 14 Dr Wensley was jointly employed by the  
 15 Transfusion Service, and only 50% employed by  
 16 Manchester Royal Infirmary. They had used  
 17 cryoprecipitate more than most centres for longer than  
 18 most centres.  
 19 Q. Do you have any sense of how much commercial  
 20 concentrates had been used? A rough proportion as  
 21 between NHS and commercial in the early eighties?  
 22 A. I don't know. I'm not sure.  
 23 Q. Did you have any sense, when you arrived there, of  
 24 what the Centre's approach had been to the response to  
 25 the risk of HIV and AIDS?

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1 A. Well, again, I was led to believe by the patients that  
 2 they had been informed by post.  
 3 Q. And did you know, do you know whether those patients  
 4 had been aware that they were being tested for  
 5 HTLV-III?  
 6 A. I'm not sure about that.  
 7 Q. And you tell us in your statement, again -- well,  
 8 I don't know whether this figure is drawn from the  
 9 National Haemophilia Database or your own records, but  
 10 you've said that there were 83 patients HIV positive,  
 11 of whom ten were under the age of 18.  
 12 A. That's derived from the National Haemophilia Database.  
 13 Q. Do you know, of those patients in Manchester, the  
 14 proportion that were severe haemophilia A patients as  
 15 opposed to moderate or mild?  
 16 A. I couldn't tell you.  
 17 Q. Do you know how many haemophilia B patients were  
 18 infected with HTLV-III?  
 19 A. I'm not sure. But it would have been a smaller  
 20 proportion, given that they were treated only with  
 21 UK concentrate and HIV spread later into the British  
 22 donor population.  
 23 Q. Do you know whether any work had been undertaken in  
 24 Manchester to ascertain the dates of seroconversion?  
 25 A. Yes. This was in the notes, and it was apparent for

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1 A. Well, I get the impression that Dr Wensley was quite  
 2 careful about this. He had, after all, been probably  
 3 the only clinician in the country to have used  
 4 porcine Factor VIII in a patient lacking an inhibitor  
 5 to minimise that risk, and he had -- their whole  
 6 approach to therapy was very conservative. And that  
 7 continued to be the case, to the extent that one of  
 8 the things that really worried me when I took over was  
 9 that I could see that, despite having the -- being the  
 10 third largest Haemophilia Centre in the country, its  
 11 budget was tiny, and the patients were using an  
 12 average of only 25,000 units per patient per year, for  
 13 severe haemophilia.  
 14 Now that compares with about an average of  
 15 300,000 units per patient per year today. But even  
 16 back in 1994, it was, by a margin, the smallest amount  
 17 being used.  
 18 Q. And was there any bank of stored samples, plasma  
 19 samples at Manchester?  
 20 A. None that I was aware. I believe that they had had  
 21 stored samples at some point, but I wasn't aware of  
 22 any when I took over.  
 23 Q. And what, if anything, did you learn about how  
 24 patients at Manchester had been informed of their  
 25 diagnosis with HIV?

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1 some patients, and when they were told about their  
 2 HIV, their -- or had subsequent discussions with my  
 3 predecessors, they were told when they had been  
 4 infected.  
 5 Q. Do you know what the date range was?  
 6 A. It was mostly 1981 through to '84.  
 7 Q. And do you know whether there had been any  
 8 seroconversions at Manchester on heat-treated  
 9 products?  
 10 A. I don't think so but I would not swear to it. I don't  
 11 think any of the products that had been known to  
 12 transmit HIV after heat treatment had been used in  
 13 Manchester.  
 14 Q. Were there partners or other family members who had  
 15 been infected with HIV at Manchester?  
 16 A. Yes.  
 17 Q. Do you recall roughly how many?  
 18 A. A handful.  
 19 Q. When you arrived in 1994, how had the care and  
 20 treatment of the patients with HIV been organised?  
 21 A. In various different ways. Dr Wensley and Dr Lucas  
 22 looked after the bulk of them. Some patients had gone  
 23 to more -- a small handful had gone to North  
 24 Manchester, where they have infectious diseases  
 25 doctors with an interest in HIV.

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- 1 Q. And what arrangements did you then follow over the  
2 next few years from 1994 as director?
- 3 A. Well, the patients who attended North Manchester  
4 continued to do so. Patients left in Manchester,  
5 I continued to look after, increasingly with input  
6 from STD, as the subspecialty of HIV specialist  
7 developed, and then we developed a joint HIV clinic,  
8 particularly once HIV treatment became a little more  
9 complicated. Because in the early days there were  
10 only one or two drugs, and then more drugs came along  
11 and -- to start with, they were all reverse  
12 transcriptase, inhibitors, which -- you know, all  
13 working in the same way, then other classes of  
14 antiretroviral drugs were developed, with different  
15 modes of action, which lent themselves to combination  
16 treatments.
- 17 None of this was as effective as one might like  
18 until triple therapy came along in 1995. Because  
19 a lot of the patients who had had treatment in the  
20 early years, because it was, by modern standards,  
21 suboptimal, that developed some degree of resistance,  
22 and it was, as much as anything, dealing with that  
23 resistance that made it increasingly necessary to  
24 involve more specialist help in their management.
- 25 Q. And what was available in Manchester in 1994, by way

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- 1 assumed that they might have been tested, and it  
2 turned out that they hadn't been, so I didn't make any  
3 assumptions.
- 4 As you've already pointed out, patients with  
5 mild bleeding disorders are seen less frequently and  
6 that, in its own right, may have led to them being  
7 tested later. So if I couldn't find a test, I'd  
8 assume that they hadn't been tested and I would test  
9 them.
- 10 Q. And when would that patient be told their test  
11 results? Would it be at a special appointment or the  
12 next routine scheduled appointment?
- 13 A. You would discuss that with the patient and at the  
14 consultation, because as I think you'll have noticed  
15 from my statement, when I arrived, I discovered that  
16 the mild bleeders were not followed systematically.  
17 This was quite a common practice back in the day. It  
18 was never my practice, nor the practice in any  
19 Haemophilia Centre I'd ever worked in. But in many  
20 cases, because they only need attention every few  
21 years, they would be told their diagnosis and said,  
22 "Well, you know, if you need surgery or you need  
23 advice, contact us and we'll see you."
- 24 Whereas the problem with that was that we'd  
25 suddenly get a communication from a surgeon in some

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- 1 of counselling or social work support?
- 2 A. Well, we had a part-time social worker. We had  
3 a nurse counsellor, and the nurse counsellor would go  
4 to patients' homes and see them in the department.
- 5 Q. Hepatitis C testing in Manchester. When, as far as  
6 you are aware, did that begin?
- 7 A. I think it began in late 1991, and most of it was  
8 conducted in 1992.
- 9 Q. Do you know whether patients had been told in advance  
10 that they were being tested for hepatitis C and their  
11 consent sought?
- 12 A. It's my understanding that they were tested in much  
13 the same way as we tested them in Liverpool and that  
14 they came along to clinic. And this was mentioned to  
15 them as an additional test.
- 16 Q. And by the time you were there in 1994, as far as you  
17 are aware, had the testing process been undertaken for  
18 all the patients?
- 19 A. I assumed that it had not been conducted for all the  
20 patients, and I reviewed that each time I saw  
21 a patient for the first time.
- 22 Q. And so were there --
- 23 A. Sorry. There were patients referred in to me also  
24 from other centres where I had assumed, since, you  
25 know, I'm thinking about 198 -- [audio disruption]

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- 1 hospital without a Haemophilia Centre who wanted to  
2 operate on one of your bleeders whom you didn't know  
3 because they hadn't been seen for ten years. So  
4 I sent an appointment for all of these patients, and  
5 of course everyone moves an average of every  
6 seven years, and so we didn't have current addresses  
7 for a lot of these patients, so it was quite  
8 a struggle to bring those patients in.
- 9 And they needed chasing up, partly because  
10 things had moved on, and partly because they needed to  
11 be tested, and in some cases you couldn't make any  
12 assumptions about HIV either. I don't think I picked  
13 up any new HIV positives in that way, but we certainly  
14 picked up some who had hepatitis C.
- 15 When you asked those patients, "What have you  
16 been treated with in the past?", they'll say, "Well,  
17 I had an injection of some clear fluid back in 1972,  
18 but I can't remember what it was, or I never knew."
- 19 So you couldn't make any assumptions about what  
20 they'd been treated with and had to assume that if  
21 they'd had any sort of treatment, it was potentially  
22 infectious, and so you just tested them all.
- 23 Q. What information would you then typically give  
24 a patient who you were telling for the first time at  
25 Manchester that they had hepatitis C?

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- 1 A. Well, I would already have had a conversation when  
2 I tested them, particularly if they'd -- were one of  
3 the mild bleeders who hadn't been followed up because  
4 those patients would have had zero awareness of  
5 hepatitis C. So they really would need a conversation  
6 about "I'm going to test you for hepatitis C. From  
7 what you've told me of your treatment history,  
8 I either think the risk is very low or I don't know".  
9 And I would arrange to see them sooner, not in six  
10 months' time, and maybe in a couple of weeks if they  
11 were clearly anxious about it.
- 12 Q. Whether at Liverpool or Manchester, these kind of  
13 discussions with patients about testing them for  
14 hepatitis C and then telling them their result and  
15 giving them information about their condition, would  
16 those typically be recorded by you in their medical  
17 notes?
- 18 A. Well, they might be very briefly. I have to admit  
19 that I've never been good at writing in the notes, and  
20 my letters are usually more informative and would  
21 often be copied to the patient.
- 22 Q. What approach did you take, whether at Liverpool or  
23 Manchester, in terms of notifying patients' GPs of  
24 their diagnosis of either HIV or hepatitis C?
- 25 A. Well, we would write to the GP. In the case of HIV,

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- 1 clinic. So we would write to the GP. We would not  
2 specifically ask the patient about that. The patients  
3 knew that we wrote to the GPs every time they came,  
4 and I could not see why they would object to us  
5 letting the GP know.
- 6 Q. What were the arrangements made at the Manchester  
7 Centre for the care and treatment of patients with  
8 hepatitis C from 1994 onwards?
- 9 A. Well, historically, Dr Warns the hepatologist had  
10 a close working relationship with the Haemophilia  
11 Centre and indeed appears as one of the co-authors on  
12 the Stevens paper and had conducted a lot of -- well,  
13 he conducted all of those liver biopsies in that  
14 series.
- 15 The non-serious liver disease we largely  
16 managed on our own. Though, again, as with  
17 Professor Gilmore, we regularly consulted with  
18 hepatology about the criteria to be used in selecting  
19 patients for treatment. And I would often send the  
20 patients to Dr Warnes for hepatology opinion.
- 21 Now, back then -- and I've discussed this with  
22 people from other Centres too. Back then, there were  
23 not so many hepatologists. I don't think the Cardiff  
24 Centre had one, at least until recently, for example,  
25 in the whole of Wales, which is unimaginable. And

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- 1 it was considered very sensitive, so there were  
2 conversations with patients about whether to write to  
3 their GP or not. Almost none of them would object to  
4 you writing to the GP, and we would argue -- well, not  
5 argue, but we would discuss with the patient that the  
6 GP might attend them in an emergency and would really  
7 need to know.
- 8 I did have one patient who lived in Wales who  
9 explained to me that he lived next door to the  
10 doctor's receptionist, and whilst they had very good  
11 relations with their neighbour, he was understandably  
12 worried about confidentiality, and we came to a  
13 special arrangement for him because he could see the  
14 intellectual reasoning for letting his GP know.
- 15 Q. And I think your statement says the special  
16 arrangement was that the GP would keep the records at  
17 the GP's own house so that the receptionist would not  
18 have access to them?
- 19 A. That's right.
- 20 Q. Did you ever tell GPs of a patient's HIV status  
21 without the patient's knowledge and consent?
- 22 A. Possibly. I don't know specifically.
- 23 Q. What about hepatitis C? What was the approach to  
24 notifying GPs?
- 25 A. Well, we wrote to GPs every time a patient came to

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- 1 because there were not many hepatologists, what  
2 hepatologists tended to do was offer an opinion, give  
3 you some instructions and send the patient back.
- 4 For those patients who had serious liver  
5 disease, my desire was that they should be joint  
6 managed with a hepatologist, and if there was any  
7 question about whether they should be treated or not,  
8 I wanted hepatological input.
- 9 Now, when Dr Warnes retired, he was replaced by  
10 Dr Harry, I think, who was far more active. And  
11 subsequently, she was replaced gradually by up to  
12 three hepatologists, and they have basically taken  
13 over all the therapy for hepatitis C. They do joint  
14 manage all our patients who have serious liver  
15 disease.
- 16 And throughout that time, the Liver Clinic  
17 again was immediately adjacent to our own follow-up  
18 clinic, so the patients would often come along to both  
19 clinics the same afternoon, and we had -- it was easy  
20 for us to have joint consultations. Throughout that  
21 time, we had a very close liaison with hepatology.
- 22 Q. I think if we put one document on screen. Soumik,  
23 it's BART0000735, please.
- 24 This is a letter from you to Dr Rejman, the  
25 senior medical officer at the Department of Health in

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1 1985. And we can see from the first two paragraphs  
 2 a problem with funding. You said:  
 3 "You were asking us yesterday to let you know  
 4 of specific problems that we have encountered in  
 5 relation to health authorities paying for alpha  
 6 interferon for the treatment of hepatitis C. Since  
 7 the Secretary of State for Health has gone on record  
 8 in the House as saying that nobody suitable for  
 9 interferon therapy should be denied this.  
 10 "I have to tell you that we have encountered  
 11 consistent problems with two of our Health  
 12 Authorities, namely central Manchester and Trafford  
 13 Health Authority. These two Health Authorities take  
 14 the rather paradoxical view that they were paying for  
 15 haemophilia services before, and we should just absorb  
 16 it within our costs, despite the fact that no  
 17 interferon was prescribed in this practice before the  
 18 product gained its licence."  
 19 It would seem from that that you did experience  
 20 difficulties at Manchester in obtaining funding for  
 21 interferon.  
 22 A. Yes.  
 23 Q. How long did those difficulties remain?  
 24 A. Well, we did eventually get it paid for, but we had  
 25 consistent problems with those two health authorities

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1 Now, what you have here is evidence of the  
 2 Health Authority still behaving as if you've got  
 3 a block contract, even though you haven't. So I was  
 4 trying to stir things up in the background, and we did  
 5 eventually get funding. And in fact, when  
 6 peg-interferon and ribavirin came along, we were able  
 7 to get funding before the liver doctors were.  
 8 Q. I'm going to move on to look at a different issue now,  
 9 Professor Hay, and to ask you some questions arising  
 10 out of recommendations produced by UKHCDO in the late  
 11 eighties and early nineties.  
 12 Soumik, can we have on screen, please,  
 13 WITN3289044.  
 14 And if we zoom in on the first half of the  
 15 page, please. This is a set of recommendations  
 16 exhibited to your witness statement, professor. This  
 17 from 1988 and it's the UKHCDO's or the Reference  
 18 Centre Directors recommendations on choice of  
 19 therapeutic products.  
 20 And I just want to show you a couple of  
 21 passages and then ask you a question about them. So  
 22 in the first paragraph, last sentence, it says:  
 23 "Whilst it is clear that risk can never be  
 24 completely eliminated, major advances have been made  
 25 in risk reduction and physicians are faced with the

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1 because I think -- I mean, the hospital's actually in  
 2 the Manchester Health Authority, but partly because of  
 3 demand, and I guess the patient population, those  
 4 Health Authorities are always short of money.  
 5 I had -- one of the first things I did when  
 6 I took over in Manchester was to move from a block  
 7 contract to a cost-per-case contract on the basis that  
 8 it would be more difficult for Health Authorities to  
 9 refuse an individual than a whole group, and because  
 10 a block contract was open to this sort of abuse.  
 11 If you have a block contract, they give you an  
 12 amount of money that is to cover everything. And  
 13 then, when a new pressure comes along, they say,  
 14 "Well, that's your problem." And of course, your  
 15 block contract will probably not cover all your  
 16 expenses in relation to therapy anyway. And the whole  
 17 of this time, we were trying to increase the intensity  
 18 of treatment to manage the haemophilia better, not to  
 19 mention increasing expenses in relation to HIV  
 20 treatment and the treatment of hepatitis C.  
 21 To give you some idea, a course of  
 22 peg-interferon and ribavirin would cost around £14,000  
 23 back in those days. And we argued that, to be honest  
 24 with you, compared with the cost of the haemophilia  
 25 itself, it was a relatively small amount of money.

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1 problem of choosing between therapeutic products of  
 2 possibly differing risks."  
 3 "The purpose of this paper is to present  
 4 a consensus view of the UK Haemophilia Reference  
 5 Centre Directors on the relative merits of therapeutic  
 6 products ..."  
 7 And then it says the intention is to update  
 8 recommendations.  
 9 Then if we go to the bottom half of the page,  
 10 please. It says this:  
 11 "It must be emphasised that our opinions about  
 12 the risks and therapeutic efficacies of different  
 13 products are based on evidence which is often  
 14 incomplete, and in many cases unpublished. Despite  
 15 these problems, physicians necessarily have to make  
 16 therapeutic decisions in the best interests of their  
 17 patients, within the resources they have available.  
 18 It has always been the case in the UK that such  
 19 decisions have often had to be made without guidance  
 20 from the regulatory authorities. Whilst this  
 21 situation is to be deprecated, it is important for  
 22 physicians to be aware of the legal framework in which  
 23 they prescribe therapeutic products ..."  
 24 And then at the bottom of the page, last two  
 25 lines, it says:

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1 "It is also important to remember that all  
2 manufacturers, including those within the NHS, have an  
3 [go over the page] interest in interpreting data  
4 concerning their own products in the most optimistic  
5 light, and vice versa."

6 I am not going to ask you about the detail of  
7 the recommendations that then follow, professor, but  
8 am I right in understanding that this was the first  
9 time the UKHCDO had formulated detailed  
10 recommendations of this nature?

11 A. Yes, I think it was. It's clearly far more detailed  
12 than the guidance that appeared in 1983 and '84.

13 Q. Does it surprise you -- and you obviously weren't  
14 a Reference Centre Director at this time, but you were  
15 now a member of UKHCDO -- does it surprise you that it  
16 took until 1988 for there to be something along these  
17 lines: detailed recommendations in which an attempt is  
18 made to analyse the risks associated with individual  
19 products? It took that long for this to be produced?

20 A. Well, not necessarily, because prior to the advent of  
21 viral attenuation there really wasn't a great deal to  
22 pick between the different brands of concentrate. It  
23 may well have been that there were differences, but in  
24 the absence of testing, you couldn't discern what  
25 those differences were. That is to say, the products

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1 so I wouldn't be overly critical that this is the  
2 first guidance because, to be honest, this therapeutic  
3 landscape had really only just emerged.  
4 Q. This document deprecates the absence of guidance from  
5 what's loosely described as regulatory authorities,  
6 and certainly it could be said that the picture that  
7 emerges from the first half of the eighties is of  
8 clinicians having to take their own decisions about  
9 how to respond of risks, whether it be of hepatitis or  
10 HIV.

11 Do you think it would have been helpful for  
12 there to have been some form of central guidance,  
13 whether from the Department of Health or the Chief  
14 Medical Officer or some other authority or agent,  
15 rather than clinicians in the hundred or so Centres  
16 across the countries being left to make up their own  
17 mind?

18 A. Yes, I think it would have been helpful.

19 Q. Some of the documents that we've seen, and you've  
20 touched on it in your statement, refer to a debate  
21 about the use of high-purity products and the  
22 availability of funding for such products. I'm not  
23 going to go to any of the documents in relation to  
24 that, but could you just briefly outline for us what  
25 the situation was in relation to so-called high-purity

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1 that were available may have carried different risks  
2 but that had been even less well quantified than it  
3 was at that point, whereas here we finally have  
4 concentrates that have been virally attenuated and  
5 purified in different ways, and clinical trials have  
6 been conducted to try to evaluate the safety and  
7 efficacy of those products, so there is far more  
8 evidence on which to formulate a recommendation. And  
9 even so, they are, I think quite rightly, stressing  
10 the limitations of the data that they have available  
11 to them.

12 In later evidence they would adopt an even more  
13 evidence-based approach to guidance where each  
14 recommendation would be given a scoring for the  
15 strength of evidence upon which it's based.

16 One of the big problems assessing the safety  
17 and efficacy of therapeutic products for haemophilia  
18 is that it's a rare disease. If you look at clinical  
19 trials of things like heparin, it starts with -- you  
20 take 10,000 people who are having hip replacement and  
21 they all followed this regime. With haemophilia  
22 you're lucky if you have a clinical trial with  
23 100 people in it. That would be a large trial, but in  
24 statistical terms it's small.

25 So many of these trials were really small, and

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1 products and what the difficulty was in terms of  
2 securing funding.

3 A. Well, in the early days of HIV, when we didn't have  
4 a test for HIV, patients were being monitored  
5 clinically, because it's a clinical diagnosis. But in  
6 the laboratory there were one or two surrogate tests  
7 you could do. You could test their CD4 count, the  
8 T-helper cells, and the lymphocyte count and the blood  
9 count in general.

10 Now, when a test emerged, it became obvious  
11 that some of those patients that we'd been monitoring  
12 in this way, not knowing whether they had been  
13 infected with the AIDS virus or not, nevertheless had  
14 a low CD4 count. And so there's a lot of debate about  
15 that, and I published the odd paper about it. And it  
16 was concluded that it was probable that there were  
17 contaminants in the concentrate, maybe immunoglobulin,  
18 perhaps other growth factors, that interfered with the  
19 immune system in a non-specific way.

20 So when higher-purity products came along, they  
21 noticed that they didn't seem to cause this problem.  
22 The higher-purity products were developed partly  
23 because we wanted the product to be as pure as  
24 possible anyway. If you looked at an old-fashioned  
25 bottle of Factor VIII from the days of intermediate

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1 purity, there would be a bottle about this size, with  
2 250 units in, a great big cake of protein at the  
3 bottom, and if you were able to take out all the spare  
4 bits that you didn't want, it would look like an empty  
5 bottle. The Factor VIII in that was just a trace.  
6 All the rest was fibrinogen and immunoglobulin and  
7 goodness knows what else.

8 And the high purity was developed partly  
9 because we wanted purer products, but also because  
10 they realised that one of the problems heat treating  
11 and so on was it was a low-purity product. And if you  
12 had a higher-purity product, you could virologically  
13 treat it more aggressively. So that's why it was  
14 developed.

15 But then with all this background of  
16 immunological abnormalities in people who didn't have  
17 HIV, we began to wonder whether it would make  
18 a difference to the progress of HIV. And there were  
19 one or two studies that were done that suggested that  
20 patients treated with high purity Factor VIII  
21 progressed in their HIV more slowly, and so that was  
22 the bigger rationale.

23 There were a number of reasons for wanting to  
24 adopt these products. We suspected that they might be  
25 virologically safer. They were certainly easier for

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1 necessary funding to use high-purity products or to do  
2 so as quickly as they would like.

3 **A.** Yes, that's right. I think the difficulty is that, to  
4 be honest with you, the evidence that influenced the  
5 rate of progression of HIV was not strong. Some of  
6 the evidence, if you'd taken it to its logical  
7 extreme, would have implied that we should give this  
8 high-purity Factor VIII concentrate to people who had  
9 acquired HIV in other ways and who didn't even have  
10 haemophilia because they seemed to progress more  
11 slowly than any other group.

12 **Q.** In terms of hepatitis B, to what extent at Sheffield,  
13 Liverpool, or Manchester, did you encounter patients  
14 who had hepatitis B and required treatment?

15 **A.** Well, in all of those Centres, we had a handful of  
16 chronic carriers. I actually needle stuck myself from  
17 one of them and had to have immunoglobulin. There  
18 were not many because although a high proportion of  
19 the patients, particularly with severe haemophilia,  
20 had been exposed to hepatitis B through their  
21 concentrate -- I think in my report, I quote the  
22 figures from my MD thesis where I found that 80% of  
23 the patients in Sheffield with severe haemophilia had  
24 been exposed to hepatitis B, and 40% of the non-severe  
25 patients.

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1 the patients to use, being higher purity, smaller  
2 volume, quicker to dissolve, the patients liked them.  
3 And finally, they might have clinical benefits for  
4 people with HIV. So I certainly canvassed for that.

5 **Q.** And I think you did introduce or you were able to  
6 introduce high-purity products at some stage when you  
7 were in Liverpool?

8 **A.** Yes, yes. I was able to do that quite quickly. There  
9 was very little resistance from the commissioners.  
10 The difficulty was I think the first product that came  
11 on the market was Monoclalte and Mononine from Armour.

12 One other thing they did at the same time,  
13 which is of interest I think to the Inquiry, was that  
14 they obtained the plasma only from the American  
15 Midwest. They stopped obtaining plasma from  
16 California and New York because those were HIV  
17 epicentres.

18 The equivalent in the UK would have been if  
19 they'd stopped obtaining plasma from London, but  
20 I don't think that was ever very actively discussed  
21 anyway. Yes, so, I managed to get them. And when  
22 I moved to Manchester, we switched over very quickly.

23 **Q.** And without going into the detail of what we see in  
24 a number of the documents, some Centres had great  
25 difficulty, it seems to be suggested, in obtaining the

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1 But fortunately, with hepatitis B, the chronic  
2 carrier rate is quite low. Only 5 to 10% become  
3 chronic carriers. Most get over their infection and  
4 it resolves, and it's only the chronic carriers who  
5 have the propensity to develop chronic liver disease.

6 **Q.** And did you have responsibility for the care of any  
7 patients who did develop chronic liver disease as a  
8 result of hepatitis B?

9 **A.** Yes. At least one of them underwent liver  
10 transplantation in Manchester. Treatment -- we used  
11 interferon and various other agents with hepatitis B  
12 started probably earlier than with non-A, non-B  
13 hepatitis. But I referred all of those patients to  
14 the hepatologist because the treatment was different,  
15 and there was never likely to develop much experience  
16 in hepatitis B therapy.

17 **Q.** And to what extent did you encounter, again, whether  
18 at Sheffield, Liverpool or Manchester, cases of  
19 patients being infected with parvovirus?

20 **A.** Well, parvovirus is a common childhood illness, and  
21 I don't recall any of my patients developing it,  
22 though it's possible I might have missed it. Some of  
23 the reports, there must have been active surveillance  
24 going on because the patients were asymptomatic.

25 90% of the adult population have already been

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exposed to parvovirus. It causes fifth disease, characterised by the classic slapped face rash, I remember I got it along with my two children when I was already a senior lecturer. It can be a nasty illness if you get it in adulthood because you can get transient arthropathy.

The significance of this in the haemophilia story is that parvovirus is a protein-coated virus, and it's relatively resistant to viral attenuation techniques, and so those isolated outbreaks of parvovirus are clinically unimportant, but they illustrate the limitations of the viral attenuation techniques, and this, along with various other agents like prions, are also extremely resistant to viral attenuation. It's probably impossible. These sort of things form a cornerstone of the argument for recombinant Factor VIII.

**MS RICHARDS:** Which is going to be my next topic, professor, but I note the time, sir, and wonder whether this would be a convenient moment for the afternoon break?

**SIR BRIAN LANGSTAFF:** Yes, it would. We'll take a break now, until 20 to four. So 20 to four.

(3.09 pm)

(A short break)

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plasma-based concentrates. Is that what happened with your patients as well?

**A.** Yes, yes. And that's an unusual situation because the company, I think probably reasonably, won't continue to provide it for nothing once it's a fully licensed product, but they will continue to supply, even though the trial has finished, until it's fully licensed. So in some cases, the patients would have been treated with recombinant Factor VIII for maybe two or three years, and then all of a sudden they're in a position where they have to go back to the old stuff for financial reasons.

**Q.** Then 1996, it became the policy of UKHCDO to recommend recombinant for all; is that right?

**A.** That's correct.

**Q.** And I don't think we need to go to it, but that was the recommendation in the later iteration of the guidance that we looked at earlier this afternoon.

**A.** Yes, it was. Although we announced the policy before we published the guidance.

**Q.** Although that was the recommendation, funding was not available for recombinant.

**A.** Yes.

**Q.** What steps were then taken to your knowledge to try and obtain funding for recombinant?

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(3.38 pm)

**MS RICHARDS:** Professor Hay, I'm going to ask you about the issue of recombinant next. And I'm going to ask you to assist us with an overview of -- a chronological overview of the attempt to obtain funding for recombinants and the various impediments and how it was ultimately resolved.

I think if we could pick it up in this way: what was the first point at which recombinants became available for use in clinical trials?

**A.** Well, I used it in clinical trials both in Liverpool and in Manchester. Those were Phase III clinical trials, so there would have been Phase I and Phase II before then. And that would have been 1993 and '94 and '95.

The advantage of Phase III is they need larger numbers, and it was the only way the patients could get access to recombinant. And the general agreement was that they would be allowed to continue on a trial product until it got licence, but then the difficulty was nobody would pay for it.

**Q.** And we've certainly come across experiences in other centres with patients who were part of that trial and receiving recombinants and then, because of the absence of funding, were expected to revert back to

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**A.** Well, we had negotiations with the companies to ask them to reduce their price, which didn't go very far. We spoke to the Department of Health, and a meeting was organised between the Haemophilia Society, myself, Professor Hill and Lord Hunt, who was the junior minister with responsibility for our clinical area at the time, to make representations to him. The patients campaigned very actively, to the extent that I remember parents chaining themselves to the railings of the Children's Hospital at one point. You can imagine the parents were particularly keen. Understandable.

I think -- well, the difficulty was the Department of Health wouldn't accept the viral safety argument. We were arguing that given everything that had happened in the past with various viral agents that, by the time they were recognised, it was too late, that we wanted to give the patients the benefit of the doubt. There had been several episodes of odd infections here or there that had shown that the viral attenuation techniques, whilst very effective were not completely effective, and we were worried that some new agent might come along.

**Q.** And I think the way you've put it in your statement is that UKHCDO argued there'd been an outbreak of

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1 hepatitis A, that there was evidence of parvovirus  
 2 transmission, and there were concerns about prions,  
 3 and that there may be other unknown pathogens  
 4 resistant to heat treatment.

5 **A.** Yes. The physical treatment required to inactivate  
 6 prions would completely denature Factor VIII. So it's  
 7 theoretically more or less impossible to attenuate  
 8 that.

9 **Q.** There came a point when the Department of Health  
 10 agreed to fund recombinant for patients under 18; is  
 11 that correct?

12 **A.** That's correct. Though, interestingly, they did not  
 13 -- they still didn't concede the viral safety  
 14 argument. They said that they were only doing this to  
 15 allay the concerns of the parents, so that allowed  
 16 them to climb down in a limited way whilst still not  
 17 changing the argument. And so, under the age of 18,  
 18 by the time the next stage came along, those  
 19 18-year-olds were in their early 20s.

20 **Q.** And that was, I think, 1998, and there was now  
 21 recombinant Factor IX available, so children with  
 22 haemophilia A and haemophilia B were able to access  
 23 recombinant from around 1998 onwards.

24 **A.** That's right.

25 **Q.** There was an issue that arose, I don't know whether

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1 a product licence is not just licensing the end  
 2 product. You also licence the process which is then  
 3 set in tablets of stone, and that process involves,  
 4 amongst other things, auditing each step of the  
 5 process, and that's where they were a little lacking.

6 So this was a huge problem because at that time  
 7 the only suppliers were Baxter and Bayer and Wyeth,  
 8 who were marketing ReFacto at that time, and so the  
 9 supply of recombinant Factor VIII effectively halved  
 10 to the whole world overnight. And this, amongst other  
 11 things, is a reflection of why so many of us have  
 12 a policy of not putting all our eggs in one basket,  
 13 because there were some Centres that only used  
 14 Kogenate which was that Bayer product, so their supply  
 15 wasn't cut in half overnight; they had no supply at  
 16 all.

17 And the other manufacturers would naturally  
 18 favour their existing customers. So I, as  
 19 Vice-Chairman of UKHCDO, organised a system of supply  
 20 swaps which had to be agreed with both the clinician  
 21 and the supplier, who would often have an existing  
 22 contract, so that we could shift supply from one  
 23 Centre to another, to at least enable the younger  
 24 children to remain on the recombinant. Because,  
 25 otherwise, you would have had the situation where

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1 you can assist us with this, about non-availability of  
 2 recombinant because of shortages of supply due,  
 3 I think, to circumstances in a manufacturing plant in  
 4 the States. Can you recall when that was?

5 **A.** Yes, I can. I mean, firstly, it's worth remembering,  
 6 because it speaks to the issue of the adequacy of  
 7 supply, that when the children went on to recombinant  
 8 in 1998, we were unable to do it fully for a period of  
 9 six months because it took that long for the  
 10 manufacturers to wind up the supply to this country,  
 11 because any supply that we were getting was in  
 12 competition with other countries. And one of the  
 13 problems that we've had negotiating lower prices until  
 14 relatively recently has been that it's been  
 15 a suppliers' market. There has been a shortage of  
 16 manufacturing capacity. That's no longer the case,  
 17 but it was the case for quite a long while.

18 Now, I think the specific episode that you're  
 19 referring to is the recombinant shortage starting,  
 20 I think, about 2001 and lasting for two years when  
 21 Bayer had an inspection of their Berkeley plant in  
 22 California and their paperwork was not adequate.  
 23 There was no suggestion that the product was unsafe.  
 24 But whilst they sorted out their auditing processes,  
 25 they were not allowed to issue a new product. Because

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1 you'd have whole Centres where all of their kids would  
 2 have had to go back to plasma derived. It was  
 3 a compromise, obviously. One would have preferred to  
 4 have kept all of them on recombinant, with that  
 5 supplier. And we also negotiated as fast as we could  
 6 for the other suppliers to increase their supply.

7 **Q.** Did it follow, however, that there were children, and  
 8 probably in particular older children, for whom  
 9 recombinant was no longer available and they had to  
 10 revert to using plasma-based products?

11 **A.** They would have been predominantly older children.

12 **Q.** Now, your statement explains that in 2003, the  
 13 Department of Health finally decided to make available  
 14 funding for patients to switch to -- now adult  
 15 patients to switch to recombinant products; is that  
 16 right?

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

18 **Q.** And what, if any, sense did you have in your capacity  
 19 as Vice Chair of UKHCDO, of the reason for the  
 20 Department's decision at that stage?

21 **A.** Well, we were all a bit puzzled. I don't know why it  
 22 happened at that point, to be honest, because nothing  
 23 much had changed. We were just very grateful, though  
 24 with slightly mixed feelings because, as you know and  
 25 I guess we're going to talk about it, the funding for

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1 that was staged.

2 **Q.** Yes. Can you explain what the situation was, then, in  
3 terms of the staging and the judgments that had to be  
4 made?

5 **A.** Off the top of my head, I can't remember the amounts.  
6 But in the final year, 44,000 -- sorry, £44 million  
7 was required. The problem financially, to put it into  
8 context, was that recombinant Factor VIII being  
9 recombinant attracted 20% VAT, whereas through some  
10 tax anomaly, plasma products are VAT exempt. And the  
11 unit price was twice as high, so recombinant products  
12 were very much more expensive than the plasma derived  
13 ones. So we needed a financial uplift to be able to  
14 change it.

15 Now, unfortunately, they staged a payment over  
16 three years, and it was very much backloaded. So  
17 I think there was something like 15 million made  
18 available in the first year, 22 million in the second.  
19 The figures may be wrong but the order of magnitude is  
20 about right.

21 And we had to devise a system to prioritise the  
22 patients. But, of course, naturally that gave rise to  
23 trouble. Because we and the Department of Health, you  
24 know, we'd have preferred not to have been in that  
25 position. We would have much preferred to have

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1 Now, the problem with bundling is that they  
2 might take three separate items of expenditure each  
3 costing, say, 10 million, and tell people to buy all  
4 that with 25 million. It's often a mechanism for  
5 actually cutting the funding. And we were very  
6 worried that that would cause us to have to revert to  
7 plasma derived which would have caused a storm of  
8 protest from everybody, not least the medical  
9 profession.

10 **Q.** You were asked in your statement the question, "Should  
11 recombinant blood products have been made available to  
12 all earlier than they were, and if so when?"

13 I'm just going to read out your answer and see  
14 if you have anything to add. You said in your  
15 statement:

16 "Yes. It was UKHCDO policy that we wished to  
17 treat all our patients with recombinant Factor VIII  
18 from 1996 and for haemophilia B from 1998, when  
19 recombinant Factor VIII and then recombinant Factor IX  
20 became available. We wanted to give the patients the  
21 benefit of the doubt about safety based on the unknown  
22 virus hypothesis. Having been at least thrice bitten  
23 by previously unknown viral pathogens and knowing that  
24 some pathogens were difficult (protein-coated viruses  
25 such as parvovirus and HAV) or impossible (prions, the

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1 switched all the patients at once. But the  
2 Birchgrove Group, I think it was, objected to us  
3 prioritising younger patients, and they felt that  
4 those patients with HIV should start on recombinant  
5 first. We felt that the patients least likely to have  
6 been exposed to viruses should logically start first,  
7 and that was the Department of Health view. And so we  
8 segregated according to age.

9 **Q.** And how long did it take, then, for recombinant to be  
10 available to all patients who wanted it, but by what  
11 year was that process complete?

12 **A.** By 2006.

13 **Q.** And you've said in your statement that towards the end  
14 of the recombinant roll-out to adults, it became  
15 apparent that funding might not be secure. What can  
16 you recall about that?

17 **A.** Well, what I think we were told was that the funding  
18 was separate; it was a separate uplift. We negotiated  
19 special contracts with all the suppliers that actually  
20 reduced the unit price and enabled us to roll things  
21 out slightly quicker. It was a very complex process.  
22 But towards the end, the Department of Health  
23 indicated to us that the money was going to be handed  
24 over to regional and district Health Authorities but  
25 that it might be bundled with other items of spending.

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1 cause of vCJD and classical CJD) to inactivate, we  
2 wish to treat the patients with a product that should  
3 theoretically be free from all human pathogens."

4 Is that right, and is there anything that you  
5 would add to that?

6 **A.** The only thing I would add to that was, whilst you're  
7 reading it out it occurred to me that, actually,  
8 I think prions were the final nail in the coffin, as  
9 far as the Department of Health's argument that we  
10 should not change over to recombinant, because there  
11 could be no certainty about the clinical significance  
12 of variant Creutzfeldt-Jacob disease at that point in  
13 time.

14 **Q.** You've also said in your statement that the  
15 department's position which you described -- in other  
16 words, that they didn't accept that recombinant  
17 Factor VIII or IX was not safer than plasma derived  
18 Factor VIII or IX -- has never changed to your  
19 knowledge; is that right?

20 **A.** Well, as far as I'm aware, that's the case.

21 **Q.** Professor Hay, that leads us on to vCJD. There are  
22 quite a few documents I might need to ask you to look  
23 at.

24 I'm going to start, sir, with a couple and then  
25 perhaps leave the rest until tomorrow morning.

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1 **SIR BRIAN LANGSTAFF:** Yes.

2 **MS RICHARDS:** So, in terms of the vCJD notification  
3 process, I just wanted to start in 1997 with --  
4 I think this is the right reference, Soumik --  
5 HSOC0015148.

6 Yes, I think I might have put in an extra  
7 digit. HSOC0015148.

8 So this is a letter dated 26 November 1997.  
9 It's co-authored by you, and it reads as a letter sent  
10 to patients. You say:

11 "I'm writing to you following the recent  
12 Panorama programme and in anticipation of further  
13 press reports to outline the current situation in  
14 relation to this condition [ie new variant CJD]. I  
15 would also like to keep you informed of the measures  
16 which we've decided to take at the Manchester  
17 Haemophilia Centre and the reasons for these."

18 You then talk in the next paragraph about what  
19 CJD is, and the infective agent being thought to be  
20 a prion. You say in the last two sentences of that  
21 paragraph:

22 "There is no evidence that CJD can be  
23 transmitted by blood or blood products. Furthermore,  
24 there have been no reports of classical CJD in  
25 patients requiring regular blood transfusion or in

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1 plasma with white cells removed and do not transmit  
2 infections associated with white cells like glandular  
3 fever or cytomegalovirus and may not therefore  
4 transmit new variant CJD."

5 Then you talk about the possibility of  
6 inactivation.

7 Then this:

8 "The Haemophilia Centre Directors concluded  
9 that there was most likely to be little or no risk of  
10 infection with [new variant] CJD from blood products.  
11 Since there can be no absolute certainty about this  
12 for some time it was felt that until the results of  
13 the DOH risk-assessment were known, that blood  
14 products of UK origin should be temporarily phased  
15 out. In their place, products manufactured from  
16 plasma taken from areas free from BSE and [new  
17 variant] CJD such as the USA will be used. There are  
18 currently inadequate supplies of these American  
19 products in the UK and so we plan to replace Replinate  
20 and Repline with alternative products as stocks run  
21 out."

22 Then you offer patients the opportunity to call  
23 the Centre and then you say you've arranged for  
24 a meeting at the main lecture centre at the Manchester  
25 Royal Infirmary on 11th December "to present the

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1 patients with haemophilia."

2 If we then go over the page, second paragraph,  
3 you then talk about new variant CJD. You explain it's  
4 different from classical CJD, appears to affect young  
5 people, and you describe how it's caused.

6 And then in the next paragraph, you go on to  
7 say that:

8 "There's a very small theoretical possibility  
9 that new variant CJD might be transmitted by blood  
10 transfusion, although experience would suggest that  
11 only a small number of susceptible individuals would  
12 be at risk. In light of this, the Government has been  
13 advised to consider the possibility of filtering out  
14 all the white cells from whole blood and is currently  
15 commissioning an independent risk assessment which  
16 will take six months to report.

17 "Three weeks ago, BPL withdrew a batch of 8Y  
18 Factor VIII concentrate because two of the donors had  
19 developed new variant CJD. Neither of the Manchester  
20 Haemophilia Centres have used these batches."

21 Then you say this:

22 "Last week, the executive committee of the UK  
23 Haemophilia Centre Directors met with experts in CJD  
24 and plasma fractionation to consider the problem.  
25 Blood products like Factor VIII are already made from

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1 evidence and discuss the matter, to which you are  
2 invited".

3 Was this, in 1997, the first main action taken  
4 by UKHCDO and then directors such as yourself in  
5 response to the developing knowledge about new variant  
6 CJD?

7 **A.** Yes.

8 **Q.** Did the meeting you've described in that last  
9 paragraph take place?

10 **A.** Yes.

11 **Q.** And what can you tell us about that meeting?

12 **A.** To be honest I can't remember that meeting but it  
13 certainly took place. I think it was well attended,  
14 and we would have had a question and answer session.  
15 I would have made a presentation about what we did and  
16 did not know.

17 **Q.** Can you recall what the reaction of patients was to  
18 news of a further potential threat to their wellbeing,  
19 and the news that there was going to be a reversion  
20 from UK-sourced blood products to US-sourced blood  
21 products, in some respects, the reverse of what had  
22 previously happened. How did patients respond to  
23 that?

24 **A.** Well, as you might imagine, their responses were very  
25 varied. We always -- well, we knew, because of the

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way that prions work, that only perhaps a third of the patients would be susceptible. Those are the ones who are homozygotes. And so -- of course, we didn't know who was homozygous or heterozygous, but we did know that it was unlikely that it would be like hepatitis C or HIV and infect people indiscriminately. There were theoretical reasons for thinking that in this particular instance, the risk of transmission by clotting factor concentrates would be low. But having learned from past experience, I felt that it was important to emphasise what we did not know. Patients understand that. And in my experience it's much better to say, "You know, this is not known, it may take years to know", than to offer them some sort of speculation that they may take away as hard and fast fact which might turn out to be untrue.

I go into my -- in my report I go into the reasons why we felt that concentrates would be much less likely to transmit this agent than a whole unit of blood. And I would describe that to patients, but I would also say, "You know, we'll just have to keep an eye on everybody that has had these products, because there may be no certainty about any of this for maybe ten or 20 years."

And some of the patients got very distressed.

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much involved from an early stage thereafter.

**Q.** I want to pick up a document trail from 2004 onwards with you, and I'll do that tomorrow morning, because there are then a range of notifications from 2004 onwards with which you were closely involved in your capacity as vice chair and then chair of UKHCDO.

But before we do that, can you recall, for after 1997 and prior to 2004, what further processes there were involving patients and providing information to patients?

**A.** Well, the reason for doing this by letter, and then following up with a meeting rather than to do it individually, was because the press were finding out about it, and we needed to get to speak to the patients as quickly as we possibly could. As many of the consequent conversations as possible were done on an individual basis, mostly in clinic but sometimes in the Centre.

Many of these conversations were quite protracted because some of the concepts involved, for example the concept of the public health risk, were very difficult for doctors to understand, let alone laypeople. And I think caused a lot of confusion. So, yeah.

**MS RICHARDS:** Sir, I'm conscious of the time. There are

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Others were quite philosophical, and probably went away with the relative reassurance that they'd been provided. At the end of the day at this point we didn't even have any evidence that variant Jakob-Creutzfeldt Disease could be transmitted by blood, let alone the other products. This was in relation to discovering variant Jakob-Creutzfeldt Disease in donors of blood and the recognition that, histologically, one of the ways in which variant Jakob-Creutzfeldt Disease differed from classical Jakob-Creutzfeldt Disease is that you could demonstrate the prion protein in the lymph nodes and in lymphocytes, which are obviously elements of the blood system, whereas classical Jakob-Creutzfeldt disease is found in the central nervous system and you don't find it elsewhere. So that raised, at quite an early stage in our knowledge of the condition, the theoretical possibility that it could be transmitted by certainly whole blood, less certainly plasma.

**Q.** This letter refers to the UKHCDO Directors Executive Committee having met with experts in CJD and plasma fractionation. At this stage, was there any particular involvement or direct involvement from the Department of Health in those deliberations?

**A.** I don't remember so -- but they were certainly very

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quite a few documents I think it will be useful to look at with Professor Hay on the CJD notification process from the UKHCDO perspective, but it might be more sensible to pick those up in the morning.

**SIR BRIAN LANGSTAFF:** Well, I think it's important evidence. It's late-ish in the day. I'm sure, professor, you've had a longish day. Can we meet again at ten o'clock in the morning?

**THE WITNESS:** Sure. Certainly.

**SIR BRIAN LANGSTAFF:** And the same rules apply as applied at every break during the day, but have a good evening and stay safe, and the same to everyone else.

I look forward to meeting you, Ms Richards, tomorrow at ten. You heard what I had to say earlier this week about the attendance of others at the hearing centre following what I imagine will be the acceptance of Parliament of the Government's proposals today about coronavirus.

Thank you very much.

**MS RICHARDS:** Thank you, sir.

**THE WITNESS:** Thank you.

(4.08 pm)

(The hearing adjourned until 10.00 am the following day)

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11/20 27/3 27/5 42/2	36/18 37/7 38/2 38/14	77/23 78/6 78/12	95/12 96/2 96/11	<b>historically [1]</b> 115/9	30/17 30/22 31/1 31/5
46/11 46/15 54/4	38/25 43/13 49/10	78/16 79/5 79/10	96/14 96/24 97/15	<b>history [3]</b> 47/11 63/8	31/6 31/9 31/14 32/9
54/23 55/24 56/4	75/11 89/8 119/9	79/11 82/19 86/6	101/17 103/1 103/8	113/7	33/7 33/13 36/5 44/16
56/10 57/9 64/18	130/2 140/21 148/2	105/8 108/8	110/5 110/10 112/14	<b>hitherto [1]</b> 46/12	60/2 68/22 69/6 69/9
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34/14 34/15 84/24	44/17 44/19 44/20	38/10 38/22 39/6	<b>hepatological [1]</b>	95/3 102/4 102/6	68/22
<b>half [12]</b> 9/18 37/1	45/1 45/2 51/18 51/21	41/20 41/22 45/15	116/8	102/25 105/25 106/25	<b>hospitals [1]</b> 3/1
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108/23 127/15	94/10 94/18 95/1 95/2	38/4 39/4 39/20 40/5	145/4	112/13	92/22 94/16 95/10
<b>handle [1]</b> 90/19	103/22 116/25 117/5	40/8 41/15 42/6 42/14	<b>high [13]</b> 4/9 25/7	<b>hm [1]</b> 28/16	102/4 103/3 105/19
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<b>hang [1]</b> 101/13	118/4 118/8 119/2	43/15 43/25 44/13	126/6 127/1 127/8	<b>hold [2]</b> 7/22 23/8	130/7 138/9 142/5
<b>happen [2]</b> 1/8 33/5	123/13 132/3 132/14	44/21 44/24 45/3 46/3	127/18 137/11	<b>holders [2]</b> 90/6 90/7	144/22
<b>happened [9]</b> 61/7	133/9 136/13 137/23	46/6 46/9 46/9 46/11	<b>high-purity [5]</b> 123/21	<b>home [32]</b> 5/5 5/9 5/9	<b>however [5]</b> 27/8
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103/21 131/1 132/16	146/24 147/21	48/2 48/4 48/7 48/17	127/8	10/18 10/22 19/2 19/6	136/7
136/22 144/22	<b>Health's [1]</b> 140/9	48/19 48/22 48/23	<b>higher [6]</b> 27/1 39/19	31/5 31/7 31/9 31/24	<b>HSOC0015148 [2]</b>
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47/13	99/16	50/3 52/5 52/9 53/6	126/1	65/13 65/20 66/7 66/8	<b>HTLV [12]</b> 79/18 80/3
<b>hard [1]</b> 145/15	<b>heard [4]</b> 65/11 66/16	59/6 59/12 77/10	<b>higher-purity [2]</b>	66/13 66/21 66/25	80/16 83/25 87/18
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134/14 134/15 140/18	29/14 30/4 33/15	112/14 112/25 113/5	52/24 102/17 102/19	145/3	87/18 88/6 88/10
142/12 145/22	49/20 49/24 60/23	113/6 113/14 113/24	114/13 132/7	<b>homozygous [1]</b>	88/14 91/12 92/17
<b>HAV [1]</b> 139/25	68/10 76/20 77/2	114/23 115/8 116/13	<b>himself [2]</b> 84/8 88/8	145/4	107/5 107/18
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(52) not... - participated



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(60) way... - years



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(61) years... - zoom