

Wednesday, 4th 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?

A. Yes, I can.

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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, I think, the Sheffield University hospitals as they

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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, it had stopped. I'm not sure exactly when it had

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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 with an acute bleed, I would be their first port of

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1 call, and I also ran the follow-up clinics under
2 supervision from Professor Preston and consequently
3 Dr Mike Greaves.

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

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

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

18 **A.** Yes, it was.

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

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

25 **Q.** Then April of 1985 to August 1986, you were back at

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1 the Royal Hallamshire Hospital under
2 Professor Preston, carrying out similar duties as you
3 had previously; is that correct?

4 **A.** Yes.

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

8 **A.** It is.

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

13 **A.** Yes.

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

15 **A.** That's correct.

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

20 **A.** Yes, it is.

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

22 **A.** Well, I was the sole consultant with responsibility
23 for haemophilia management. There were two other
24 consultants, and we shared the malignant haematology
25 equally between the three of us. So I was clearly the

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1 busiest of the three.

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

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

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

8 **A.** Yes.

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

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

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

16 **A.** Correct.

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

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

23 **Q.** And then amongst other matters, you have given written
24 and oral evidence to the Penrose Inquiry, and you
25 acted as an expert witness for the defence in the

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1 hepatitis C class litigation?

2 **A.** I did.

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

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

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

23 But with the passage of time, we acquired
24 a haemophilia nurse specialist, and we organised joint
25 orthopaedic clinics. And on a grace and favour basis,

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

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1 **A.** No, that was regular. That was once a week.
 2 **Q.** In terms of the number of patients with the Sheffield
 3 Haemophilia Centre, your statement tells us that --
 4 and you, I think, ascertained this from looking at the
 5 National Haemophilia Database -- that in 1983 there
 6 were 166 patients who were registered with the Centre.
 7 **A.** Yes.
 8 **Q.** We've already touched on the Home Treatment Programme.
 9 Was that well established and well under way by the
 10 time you arrived in April 1983?
 11 **A.** My impression is that Sheffield was at the forefront
 12 of adopting home therapy. I had assumed that all the
 13 other centres were the same. It was only as
 14 I recently read through various minutes I realised
 15 that some centres had been far slower to establish
 16 home therapy. But, to be honest, most of the patients
 17 were on home therapy even when I was a houseman in
 18 1977. And certainly by 1983 it was more or less
 19 universal, except for the odd patient that never took
 20 to self-injection.
 21 **Q.** And the patients who would have been on home therapy
 22 were typically patients with severe haemophilia A?
 23 **A.** Yeah, either severe haemophilia A or B, or moderate
 24 severity with the severe phenotype. There is
 25 a clinical overlap. The frequency of bleeding doesn't

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

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

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- 1 **A.** Autoplex was another activated prothrombin complex
 2 concentrate similar to FEIBA, manufactured by
 3 a different manufacturer, thought to be a little bit
 4 more activated than FEIBA but used similarly for
 5 inhibitor patients.
- 6 **Q.** Then we can see reference to cryoprecipitate, and
 7 Professor Preston has already told us that
 8 cryoprecipitate was only used, by that time, to
 9 a limited extent.
- 10 For what categories of patients can you recall
 11 cryoprecipitate being used in '83, '84?
- 12 **A.** Well, predominantly patients with von Willebrand's
 13 disease. And I would also expect it might have been
 14 used in people that needed very infrequent treatment.
- 15 **Q.** Did you have any role in deciding what products should
 16 be used at the Centre?
- 17 **A.** No, not really.
- 18 **Q.** In terms of arrangements for the supply of products,
 19 do you know whether the NHS concentrate was obtained
 20 from the Transfusion Centre or from BPL?
- 21 **A.** To be honest, I can't remember.
- 22 **Q.** In terms of arrangements for the supply of commercial
 23 concentrates, did you have any involvement in those
 24 arrangements or do you know what they were?
- 25 **A.** No, to both questions.

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- 1 **Q.** And in terms of cryoprecipitate, to the extent it was
 2 used, was that obtained from the Regional Transfusion
 3 Centre or elsewhere?
- 4 **A.** It was obtained from the Regional Transfusion Centre,
 5 and I would imagine that that would have been the case
 6 everywhere.
- 7 **Q.** Now Professor Preston has told us and Professor Makris
 8 has told us in a written statement that two of
 9 Professor Preston's guiding principles, in terms of
 10 his approach to treatment, were not to put all your
 11 eggs in one basket, so to have more than one source of
 12 commercial product?
- 13 **A.** Yeah.
- 14 **Q.** And to keep patients on the same treatment and same
 15 batch as far as possible?
- 16 **A.** Yes.
- 17 **Q.** Does that accord with your collection?
- 18 **A.** Absolutely, and I think I've written exactly the same
 19 thing in my statement. And to be frank, I've followed
 20 that principle ever since.
- 21 **Q.** What did you understand, in 1983, the rationale for
 22 that principle to be?
- 23 **A.** There was some weak epidemiological evidence that some
 24 patients had had more than one episode of non-A, non-B
 25 hepatitis.

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- 1 Now, you know, these are sort of case
 2 presentations. I think it is accepted that some
 3 patients certainly did, and we didn't know really
 4 whether that was because they'd received concentrate
 5 from a different geographical origin or just been
 6 unlucky and exposed to another strain. As I'm sure
 7 you know at this stage in the Inquiry, there are
 8 a number of different hepatitis C genotypes but we
 9 didn't know that at the time.
- 10 So it was felt that if you kept the patients to
 11 a single brand and took some care to make sure that that
 12 was the case, they might be less likely to be infected
 13 for a second time. And the principle behind not putting
 14 all your eggs in one basket is because all of these
 15 manufacturers have interruptions of supply from time to
 16 time; and if you only had one supplier, you might
 17 suddenly find yourself very short of Factor VIII.
- 18 **Q.** Do you know how it was decided which patients would
 19 get NHS concentrate and which patients would receive
 20 a commercial concentrate?
- 21 **A.** If I did know, I can't remember, to be perfectly
 22 honest.
- 23 **Q.** Do you recall whether there were any particular
 24 difficulties in terms of the supply of NHS
 25 concentrate? Was there enough?

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- 1 **A.** Well, there wasn't enough. There wasn't enough
 2 nationally. And that's why, as you go through the
 3 returns and the minutes of various UKHCDO committees,
 4 which I've done recently, but was unaware of way back
 5 then, you discover that the proportion of commercial
 6 concentrate used in the late seventies and early
 7 eighties was going up and up and up, because BPL could
 8 not supply enough.
- 9 And I can remember that when I was a senior
 10 registrar there, they were distributing product on
 11 a pro rata basis, depending on how much plasma was
 12 sent for fractionation by the local transfusion
 13 centre. And I think we got about 40% -- that's my
 14 recollection, anyway -- of our requirement, as BPL
 15 product, on that basis.
- 16 And that actually, was a reflection of the fact that
 17 our local Transfusion Centre sent more than average to
 18 be fractionated. So that was considered a good
 19 proportion. But the problem just got worse and worse
 20 because if you look at the amount of Factor VIII that is
 21 consumed by the patients, over the years you see that
 22 over a 40, 50-year period, the amount used goes up by 7%
 23 or 8% every single year until very recently.
- 24 **Q.** And you've exhibited a graph taken from the 1986
 25 annual report of UKHCDO.

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1 Henry, it's WITN3289045.
 2 We can see from this that the top line, which has
 3 the circles, gives us the total amount of Factor VIII
 4 concentrates used in the period that this figure covers,
 5 roughly 1970 until a little bit beyond 1985. And then,
 6 as I understand it, the line broken up by triangles
 7 shows us the amount of commercial Factor VIII usage, the
 8 line which is broken up by crosses shows us the NHS
 9 Factor VIII usage. And then the line which has the dark
 10 squares shows us the usage of cryoprecipitate. And we
 11 can see the use of cryoprecipitate declining whilst the
 12 use of the concentrates goes up.

13 Have I correctly understood this document --

14 **A.** Yes.

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

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

17 **Q.** We saw with Professor Preston copies of a handwritten
 18 ledger which ran from 1976 to 1981. We haven't
 19 burdened you with it, Professor Hay, because it's
 20 before you arrived, but it's a handwritten book in
 21 which patient details for every attendance are
 22 recorded, the nature of the bleed, the particular
 23 product given, and the batch number. Can you recall,
 24 by the time you arrived in 1983, what, if any, system
 25 there was for recording treatments and batch numbers.

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1 Presumably you needed to record batch numbers because
 2 you had your policy of trying to keep patients on the
 3 same batch.

4 **A.** We recorded batch numbers partly for that reason, and
 5 partly because if there was a specific problem with
 6 a given batch, you could trace who'd had it.

7 It was very common to get allergic reactions,
 8 particularly to plasma or cryoprecipitate but also, to
 9 a lesser extent, to the relatively crude concentrates
 10 that were being used at that time. And some batches
 11 were much worse, and occasional batches were actually
 12 withdrawn. And you have presented me with some
 13 correspondence with Armour, that I'd long since
 14 forgotten, that details how we actually withdrew the
 15 small number of bottles of their product that we had at
 16 one point.

17 You know, people still use ledgers like that.
 18 I have a ledger like that in my Haemophilia Centre. So
 19 if we send product out to a patient, we record all those
 20 details in the ledger. If a patient comes in or is
 21 having surgery, every dose that they get is put into
 22 that ledger.

23 **Q.** And in terms of home treatment, I know the programme
 24 was already well established by the time you took up
 25 your post in 1983 --

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1 **A.** Yes.

2 **Q.** -- but were patients on home treatment generally
 3 required to keep detailed records of their usage of
 4 product?

5 **A.** Um, well, they were supposed to. Compliance with that
 6 was variable. There's something called Factor VIII
 7 returns. They'd have to fill out a line lease on
 8 a form to give details of what they'd used the product
 9 for, whether they'd responded, whether there were any
 10 side effects, and what they'd used, and they were
 11 supposed to return those by post or bring them in when
 12 they came in. And that provided useful clinical
 13 information because when you're assessing the patient,
 14 you'd know how often they were bleeding, which joint
 15 they were bleeding into, and you could assess whether
 16 they were treating themselves adequately or not,
 17 because some patients were very stingy with the
 18 treatment. And the actual doses that were used to
 19 treat bleeds increased progressively, with an evidence
 20 base. Because when we were using cryo, six bags of
 21 cryo would be equivalent to, I think, one tiny little
 22 250-unit bottle of concentrate, which is now regarded
 23 as a paediatric dose. And that's what the patients
 24 were treating themselves with, and they weren't
 25 getting a very good response. By the time I came

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1 along in '83, the standard dose was about 500 units
 2 and it crept up; today it would be 2,000 units.

3 **Q.** Now how frequent were the regular appointments at the
 4 Haemophilia Centre in Royal Hallamshire? So not those
 5 who were attending to outpatients with a particular
 6 bleed but those patients you were seeing regularly.

7 **A.** Well, to start with, and assuming those specific
 8 problems, they would be reviewed every six months.
 9 When HIV came along, we reviewed the patients that we
 10 knew to have HIV more frequently, particularly once
 11 treatment came along, every three months. The
 12 patients had open access to the service. This is
 13 a universal arrangement with any Haemophilia Centre,
 14 that the patients can bypass the switchboard, in
 15 a sense, and phone up and speak to a doctor for
 16 advice, or pop into the Haemophilia Centre when they
 17 feel the need to do so.

18 **Q.** So at a typical six-month routine appointment with the
 19 patient, an existing patient with severe
 20 haemophilia A, could you just talk us through, to the
 21 extent that you're able to, from 1983 and 1984, what
 22 that typical appointment would entail? What kind of
 23 discussions, what kind of tests?

24 **A.** Well, you would ask them about any bleeds that they'd
 25 had, and you'd ask them how they'd treated themselves.

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1 If they had returns, you would examine these, because
 2 they would give, hopefully, a more accurate view of
 3 how often they were bleeding. If you thought that
 4 they had non-A, non-B hepatitis, you'd examine their
 5 abdomen as well as their joints. You might discuss
 6 that, you might arrange an ultrasound if they hadn't
 7 had one for a while. And as time wore on, we talked
 8 more about HIV.

9 **Q.** In terms of decisions about the products they would
 10 receive by way of treatment, would your role have been
 11 essentially just to continue the status quo or were
 12 there occasions when you would be recommending
 13 a change of -- or wanting to consider a change of
 14 treatment?

15 **A.** Well, during that period, we -- following the
 16 principles I've already discussed, we more or less
 17 maintained the status quo, to be frank, until virally
 18 attenuated products came along. There wasn't a great
 19 deal to pick and choose between the products that we
 20 had available to us.

21 We did participate in one or two studies of
 22 virally attenuated products during that time, as you
 23 know from the publications. We tested an Armour
 24 product, for example, and you'll have remembered the
 25 letter to The Lancet about two patients, both of whom

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1 became quite ill with quite severe non-A, non-B
 2 hepatitis after administration of that product.

3 And then the unit also participated in the
 4 multi-centre study of Alphanate, and I was very
 5 peripherally involved in that, which you might guess
 6 from the absence of my name in the list of authors.
 7 A lot of it -- that trial actually took place when I was
 8 out of the department, at the Children's Hospital, but
 9 I was aware of it at the time.

10 **Q.** So if there needed to be a decision to change
 11 treatment, whether it's changing to a different
 12 concentrate or use of a heat-treated concentrate,
 13 would that be something that you would then discuss
 14 with Professor Preston or --

15 **A.** Well, to be honest, my recollection is that if there
 16 were any changes of treatment, he would make the
 17 decision. I mean, the decision about Alphanate, which
 18 I expect we're coming to at some point, was entirely
 19 his, and -- apart from that, there were very few
 20 changes of treatment, and where they occurred, they
 21 probably would have related to difficulties with
 22 supply. Sometimes companies had some technical
 23 problem that caused supply issues, and then the
 24 patients treated with that product had to change.

25 **Q.** And then, in terms of the liver function tests that

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1 you would undertake at the routine outpatient
 2 six-monthly appointment, '83, '84, what tests, broadly
 3 speaking, would you undertake and what discussions
 4 would you hold with patients about them?

5 **A.** Well, all of the patients were tested for the markers
 6 of hepatitis B, and from 1982 they were all
 7 vaccinated. We obviously didn't have a test for
 8 non-A, non-B hepatitis at the time but we checked the
 9 liver function tests, and these would be plainly
 10 transaminases but basically a liver function profile,
 11 and we checked their blood count, and probably their
 12 electrolytes, and not a lot else. They would have an
 13 abdominal ultrasound every couple of years.

14 **Q.** And if the outcome of the liver function tests gave
 15 rise to any cause for concern, how and when would that
 16 be communicated to the patient? Would it be at the
 17 next six monthly appointment?

18 **A.** Yes, it would be at the next six-month appointment.

19 **Q.** And was it your routine practice to tell patients
 20 the -- what their test results showed?

21 **A.** Well, as far as I recall, yes.

22 **Q.** We understand from other evidence -- again,
 23 Professor Makris, Professor Preston -- that at
 24 Sheffield there were stored blood samples, a system
 25 which I think predated your arrival there. What, if

23

1 anything, can you tell us about that?

2 **A.** Well, these were plasma samples stored in the lab.
 3 There would probably also have been samples stored
 4 routinely in virology, because they retained samples
 5 for three years.

6 **Q.** Were those samples taken at every routine appointment,
 7 to your knowledge?

8 **A.** I don't think so.

9 **Q.** Were you, as far as you can remember, ever involved in
 10 taking those samples for storage?

11 **A.** I presume I must have been.

12 **Q.** Can you recall what, if anything, was said to patients
 13 about that?

14 **A.** No, I can't.

15 **Q.** In terms of providing patients with information about
 16 non-A, non-B hepatitis, we take first of all the case
 17 of a patient who you don't currently suspect has
 18 non-A, non-B. What, if any, information would you
 19 give a patient in this 1983/1984 period about the
 20 risks of non-A, non-B from treatment with factor
 21 concentrates?

22 **A.** Are we talking about a patient with severe
 23 haemophilia?

24 **Q.** Yes.

25 **A.** Well, by that stage, they'd all been treated with

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1 concentrate, and I think we would have understood
2 that, although we couldn't quantify the risk, there
3 was a very high risk that they'd been exposed to
4 hepatitis C. But what we didn't know was how many of
5 those patients would clear the virus. We now know
6 it's about a third. So we really didn't know whether
7 patients with normal liver function tests were viremic
8 or not. But, you know, we would have said to them
9 that it was a possible risk.

10 Q. And would you have told them, and if you can remember,
11 would you have told them, do you think, that there was
12 a possible risk of non-A, non-B hepatitis, or would
13 you have also told them there was a possible risk of
14 them developing chronic or serious liver disease?

15 A. Well, when I first went there, although there were
16 papers in the literature that showed very high
17 incidence of abnormal liver function tests in patients
18 with haemophilia, all the liver biopsy studies up to
19 that point, including Professor Preston's study of
20 1978, tended to show very mild liver disease, and it
21 was the consensus of opinion at that time that non-A,
22 non-B hepatitis was by and large benign and
23 non-progressive.

24 Now, we know that that's a very poor generalisation
25 now, but back then, that would have been the consensus.

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1 So I think the patients would have been generally
2 reassured. But as you know from my statement, I made
3 a clinical observation that drew that into question, and
4 we started to biopsy our patients more extensively to
5 find out what was happening.

6 Q. I'll come back to possibly the consensus and the
7 medical literature in a little while, Professor Hay,
8 but just sticking with the information given to
9 patients, because of the -- as I understand your
10 evidence -- please correct me if I'm wrong -- because
11 of your understanding that it was perceived as
12 a relatively mild and non-progressive condition,
13 patients, is this right, might have been told of the
14 risk of non-A, non-B hepatitis but would have been
15 given reassuring information that it wasn't something
16 for them particularly to worry about?

17 A. Well, that's right. I mean, I can't speak for other
18 centres. One of the things I think you should
19 recognise about the Sheffield Centre is that because
20 of the longstanding interest in liver disease, it
21 assumed a much higher profile in that centre than
22 I believed to be the case in many others.

23 Q. Then for patients who were not severe haemophiliacs,
24 so patients who were infrequently treated, or mild
25 haemophiliacs, would there be any different

26

1 conversation that you might have with those patients
2 about non-A, non-B hepatitis and its risks?

3 A. Well, however mild or not non-A, non-B hepatitis was,
4 one didn't want to transmit it. For most of the
5 patients with severe haemophilia, it was probably too
6 late at that point, but patients with mild bleeding
7 disorders required treatment infrequently, and so
8 those patients would have been much less likely to
9 have been already exposed to non-A, non-B hepatitis.
10 And it was the unit policy to try to minimise any
11 further exposure. And so those patients would have
12 been treated with DDAVP if the patient was known to
13 have an adequate response to it, or cryoprecipitate,
14 or they would have had a discussion about the relative
15 risks of non-A, non-B hepatitis.

16 A lot of the patients who were treated for the first
17 time with some of these agents, and particularly the
18 trials of virally attenuated products, would have had
19 that conversation because one of the problems of DDAVP
20 is tachyphylaxis. That's particularly a problem with
21 haemophilia so that each dose has 40% less response than
22 the dose before. So the response may be adequate for
23 a minor procedure such as a dental extraction, but if
24 the patients are to undergo more invasive surgery, the
25 effective DDAVP would wear off, and the patient would be

27

1 exposed to an excessive bleeding risk. So they may have
2 no alternative but to have concentrate or possibly cryo.

3 Cryo is quite difficult for surgery because you need
4 such huge doses. You might be giving a patient 24 bags
5 a day or more, and very soon you get into the sort of
6 territory where they're exposed to a significant
7 hepatitis risk anyway.

8 Q. Now, you've mentioned already the use of heat-treated
9 products.

10 A. Mm-hm.

11 Q. What more, if anything, are you able to tell us about
12 the Centre's involvement in 1984 in those early uses
13 of heat-treated products? Do you know how it came
14 about, for example?

15 A. I'm not entirely sure how it came about, but we had
16 previously tried heat-treated Armour products, and
17 clearly the heat treatment was inadequate to exclude
18 non-A, non-B hepatitis. And then Alpha came along
19 with Alpha Profilate, and that needed to be tested in
20 a PUP study, a Previously Untreated Patient study.
21 And that trial was conducted between Sheffield, the
22 Royal Free and St Thomas', I believe, and they put 27
23 patients into it, of whom 24 did not develop non-A,
24 non-B hepatitis, and 3 did.

25 So, clearly, that was a big step in the right

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1 direction, but when they ultimately came to market this
2 product, and indeed a number of others, they were
3 marketed as hepatitis-reduced products. Now, people
4 used them partly because of HIV and because it was
5 obviously a step in the right direction, but they didn't
6 think it was the full answer.

7 **Q.** As far as you can recall, was the Centre's involvement
8 in the use of these -- the two heat-treated products
9 on a trial basis, was that a response to the risk of
10 hepatitis in 1984, or was it a conscious response to
11 the risk of AIDS?

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

22 **Q.** Do you know, you may not, but do you know whether, for
23 the purpose of these heat-treated trials,
24 Professor Preston approached the pharmaceutical
25 companies to ask to enroll some of his patients in

29

1 them, or the pharmaceutical companies approached
2 Professor Preston?

3 **A.** I really don't know. But I would imagine it was the
4 pharmaceutical company approaching him. That is
5 usually the way round it comes. And they may have
6 approached him and the Royal Free because both of
7 those centres had a historical interest in liver
8 disease and had indeed published on the use of virally
9 attenuated products.

10 **Q.** I just want to ask you a little about the Children's
11 Hospital. I know you were there for a shorter period
12 of time, from August '84 to April '85 first of all,
13 and then you went back for a further six months,
14 August '86 to April '87.

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

18 Henry, it should be HCDO0000139_004. So we can see
19 here, Professor Hay, it's the annual return for 1983 for
20 Sheffield Children's Hospital: total number of
21 haemophilia A patients treated during the year, 17; no
22 von Willebrand's patients; no carriers. Then we can see
23 cryoprecipitate being used, 1,135 bags in hospital, none
24 for home treatment ... NHS Factor VIII being used,
25 26,185 units in hospital, 147,622 units for home

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1 treatment. And then a small amount of commercial
2 concentrate, Factor VIII, 5,266 units in hospital, 8,500
3 for home treatment, and then the other material that we
4 see there is Autoplex.

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

19 Professor, that paints a picture, at least for 1983,
20 and I'm afraid we don't have the returns for '84 or '85
21 at the moment, of a -- predominantly NHS concentrate,
22 a more substantial use of cryoprecipitate than at the
23 Royal Hallamshire, and a very modest role for commercial
24 concentrates.

25 Does that assist in triggering your recollection of

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1 the products that were used at the Children's Hospital
2 at all?

3 **A.** Well, I think they had a very small number of patients
4 with haemophilia, and they were able to use NHS
5 products to a greater degree. Most of the patients
6 with haemophilia B throughout the country were managed
7 with UK Factor IX concentrate because there were far
8 fewer of them. So we were, essentially,
9 self-sufficient in Factor IX concentrate.

10 **Q.** And, broadly speaking, what was the role that you
11 undertook at the Children's Centre during those two
12 6-month placements there?

13 **A.** Well, I worked closely with the junior registrar in
14 paediatrics, and we worked as a team. And he was not
15 a haematologist, or she, and we managed mainly
16 patients with childhood leukaemia, childhood solid
17 tumours, and occasionally saw patients with bleeding
18 disorders and outpatients, but it was a much smaller
19 Haemophilia Centre than the adult one.

20 **Q.** And were the decisions as to what products to use,
21 therefore, down to Dr Lilleyman?

22 **A.** Yes, definitely.

23 **Q.** Do you happen to know if the policy or system of
24 keeping a patient on the same treatment and same batch
25 was in use at the Sheffield Children's Hospital?

32

- 1 A. I don't recall.
- 2 Q. And do you recall whether you had any involvement in
3 talking to the patients' parents about risks of non-A,
4 non-B hepatitis whilst you were there?
- 5 A. I honestly don't remember.
- 6 Q. As far as you can recall, did the Children's Hospital
7 have any involvement in or access to the early use of
8 the heat-treated products?
- 9 A. Well, I don't think so. You know, when we switched
10 over to Alphanate, my recollection is that the supply
11 was extremely limited and that there was some special
12 negotiation whereby they agreed to supply those
13 centres that had participated in the clinical trials.
- 14 I think Dr Mark Winter may have been able to
15 switch his patients because of his close association
16 with St Thomas' because I don't think he participated
17 in a clinical trial. But to start with, there
18 certainly wasn't enough of the stuff to supply the
19 whole of the UK.
- 20 Q. Now, can I just ask you more generally about how you
21 would keep up to date with literature publications in
22 the early '80s. You've already told us about the
23 Journal Club.
- 24 What magazines, as in medical journals and
25 publications, would you read in the early '80s?

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- 1 A. Well, I got The Lancet, The New England Journal of
2 Medicine. I was a member of the British Society of
3 Haematology and therefore got the British Journal of
4 Haematology. I was not yet an ASH member, so I'd have
5 to go to the library for the -- for blood. And, oh,
6 yes, I was a member of ISTH, so I got Thrombosis and
7 Haemostasis which was the journal of the International
8 Society of Thrombosis and Haemostasis.
- 9 And those would be the journals I would read
10 regularly, but if someone pointed me at an article or
11 it came up in discussion in another journal, one might
12 go to the library and take it out.
- 13 Q. Prior to 1987 when you became a member of UKHCDO as
14 a director at Liverpool, do you -- did you have access
15 to the reports that were produced for UKHCDO meetings
16 by, for example, Dr Craske or the Hepatitis Working
17 Party, or access to the minutes of the annual meetings
18 or the Reference Centre Director meetings?
- 19 A. No.
- 20 Q. So your knowledge of what was being said by UKHCDO to
21 the extent that you -- it was disseminated to you,
22 would it have been by Professor Preston at, for
23 example, the weekly meetings you've described?
- 24 A. Yes.
- 25 Q. On the question of what information to provide to

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- 1 patients about risks, was that something that was
2 covered in your training, either your general medical
3 training or your specialist haematology training?
- 4 A. In my specialist haematology training.
- 5 Q. So would you have picked up what -- that advice, or --
6 essentially from Professor Preston, or from others --
- 7 A. Yes.
- 8 Q. You've described what you referred to as there being
9 a consensus, or an international consensus, in the
10 early 1980s that non-A, non-B hepatitis was relatively
11 benign and non-progressive. Can you assist us with
12 what material you're there referring to to support the
13 existence of this international consensus?
- 14 A. Well, there were a number of patients showing
15 incidence of abnormal liver function tests. Some
16 focused on the use of cryoprecipitate, for example,
17 the paper of Kevin Rickard from Australia, others on
18 the incidence after the introduction of concentrate.
19 It was clear that both agents transmitted whatever the
20 agent was that caused it.
- 21 There are a whole series of liver function -- sorry,
22 liver biopsy papers. One from, actually, the Children's
23 Hospital, from Professor Lilleyman. Then there was
24 Eric Preston's in 1978 and, more recently, the Stevens
25 paper from Manchester, which we parodied in the title of

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- 1 my own paper. And Mannucci and Colombo also did liver
2 biopsy studies and they all showed mainly low grade of
3 inflammation or no inflammation at all. So, you know,
4 Mannucci in particular at that time was particularly
5 going around saying that this was non-progressive.
- 6 That title, of the Stevens paper -- or Dick Stevens,
7 actually, I think in the British Journal of Haematology
8 1981, was "Non-A, non-B hepatitis in haemophilia: an
9 overstated problem?"
- 10 Q. Professor Hay, we're currently losing the visual sight
11 of you. We can currently see your tie and nothing
12 else. Given the time, it's five past 11, I'm going to
13 suggest we take a break there, and try to sort that
14 out in any event. But it's probably about the right
15 time for a break anyway.
- 16 **SIR BRIAN LANGSTAFF:** Yes, it is. I think you're probably
17 ahead of us in having had a restorative drink during
18 the course of the morning, but we take half an hour
19 now, professor.
- 20 A. Okay.
- 21 **SIR BRIAN LANGSTAFF:** So we'll come back at 25 to 12.
- 22 By then, I hope we can see more of you than your
23 tie, nice though it is to look at.
- 24 **MS RICHARDS:** Sir, if Professor Hay can be given the usual
25 warning.

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1 **SIR BRIAN LANGSTAFF:** Yes, what I say to all witnesses,
 2 you may be accustomed to this from previous
 3 experience, but is this: you're giving evidence you're
 4 on oath, you must not discuss what you have said in
 5 evidence or what you think -- whatever you think you
 6 might be asked about to come in evidence. You can
 7 discuss anything else you like with anyone, but you
 8 can't discuss your evidence, past or to come, with
 9 anyone at all, whoever they are.

10 Thank you very much.

11 (11.06 am)

(A short break)

13 (11.36 am)

14 **SIR BRIAN LANGSTAFF:** Professor, we're back in session.
 15 I gather that you may have problems perhaps seeing
 16 some of the documents. If you need them enlarged
 17 just, please say.

18 **THE WITNESS:** I will.

19 **MS RICHARDS:** Professor Hay, I've been asking you about
 20 what you described as an international consensus as to
 21 the nature of non-A, non-B hepatitis. You had
 22 referred to a number of papers, Mannucci and the
 23 Stevens paper, which I understand.

24 You referred also to the paper co-authored by
 25 Dr Lilleyman, and I'm just going to ask for that to go

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1 on screen so we could have a look at that.
 2 Henry, it's OXUH0001751_003. And can we just zoom
 3 in a bit closer, please, to the top half of the page.

4 Is this the paper to which you were referring,
 5 Professor Hay?

6 **A.** No. I was referring to one from 1975, actually.

7 **Q.** We don't, I think, have that. In relation to this
 8 paper, was this a paper that you were aware of at the
 9 time?

10 **A.** I don't remember it.

11 **Q.** Don't worry. In that case, I won't ask you anything
 12 further about this particular paper.

13 Could we then have on screen, Henry, BART0002487.
 14 Again, if we could zoom in to the top half of the letter
 15 so we can see what it is.

16 Professor Hay, this is a letter -- I don't suggest
 17 you would have seen this at the time. It's a letter
 18 dated 27 April 1979, and it's from Dr Kernoff, who, as
 19 you've already referred to, had a particular
 20 longstanding interest in hepatitis, to Dr Colvin.

21 Henry, can we go to the second page, please. Could
 22 you zoom in on -- can we have the whole of that second
 23 paragraph, thank you.

24 You'll see there's a paragraph, professor, beginning
 25 "Types of therapeutic material available".

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1 Then if we go about two-thirds of the way through
 2 that paragraph, there's a sentence beginning "The
 3 clinical reason ..." Actually, I'll pick it up just
 4 before that to make sense of it.

5 "Not only is commercial concentrate expensive, but
 6 there are both clinical and moral reasons for preferring
 7 the NHS material. The clinical reason is the growing
 8 awareness of the probability that commercial
 9 concentrates have a higher risk of transmitting non-A,
 10 non-B hepatitis than NHS material. This is a serious
 11 disease with long-term consequences which, as far as is
 12 known, is at present much less common in the UK than in
 13 those parts of the world -- particularly the USA --
 14 where donor blood for commercial concentrates is
 15 collected."

16 Now, I'm not asking you, professor, about the --
 17 whether there was a different risk from NHS and
 18 commercial concentrates. But just in terms of
 19 Dr Kernoff's characterisation of non-A, non-B hepatitis,
 20 he describes it as a serious disease with long-term
 21 consequences. Was that your understanding in the early
 22 1980s and that characterisation of non-A, non-B
 23 hepatitis?

24 **A.** No.

25 **Q.** So you would not have characterised it as -- would you

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1 disagree with serious or long-term consequences or
 2 both?

3 **A.** Well, I think the long-term consequences were unknown.
 4 And, I mean, it clearly is a correct statement, as we
 5 now know it, but at that time, the long-term
 6 consequences were not known. I think that was part of
 7 the problem. The liver biopsy studies that had been
 8 published were all looking at the early stages of the
 9 disease. And there was a consensus forming around
 10 that time that this was not a serious problem.

11 **Q.** Other than the papers to which you've referred, so
 12 I think you've told us about Mannucci in '82, the
 13 Richard Stevens paper in '81, and you referred to a
 14 Lilleyman paper, 1975, which I'm afraid we don't have
 15 available at the moment --

16 **SIR BRIAN LANGSTAFF:** There's also the Australian paper
 17 from Rickard.

18 **MS RICHARDS:** Oh, yes. And an Australian paper.

19 Are those the sources of your understanding that
 20 there was an international consensus, or was it your
 21 training, or discussions, or something else?

22 **A.** Well, it was partly my training, but I just
 23 highlighted some of the papers. I mean, I think there
 24 are about 300 references in my antithesis, but those
 25 are perhaps the most important.

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1 Q. And what about Professor Preston's own 1978 work?
 2 What was your understanding in 1983 of what that paper
 3 showed?
 4 A. Well, it showed a variety of different types of
 5 hepatitis, histologically, which included mostly
 6 relatively low grades in inflammation.
 7 Q. Sorry. Included relatively ...?
 8 A. Mostly relatively low grades of inflammation.
 9 Q. Can we just have a look at that?
 10 Henry, it's PRSE0003622. If we could zoom in on
 11 the top half of the right-hand column, please, Henry.
 12 So we've got the paper there; I know you're familiar
 13 with it. Professor Preston, September 16, 1978. We
 14 have the title of it there, "Percutaneous liver biopsy
 15 and chronic liver disease in haemophiliacs". Then the
 16 summary refers to:
 17 "Liver biopsies being carried out on eight
 18 symptom-free patients under Factor VIII cover. A wide
 19 spectrum of chronic liver disease was demonstrated,
 20 including chronic aggressive hepatitis and cirrhosis."
 21 Then if we go to the second page, please, just the
 22 table at the bottom of the page. I'm not proposing to
 23 go through the detail of it with you, professor, but we
 24 looked at it with Professor Preston, and he set out what
 25 he was referring to by reference to the term -- the

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1 various terms there set out.
 2 Is it -- do you say that this paper supports
 3 a consensus that non-A, non-B hepatitis was mild and
 4 non-progressive?
 5 A. Well, it's certainly less supportive than some of the
 6 others because there are two cases of cirrhosis there.
 7 But apart from that -- you know, and I'm not sure
 8 exactly how these patients were selected either,
 9 because the two cases of cirrhosis may have had
 10 physical signs that led to their liver biopsies.
 11 But the papers of Mannucci showed only one case of
 12 cirrhosis, and he referred to it as the
 13 non-progressive course of non-A, non-B hepatitis, and
 14 I think that similar findings from the paper of
 15 Stevens et al.
 16 Q. What we also see from this table, as well as the two
 17 cases of cirrhosis, are two cases of chronic
 18 aggressive hepatitis, which was characterised for us
 19 by Professor Preston as being more serious and
 20 significant than chronic persistent hepatitis was then
 21 understood to be.
 22 Do you disagree with that characterisation?
 23 A. No. It's now known as chronic active hepatitis. In
 24 non-A, non-B hepatitis, or rather hepatitis C, it can
 25 progress to cirrhosis, though there are also instances

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1 of it going back to chronic persistent hepatitis.
 2 Q. Professor Hay, the paper by Mannucci may be said to
 3 lend some support for your view of how non-A, non-B
 4 hepatitis was understood at least by some.
 5 Do you maintain your view, however, that that was
 6 the consensus view, as opposed to there being
 7 potentially a range of different views emerging in the
 8 literature?
 9 A. Well, there's always a range of views, but I think the
 10 consensus view was that it was relatively benign and
 11 non-progressive.
 12 Q. You referred in your statement to one professor using
 13 the term "a biochemical curiosity" about non-A, non-B
 14 hepatitis, or about the liver function abnormalities.
 15 Who was that, professor, and when was that, roughly?
 16 A. That was Professor Sam Machin. That would have been
 17 about 1983, '84, when I was chatting with him about
 18 our findings. And he expressed surprise that we were
 19 still interested in this liver disease because he said
 20 it was a biochemical curiosity. Naturally, by that
 21 stage, I would have violently disagreed with that
 22 view.
 23 Q. By 1983, 1984, you would have disagreed with that
 24 view?
 25 A. Yes.

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1 Q. And what was it that led to your own personal
 2 realisation that non-A, non-B hepatitis was not benign
 3 and non-progressive?
 4 A. Well, I observed a patient in clinic who came along
 5 and told me he'd been admitted to the local hospital,
 6 having sort of gone to sleep. And he gave a very
 7 vague story. His wife was with him. But I examined
 8 him, and he had clear physical signs of cirrhosis of
 9 the liver. But he was one of the patients with
 10 chronic persistent hepatitis previously reported by
 11 Professor Preston. And our understanding was that
 12 that particular histological appearance, which is a
 13 very mild inflammation, not chronic active hepatitis,
 14 was thought to be benign and non-progressive. So this
 15 was clearly a very odd thing. He was relatively
 16 elderly, but he progressed from chronic persistent
 17 hepatitis in the late '70s to full-blown cirrhosis
 18 with hepatic encephalopathy, which implies a degree of
 19 hepatic failure in the space of only six years.
 20 So I brought this to the attention of
 21 Professor Preston and Dr Triger, who was the
 22 hepatologist, and they agreed that this was a
 23 remarkable observation, and they agreed that we should
 24 be monitoring our patients more closely with liver
 25 biopsy.

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1 Q. Doing the best you can, was that 1983 or 1984?
 2 A. I think it may have been late 1983.
 3 Q. If we just look at the paper that was then published
 4 in The Lancet in June of '85. Henry, it's
 5 PRSE0004229. And if we zoom in on the bottom half of
 6 the page, Henry.
 7 This is the paper co-authored between yourself,
 8 Professor Preston, Dr Triger and Dr Underwood.
 9 "Progressive liver disease in haemophilia: an
 10 understated problem?"
 11 I'm just going to read the summary for the benefit
 12 of those following:
 13 "In an eight-year study of 79 unselected patients
 14 with haemophilia who had received clotting factor
 15 concentrates, there was evidence of chronic progressive
 16 liver disease in at least 17 (21%). Eight patients had
 17 chronic active hepatitis, and nine had cirrhosis, five
 18 with oesophageal varices. Histological evidence
 19 suggested that non-A, non-B hepatitis was mainly
 20 responsible, although the influence of other viruses
 21 could not be excluded. Serial liver biopsies showed
 22 progression from chronic persistent hepatitis to chronic
 23 active hepatitis and cirrhosis within six years,
 24 suggesting that chronic persistent hepatitis in
 25 haemophiliacs is not as benign as hitherto supposed."

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1 And then the last sentence of the summary:
 2 "It's anticipated that liver disease in
 3 haemophiliacs will become an increasing clinical problem
 4 in the future."
 5 So this was the result of work that had in fact been
 6 undertaken over an eight-year period, so prior to your
 7 joining.
 8 A. Well, yes, it's an eight-year period because it
 9 includes all the data from Professor Preston's earlier
 10 study.
 11 Q. And then in terms of the process of undertaking
 12 further biopsies, the serial liver biopsies referred
 13 to, were you directly involved in that process?
 14 A. Yes.
 15 Q. This tells us that the eight-year study of patients
 16 was of 79 unselected patients. How were patients
 17 identified or selected for biopsy; can you recall?
 18 A. Well, the patients who had been biopsied before -- who
 19 did not have cirrhosis, or at least hadn't had
 20 cirrhosis before -- were approached to -- for consent
 21 to (inaudible) biopsy again to see if their liver
 22 disease had changed. And it was explained to them
 23 that we had some doubts about the current view about
 24 the natural history of non-A, non-B hepatitis, and we
 25 couldn't make any assumptions, and we wanted to know

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1 what was happening with their liver disease, and the
 2 only way to find out was to do a liver biopsy. And
 3 further patients who had abnormal liver function tests
 4 were approached, and a similar conversation took
 5 place.
 6 Q. And if we go to the second page, please, Henry, if we
 7 look at the bottom half of the page under the
 8 left-hand column under the heading "Results", please,
 9 Henry.
 10 We can see this is what is recorded:
 11 "Initial biopsy in 34 patients showed chronic
 12 persistent hepatitis in 20; chronic lobular hepatitis in
 13 one."
 14 Pausing there. Could you just explain for us
 15 "chronic lobular hepatitis" as distinct from "chronic
 16 persistent" and "chronic active"?
 17 A. I think chronic lobular hepatitis is a similar low
 18 grade of inflammation.
 19 Q. Then:
 20 "Chronic active hepatitis in 9, established
 21 micronodular cirrhosis in 4."
 22 And then the next paragraph refers to 9 patients
 23 having a second biopsy. And we can then see that you
 24 set out various matters relating to that, and you say:
 25 "Cirrhosis was present in at least 9 of the 34

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1 patients."
 2 And then we can see the table with the results of
 3 the serial liver biopsies. The first biopsy, having
 4 shown chronic persistent hepatitis in 6, and then
 5 there's 4 in chronic -- showing chronic active
 6 hepatitis.
 7 And then the second biopsy showing, as I
 8 understand it, that in patients 3 and 4, the chronic
 9 progressive hepatitis was now showing to be chronic
 10 active hepatitis. Patients 5 and 6 had progressed to
 11 cirrhosis. Likewise, patients 8 and 9. Patient 7,
 12 perhaps somewhat curiously, had gone from chronic
 13 active hepatitis to chronic persistent hepatitis.
 14 Is that a correct reading of that part of the
 15 results?
 16 A. Yes, it is.
 17 Q. So is it fair to say that the significance of this
 18 paper was the further light it shone on chronic
 19 persistent hepatitis and its potential to progress to
 20 serious liver damage?
 21 A. Yes.
 22 Q. And then, Professor Hay, for the sake of completeness,
 23 we'll just look at the two other applications from the
 24 Lancet in 1985 to which you contributed.
 25 Henry, could we have PRSE0004594, please.

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1 If we could just zoom in on the bottom half of the
2 page, please, Henry.

3 So this is July 1985 in The Lancet, professor, and
4 we can see it's a letter co-authored by
5 Professor Preston, you, Dr Dewar, Dr Greaves, Dr Triger:

6 "Non-A, non-B hepatitis and heat-treated Factor VIII
7 concentrates."

8 Is this the letter that you were referring to
9 earlier which talked about the problems experienced with
10 the trials of the Armour heat-treated products in 1984?

11 A. It is.

12 Q. And the two patients who developed significant non-A,
13 non-B hepatitis within a fairly rapid period of time?

14 A. Yes. Quite short incubation, unusually severe.

15 Q. And then the third article in The Lancet from 1985 is
16 WITN3289051, please, Henry.

17 And if you go to the next page. In fact if you move
18 to -- if you go down the page, please. Next page,
19 sorry, Henry.

20 There are two letters entitled "Liver disease in
21 haemophilia". If we zoom in on this one. So this is
22 the second letter, entitled "Liver Disease in
23 Haemophilia", is the one authored by you, Dr Preston,
24 Dr Triger and Dr Underwood.

25 A. Yes.

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1 Q. And I think you refer to this in your statement. This
2 is the disagreement that emerged, through the pages of
3 The Lancet, between those undertaking the work at
4 Sheffield that we've just looked at, and
5 Professor Mannucci and Dr Colombo.

6 A. Indeed.

7 Q. And this letter identifies two possible reasons for
8 difference: the age of the cohort being biopsied and
9 studied; and patient selection.

10 Is that a fair summary?

11 A. Yes, I guess so.

12 Q. Before we leave this, is there anything further you
13 wanted to say about this letter?

14 A. No, not particularly. I think the significance is
15 that it was not immediately accepted by everybody.
16 And Mannucci argued back, in defence of his own
17 earlier assessment.

18 Q. I'm going to move on to ask you about the developing
19 knowledge of the risk of AIDS.

20 SIR BRIAN LANGSTAFF: Well, before you do that, can I just
21 ask you one further question about the consensus.

22 The title of your article in The Lancet was
23 "... an understated problem?"

24 A. Yes.

25 SIR BRIAN LANGSTAFF: And you said that was a parody of

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1 Stevens' article in 1982 --

2 A. No, it was 1981's.

3 SIR BRIAN LANGSTAFF: '81, I'm sorry. Where he said,
4 effectively: is it an overstated problem?

5 A. Yes.

6 SIR BRIAN LANGSTAFF: Why would he think that it was an
7 overstated problem if the consensus was that it
8 wasn't?

9 A. Well, he published that before Mannucci came along and
10 published his paper in 1982. So there clearly was
11 some diversity of opinion. But by the early eighties
12 I think the consensus was, oh, well, it's not so much
13 to worry about. And in the seventies people sort of
14 became aware of the problem, and would naturally have
15 been worried about it. We know that hepatitis B can
16 progress to cirrhosis and hepatocellular carcinoma in
17 chronic carriers, for example, so there would
18 certainly have been concerns about the progress of
19 non-A, non-B hepatitis based on theoretical
20 considerations alone. But various live biopsies had
21 been done, and as time went by, they appeared, or at
22 least were interpreted to suggest that, well, maybe
23 this isn't as big a problem as we thought it was.
24 And, you know, I think it's against that context.

25 So you've got the Stevens paper and then another

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1 liver biopsy series from Mannucci which also, in its
2 title, talked about it being non-progressive.

3 But the interesting thing is, a lot of this is
4 about interpretation, because even the Mannucci paper,
5 it was about 11 patients, quite a small series to base
6 any sort of conclusion on, and one of those patients
7 had cirrhosis.

8 So looking at the same data, and I think in our
9 correspondence we point out that to him, you could argue
10 that, well, ten per cent of your patients have got
11 cirrhosis. And we're showing 15 per cent. So why are
12 you arguing the toss?

13 SIR BRIAN LANGSTAFF: Yes, I see.

14 So the one thing that seems to be clear, tell me
15 if this is fair, is that there was a significant
16 risk -- sorry, a risk that serious hepatitis might
17 result, but people were at odds over time, views
18 differing, as to quite how serious the risk was. Is
19 that fair?

20 A. Particularly in the seventies there was probably
21 greater dichotomy of opinion. But by the early
22 eighties I think that they'd settled around thinking,
23 oh, well, it wasn't such a big problem after all.
24 That was my perception, talking to colleagues from
25 around the country, and reading the literature. And

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1 I think it was Professor Preston's perception too, to
2 be honest. But then we started to see more people
3 with more serious liver disease, and the closer we
4 looked, the more we found.

5 Not everyone with cirrhosis will have physical
6 signs of cirrhosis. They often don't. So it's only
7 if you do a liver biopsy -- or, more recently, we
8 would, of course, do a fibroscan, we have non-invasive
9 methods now, but back then the only way to find out
10 was to do a liver biopsy.

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

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

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

19 Now, pneumocystis pneumonia is a type of pneumonia
20 that haematologists are very familiar with because we
21 see it in our immunosuppressed patients with lymphoma or
22 leukaemia. But it's not common. It's caused by an
23 opportunist pathogen. And the CDC in the United States
24 realised that this was -- this sudden increase was being
25 used in a different risk group, and it was predominantly

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1 being used for homosexual men who were presenting with
2 pneumocystis pneumonia. And it was at that point,
3 I think 1981, maybe '82, that they really began to
4 realise that there was a new disease out there.

5 **Q.** We know there were reports in July 1982 in the MMWR
6 publication produced by CDC of PCP observed in
7 haemophiliacs?

8 **A.** Yes.

9 **Q.** This was shortly before you'd be taking up your post
10 at the Blood Transfusion Service?

11 **A.** Yes.

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

14 **A.** No.

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

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

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

25 **A.** Sorry, it's a slightly unfair question without

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1 showing you the document.

2 It's PRSE0002410. It's New England Journal of
3 Medicine, January 1983, "AIDS and preventive treatment
4 in haemophilia".

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

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

9 And then there's further discussion about the
10 presentation of AIDS. And then if we go over the page
11 the last paragraph, please, left-hand column, Henry, it
12 says:

13 "The fact that haemophiliacs are at risk for AIDS is
14 becoming clear. The use of cryoprecipitate will
15 minimise this risk, the current home infusion programme
16 needs to be revised."

17 And then the last two sentences:

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

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

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

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

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

8 **A.** -- take the Lancet, however. I don't think I was
9 taking the New England Journal at that point.

10 **Q.** Now we know that in around December of 1982 there were
11 reports of a baby, a San Franciscan baby, 20-month old
12 baby transfused with platelets developing the AIDS
13 syndrome, and we know that that is something that, as
14 a matter of fact, came to the attention of
15 Professor Preston, along with an update of what the
16 current position was in terms of AIDS and
17 haemophiliacs at a meeting in late January 1983.

18 Now that, of course, is whilst you're still at the
19 Regional Transfusion Centre and three months before
20 you joined the Royal Hallamshire.

21 When you joined the Royal Hallamshire in
22 April 1983, can you recall what discussions there were
23 about AIDS and the risk of AIDS being transmissible by
24 blood or blood products?

25 **A.** I can remember that it was recognised that it was

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1 beginning to appear in patients with haemophilia. And
2 that we assumed that it was caused probably by
3 a virus. There were some contrary hypotheses, but
4 they never gained much traction. So I think we
5 assumed it was caused by an unknown virus, and we
6 didn't know what the risk was.

7 We assumed that all blood products might carry it,
8 I think, because it was beginning to appear in the UK
9 population as well. By "UK population" I mean the
10 general population.

11 **Q.** We also know that in around March 1983 Haemophilia
12 Centre Directors were asked to look out for symptoms
13 or signs of AIDS in their patients and report back to
14 Dr Craske if they detected any such signs.

15 **A.** They did.

16 **Q.** Do you recall whether -- is that something you were
17 asked to undertake as part of your routine care of
18 patients, to look out for signs of AIDS, and if so,
19 alert Professor Preston?

20 **A.** Yes.

21 **Q.** And then did you, as a matter of fact, identify, as
22 far as you can recall, in any of the patients at the
23 Sheffield Centre at that time, any such signs?

24 **A.** I don't remember.

25 **Q.** Then you've produced a document from June 1983.

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1 Henry, could we have WITN3289041. If we just zoom
2 in on that.

3 This the letter of 24th June 1983 sent to Centre
4 Directors by Professor Bloom and Dr Rizza, following
5 a special meeting of Reference Centre Directors, and it
6 sets out in the two numbered paragraphs there two
7 general recommendations.

8 If we just look at those recommendations, it says
9 at (1):

10 "For mildly affected patients with haemophilia A or
11 von Willebrand's disease and minor lesions, treatment
12 with DDAVP should be considered. Because of the
13 increased risk of transmitting hepatitis by means of
14 large pool concentrates in such patients, this is in any
15 case the usual practice of any Directors."

16 Was that the usual practice at the Sheffield Centre
17 at that time?

18 **A.** It was already the usual practice because of non-A,
19 non-B hepatitis.

20 **Q.** And then in (2), it says:

21 "For the treatment of children [and we can leave
22 that aside] and mildly affected patients or patients
23 unexposed to imported concentrates many Directors
24 already reserve supplies of NHS concentrates
25 (cryoprecipitate or freeze-dried) and it would be

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1 circumspect to continue this policy."

2 So taking, first of all, mildly affected patients,
3 this is a suggestion that if you have an existing policy
4 of treating them with cryo or NHS concentrates,
5 continue. Did this lead to any change of approach for
6 your mildly affected patients? Or were you already
7 predominantly using DDAVP?

8 **A.** I think we were already doing that. And as you've
9 already pointed out to me, at the Children's Hospital
10 they were using predominantly cryoprecipitate or NHS
11 concentrate at that time.

12 **Q.** And then in terms of patients unexposed to imported
13 concentrates, was there any particular approach or
14 policy agreed at the Sheffield Centre in relation to
15 that category of patients in light of this letter?

16 **A.** Well, I don't think it changed very much, because we
17 already had a policy of keeping people to the brand
18 that they were on. So, you know, if people had been
19 treated exclusively with British products, that would
20 continue.

21 **Q.** But if it was a patient who was a new patient,
22 maybe -- I don't know that you didn't come across any
23 in your time there -- a new patient who hadn't
24 previously been treated with imported concentrates,
25 would they have been started on NHS concentrates or

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1 would it have depended on availability?

2 **A.** It would have depended on availability, I think.

3 **Q.** And then other than the continuation of the existing
4 policies you have described and the early use of
5 heat-treated products, which you've already referred
6 to, were there, as far as you know, any other changes
7 to the approach to treatment at the Sheffield Centre
8 in '83, '84 in response to the risk of AIDS?

9 **A.** I can't think of any. I think we deferred some
10 surgery.

11 **Q.** Do you know whether that would have been 1983 or '84
12 or indeed later?

13 **A.** I'm not sure, to be honest. But I seem to remember
14 that some surgery was deferred. That happened in
15 quite a few places.

16 **Q.** Was any consideration given to a suspension, at least
17 on a temporary basis, of the Home Treatment Programme?

18 **A.** Well, I think this was discussed. I can't say exactly
19 when because, as you've pointed out, the suggestion
20 did come up in the literature occasionally, so it
21 wasn't something that was completely ignored. But it
22 was certainly Professor Preston's view, and I think
23 that this was commonly the case, that this would be
24 resisted by the patients, was not recommended by the
25 Haemophilia Society or the World Federation of

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1 Haemophilia.
 2 And I think what people were trying to do -- this
 3 comes across in some of the minutes involved with
 4 Professor Bloom -- was to try to balance out the
 5 risks. Now, on the one hand, if you go back to cryo,
 6 you have an immediate supply problem because cryo
 7 wasn't being very much produced, and the requirement
 8 for Factor VIII had tripled during for the previous
 9 decade.
 10 So I'm not sure there would have been enough cryo.
 11 Certainly, you would have had to turn the Transfusion
 12 Service on its head to suddenly produce a whole lot of
 13 cryo, which would not have happened overnight. Then
 14 you would have reverted to the life expectancy that
 15 had pertained before that event of concentrate.
 16 Now, the introduction of cryo improved life
 17 expectancy enormously, because in the pre-treatment
 18 era, it was 10 to 15 years, and it increased to about
 19 40. Actuarial methods published by Charlie Rizza
 20 et al suggested that we'd nearly normalised life
 21 expectancy.
 22 So changing back to cryo would have been expected to
 23 have reduced life expectancy, maybe not dramatically,
 24 but to some extent. And they were trying to balance
 25 this up, because this was all knowledge that was known

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1 at the time. Trying to balance this up against the big
 2 unknown.
 3 Now, of course, if we'd known then what we know now,
 4 the argument for switching to cryo would have been very
 5 much stronger. But they were trying to balance a known
 6 change in life expectancy on the one hand against an
 7 unknown effect of AIDS. And I think at the time they
 8 were doing that in 1983, there was one patient reported
 9 with AIDS, and by the following year it had gone up to
 10 about three, as far as I can recall.
 11 So, you know, numerically, the problem didn't appear
 12 big, but there clearly was an enormous degree of
 13 uncertainty. Because the natural history of HIV had not
 14 yet unfolded, and we had no idea how many patients were
 15 affected.
 16 **Q.** Can I try and unpick some of that with you, professor?
 17 **A.** Yes.
 18 **Q.** First of all, as far as Sheffield is concerned, can
 19 you recall whether there was -- whether positive
 20 consideration was given, whether at the weekly
 21 meetings you've described or otherwise, to reverting
 22 to cryoprecipitate, either in whole or in part? Was
 23 there actual discussion about that in Sheffield?
 24 **A.** Yes, there was.
 25 **Q.** And what was the forum for that? Was that on

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1 a regional basis, or was it in the weekly meetings
 2 you've described?
 3 **A.** Well, we certainly discussed it in the weekly
 4 meetings. Whether it was more widely discussed,
 5 I don't know. But Professor Preston rejected it. As
 6 far as I'm aware, John Lilleyman rejected the idea as
 7 well. And they quoted other colleagues' consensus
 8 documents. You know, I think it was considered fairly
 9 widely.
 10 **Q.** You've raised one possible practical impediment, that
 11 of supply.
 12 **A.** Yeah.
 13 **Q.** Now, we've seen evidence, for example, from -- and I'm
 14 not suggesting you would necessarily have been aware
 15 of this at the time -- from an October 1983 UKHCDO
 16 meeting, where Dr Chisholm in Southampton said that
 17 she had unlimited supplies of cryoprecipitate -- her
 18 problem was getting commercial concentrates -- and
 19 some other directors agreed. So in --
 20 **A.** I think it would have varied from region to region
 21 because this is a product that's produced by the local
 22 Transfusion Centre, and it's not just used for
 23 haemophiliacs. It was also used for the treatment of
 24 disseminated intra-vascular coagulation and other
 25 acquired bleeding problems. But, you know, it varied

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1 from centre to centre.
 2 When I got to Manchester, for example, admittedly
 3 much later than this, they'd stopped manufacturing
 4 cryoprecipitate altogether, and I had to actually ask
 5 them to start making it again.
 6 **Q.** Do you know whether Professor Preston or indeed
 7 Dr Lilleyman approached the Sheffield Regional
 8 Transfusion Centre, or Dr Wagstaff, to explore with
 9 them the possibility of increasing production of
 10 cryoprecipitate?
 11 **A.** If he did, I don't know about it.
 12 **Q.** Then in your statement, you've set out a number of
 13 concerns about possible reversion to cryoprecipitate,
 14 some of which you've touched on in your oral evidence.
 15 You'd said in your statement that cryoprecipitate was
 16 incompatible with home therapy. We've heard evidence
 17 that -- of a number of haemophiliacs in the course of
 18 the 1970s receiving home treatment through the use of
 19 cryoprecipitate.
 20 Would you accept that incompatible is perhaps an
 21 overstatement?
 22 **A.** Well, I wasn't aware of that at the time. I am aware
 23 of it now. But what I would say about that is that it
 24 was a minority of centres that had some pilot -- what
 25 I'd describe as pilot projects of home therapy with

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1 cryo, because logistically it was quite challenging.
 2 You'd need a minus 40 to minus 60 freezer. A domestic
 3 freezer would not do. These are sort of great big
 4 bulky things. They're quite expensive. Not everyone
 5 would have room for it. Many of the patients actually
 6 complained about the amount of space their Factor VIII
 7 concentrate took up in their fridge. Some patients
 8 had to have more than one domestic fridge. But at
 9 least the concentrate you could keep in a domestic
 10 fridge, whereas with cryo, it has to be delivered from
 11 the Transfusion Centre, without breaking the cold
 12 chain, to the patient's home and then stored in
 13 a minus 40 freezer. And even as home therapy, there
 14 would be a delay in being able to treat yourself
 15 because you've got to defrost it and draw it all up.
 16 It's much more difficult drawing up, you know, 6 or 12
 17 bags of gloopy stuff than it is having concentrate.

18 So, yes, there was limited use of cryo for home
 19 therapy, but it depended on a number of factors, and it
 20 was never widespread.

21 **Q.** Yes, well, I mean, we've heard a range of evidence in
 22 relation to that, so I'm not sure the evidence we've
 23 heard would support the characterisation of it as
 24 pilot in terms of its usage in the '70s.

25 **A.** Well, I honestly don't think there were large numbers

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1 of patients on home therapy with cryo, and most
 2 centres weren't doing it at all.

3 **Q.** In terms of your own direct experience, is this right:
 4 that you would have had no experience or little
 5 experience of patients in Sheffield on the home
 6 therapy with cryoprecipitate because by the time 1983
 7 came along, it was all concentrates?

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

15 **Q.** And then you've said in your statement and again in
 16 your oral evidence this: that changing to
 17 cryoprecipitate or no treatment would dramatically
 18 increase the risk of haemorrhagic death, decrease life
 19 expectancy dramatically, and lead to more rapid
 20 deterioration of haemophilic arthropathy.

21 Now, if we take out the reference to no treatment,
 22 professor, what's the evidential basis for your
 23 assertion that changing to cryoprecipitate in 1983
 24 would have dramatically increased the risk of death as
 25 a result of haemorrhage?

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1 **A.** Well, haemorrhage at that time was the commonest cause
 2 of death in severe haemophilia, and the life
 3 expectancy estimate, before the introduction of
 4 concentrates, was about 40 years, whereas I think
 5 Rizza et al, based on the early returns to Oxford, the
 6 National Haemophilia Database, calculated that life
 7 expectancy was about 67, 68.

8 **Q.** Is the answer to my question that the factual or
 9 evidential basis for that assertion is Dr Rizza's
 10 paper?

11 **A.** Yes.

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

22 **A.** Well, I mean, it would have -- for that period of
 23 time, they would have been more at risk of dying from
 24 haemorrhage. Now, okay, yes, it's a limited period of
 25 time, and that would reduce the danger, but for most

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1 patients it would have meant reverting to
 2 hospital-based treatment.

3 Now, this was one of the great advantages of
 4 concentrate because we knew that with haemophilic
 5 bleeding, the earlier you treated it, the less damage
 6 is done. So when the patients had the treatment at
 7 home, they were told: if you think you've got a bleed,
 8 treat yourself immediately. It may not be a bleed,
 9 but, you know, you have a lot of personal experience,
 10 and they would be able to do so.

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

23 Now, with a haemarthrosis, the result of that is
 24 that there is far more joint damage and the
 25 haemarthrosis takes a lot longer to resolve, but I think

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1 you can probably argue that doesn't make a difference to
2 life expectancy.

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

14 **Q.** On this hypothetical scenario, the delay that you're
15 describing could have been dramatically reduced by the
16 provision of cryoprecipitate as a home therapy, to be
17 used --

18 **A.** Yes.

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

21 **A.** Yes, but I would suggest that -- well, you know, home
22 therapy with cryo happened in a few centres,
23 a relatively small number of patients. Setting it up
24 on a national basis, with the purchase of all those
25 refrigerators, some patients wouldn't have had any

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1 room for it, would have been a major undertaking that
2 couldn't have happened very quickly, I would imagine.
3 When do you suggest that they should have done that?

4 **Q.** Professor, I'm exploring with you what options were
5 considered and what difference they might --

6 **A.** Okay.

7 **Q.** What the practical impediments might have been. Do
8 you --

9 **A.** I think in most centres, they considered that it was
10 not a suitable product for home therapy, for logistic
11 reasons.

12 **Q.** Do you accept or agree that the question of whether to
13 take that risk of possibly delayed treatment in the
14 event of a headache, or to take the risk of having
15 less than ideal treatment for other bleeds and
16 possible risks of joint damage was a decision for the
17 patient to take, rather than for the physician to take
18 for the patient?

19 **A.** That's an interesting philosophical question, because
20 the big problem is that these decisions were being
21 made on the basis of very little information. And,
22 you know, even the guidelines that came out were not
23 as evidence based as we like our guidelines to be
24 because they were based on opinion, and that opinion
25 was very poorly informed because there were so many

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1 reasonable questions about AIDS, and subsequently HIV,
2 that just were not known. A lot became clearer once
3 the tests became available.

4 **Q.** Were patients, as a matter of fact, at the Sheffield
5 centre [audio disruption] --

6 **A.** -- questions --

7 **Q.** -- told --

8 **A.** And I think it would have been an order of magnitude
9 more difficult for the patients, because, you know,
10 the conversations were to be relatively uninformed.

11 **Q.** Sorry, professor, we had a slight problem with the
12 Internet connection then but I think we got your
13 answer.

14 **A.** Okay.

15 **Q.** Were patients, as a matter of fact, from -- in the
16 time you were at Sheffield, so from April 1983
17 onwards, told of the possible risk of AIDS from the
18 continuing use of factor concentrates?

19 **A.** I do recall having conversations with the patients
20 about AIDS. It was widely reported, patients did ask
21 about it. And to be honest, we weren't able to
22 quantify the risks.

23 **Q.** Were patients routinely given that information, such
24 information as you had, or was it only discussed with
25 them if they raised it with you?

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1 **A.** They were routinely given that.

2 **Q.** And what kind of information in 1983, '84, do you
3 think they were given?

4 **A.** I think they would have been told that there was some
5 evidence that recipients of blood or blood products
6 were developing AIDS but that there were very few
7 cases, and they were probably told that, as far as we
8 could see, the risk was relatively small at that time.
9 I think that was the general view.

10 **Q.** Was any patient, as a matter of fact, given the choice
11 to revert to cryoprecipitate?

12 **A.** I don't recall that.

13 **Q.** Were there any attempts made in '83/'84, to acquire
14 more NHS concentrate in view of what was thought to be
15 the increased risk of AIDS associated with commercial
16 concentrates?

17 **A.** Er ... there may well have been, but I don't recall.
18 There was always a supplier problem with
19 NHS concentrates. We could never get enough of them.

20 **Q.** Was any consideration given, as far as you can recall
21 in this '83/'84 period, to using porcine products for
22 non-inhibitor patients in response to the risk of
23 AIDS?

24 **A.** Very little. There's several things you need to know
25 about porcine. I mean, in actual fact, the one

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1 clinician who used porcine Factor VIII for
 2 non-inhibitor patients during this period was my
 3 predecessor in Manchester, who actually published
 4 a paper on this. And he had used it for surgery in
 5 little-treated patients to avoid the risk of
 6 non-A, non-B and, possibly, whatever the AIDS virus
 7 was.

8 But the product that was available at that time was,
 9 by modern standards, an intermediate purity product.
 10 It's essentially a concentrate of porcine Factor VIII.
 11 If you use it in a non-inhibitor patient, a significant
 12 portion of patients will develop antibodies which are
 13 specific anti-porcine antibodies, and then you won't be
 14 able to use it again. And some will develop transfusion
 15 reactions with the product. And it intended to make
 16 your platelet count fall in a very predictable way,
 17 because it also included quite a lot of porcine
 18 von Willebrand factor which causes human platelets to
 19 aggregate.

20 **Q.** Was the predecessor at Manchester who used that, are
 21 you referring to Dr Wensley?

22 **A.** I am.

23 **Q.** And do you recall the use of porcine product in the
 24 way that I've just discussed being actively considered
 25 at Sheffield by Professor Preston or is it that it

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1 wasn't considered and you're suggesting reasons why it
 2 might not have been considered?

3 **A.** I can't remember it being discussed or considered.
 4 I only found out about Dr Wensley much, much later.

5 **Q.** You've referred in your statement, and indeed
 6 Professor Preston made reference to them, to there
 7 being a meeting or meetings involving a number of
 8 patients at the centre to discuss the risk of AIDS or
 9 to discuss AIDS. Can you recall anything further
 10 about those meetings and how they were set up, and
 11 what kind of matters were discussed?

12 **A.** Sorry, you broke up a little bit there.
 13 Are we talking about the Journal Club or the
 14 multi-disciplinary meetings?

15 **Q.** No, I'm sorry, neither. My apologies, Professor Hay.
 16 Professor Preston told us about there having been
 17 a meeting with patients, and your statement I think
 18 also reflects that: a larger meeting, not a one-to-one
 19 patient meeting, a larger meeting or meetings to which
 20 patients were invited to discuss AIDS.

21 **A.** Yes.

22 **Q.** What, if anything, can you recall about those?

23 **A.** I didn't -- I can't remember actually attending these.
 24 They were meetings between Eric and any patients who
 25 wanted to come along and I believe he discussed with

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1 them what was known about the issue at the time. And
 2 he had a number of them as the state of knowledge
 3 progressed, particularly once we had a test. Because
 4 the state of knowledge progressed very rapidly after
 5 that.

6 **Q.** In terms of the Children's Hospital, and you
 7 returned -- you were at the Children's Hospital for
 8 your first 6-month period, August '84 to April of
 9 1985, can you recall what, if any, discussion there
 10 was with the parents of patients at that hospital
 11 about the risks of AIDS?

12 **A.** I can't recall. I'm sure we will have discussed it
 13 with them. But I can't remember the nature of those
 14 discussions. I'm sure it would, amongst other things,
 15 have come up during the regular reviews.

16 **Q.** Do you or would you agree that the parents of children
 17 who were receiving factor concentrates that might
 18 expose them to a risk of AIDS were entitled to be told
 19 of that risk?

20 **A.** Yes, of course.

21 **Q.** Now you'd then returned to the Royal Hallamshire
 22 Hospital in I think April 1985. By that time, what
 23 was the position in terms of the use of heat-treated
 24 products?

25 **A.** Well, I think Eric had switched over -- in, I think,

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1 December of the previous year -- as many patients as
 2 he could to Alpha Profilate, on the basis that there
 3 was some evidence of a model virus, which they thought
 4 would be similar to what turned out to be the
 5 causative agent of AIDS, being heat labile.

6 So it was quite a leap, to be perfectly honest,
 7 but, you know, I was giving the patients the benefit
 8 of the doubt. This was the safest product we had
 9 available to them. And there was no direct evidence
 10 that it was safe from the HIV point of view, but he
 11 thought that it might be.

12 It clearly wasn't completely safe, but from the
 13 point of view of non-A, non-B hepatitis. But we didn't
 14 know at that time that the HIV virus was more heat
 15 labile than the hepatitis viruses, so it was actually
 16 easier to eradicate it using heat treatment methods that
 17 might be inadequate for hepatitis.

18 **Q.** We know that in December 1984, and you've exhibited
 19 the statement to the relevant document, UKHCDO
 20 produced a set of recommendations which included the
 21 recommendation to use heat-treated product.

22 Your statement says, at paragraph 48.4, that most
 23 Haemophilia Centres were obliged to continue to use
 24 some untreated concentrates until sometime in 1985.
 25 Was that because of insufficient supplies of the

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1 heat-treated products?
 2 **A.** Yes, and some centres still had a preference for
 3 British products, which was impossible to satisfy,
 4 because BPL had been so slow to even begin to address
 5 the issue of heat treatment. And what they did, as
 6 I recall, was to withdraw their unheated products and
 7 stick them in an oven and heat-treat them, and send
 8 them back.

9 And the first heat-treated product that they
 10 produced in that way was essentially insoluble, and we
 11 couldn't use it. So there was, in effect, quite an
 12 interruption in supply of British products, and it took
 13 a while to sort out.

14 And people were scratching around for any
 15 heat-treated product they could find. A lot of it was
 16 unlicensed. And there wasn't enough of it.

17 **Q.** Do you know how long it took into 1985 for Sheffield
 18 to no longer be using untreated concentrates and to
 19 have exclusively heat-treated concentrates?

20 **A.** I can't remember exactly. I have actually looked at
 21 the annual returns for that year, from the database,
 22 in anticipation of this question. I couldn't get
 23 a clear view from that either, because it was quite
 24 clear that a variety of products were used during the
 25 course of that year. And that is despite the fact

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1 that Alpha was supplying preferentially those Centres
 2 that had participated in their clinical trial.

3 **Q.** Then in relation to those with haemophilia B who had
 4 I think at Sheffield consistently been treated with
 5 NHS Factor IX concentrate --

6 **A.** Yes.

7 **Q.** -- do you have any recollection as to the point in
 8 time at which heat-treated Factor IX concentrate was
 9 available for the Sheffield patients?

10 **A.** Well, I think that they had to use AlphaNine, if my
 11 memory serves me correctly, which was commercial.
 12 Because it was later in '85, I think, that 9A
 13 heat-treated UK Factor IX became available, and in the
 14 interim the only heat-treated Factor IX available
 15 would have been commercial.

16 **SIR BRIAN LANGSTAFF:** If it helps, it was
 17 2nd October 1985, that all the Factor IX issued by BPL
 18 was heat treated. That's my note.

19 **A.** Thank you.

20 **MS RICHARDS:** I wanted to ask you about the process of
 21 testing patients for HIV, HTLV-III, at the Royal
 22 Hallamshire and then, to the extent that you can
 23 recall, at the Children's Hospital.

24 The testing at the Royal Hallamshire, from
 25 material that we've seen, probably began in late 1984,

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1 and you'd have been at the Children's Hospital at that
 2 stage. But we understand from Professor Makris that
 3 the testing was on the basis of the stored samples.

4 Do you have any knowledge yourself of the
 5 arrangements that were made for testing patients at
 6 the Royal Hallamshire for HTLV-III in late '84, or
 7 early '85?

8 **A.** Well, I wasn't there when it all started. I didn't
 9 remember it being from stored samples. I'm sure that
 10 stored samples were tested because that gives you
 11 historical background and a basis on which -- from
 12 which to tell the patient not only whether they've got
 13 HIV but when they contracted the infection. It's
 14 useful to know.

15 But my recollection is of patients coming up, having
 16 a chat, and then having a blood sample taken.

17 **Q.** So is your recollection that patients were told in
 18 advance that they were going to be tested for HIV,
 19 HTLV-III?

20 **A.** Yeah. I mean, it may well be that Professor Preston
 21 sent stored samples off to Professor Tedder in London
 22 at a point when the test was very experimental. And
 23 the difficulty with that sort of thing -- I mean, it
 24 was difficult enough once the test had been validated
 25 because when you sit down with the patient and you

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1 discuss the result, the implications of the test are
 2 not fully known. So it's quite a difficult
 3 conversation.

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

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

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

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

24 **Q.** And you're not in a position, from the information you
 25 had, to break it down by reference to whether it was

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1 haemophilia A or B, von Willebrand's and
 2 -- (overspeaking) --
 3 **A.** No.
 4 **Q.** Did you have any involvement in the testing of family
 5 members for HIV at the Royal Hallamshire?
 6 **A.** I honestly don't remember. Family members would have
 7 been offered a test, particularly since it was
 8 recognised from a very early stage that the causative
 9 agent could be sexually transmitted.
 10 **Q.** The process of giving information to patients about
 11 their diagnosis and its significance, that was
 12 undertaken, was it, by Professor Preston, rather than
 13 by you?
 14 **A.** Largely. Though, you know, obviously, I would have
 15 come across these people in clinics, and naturally
 16 they would have wished to discuss it there too. And
 17 as far as partners are concerned, we were all
 18 encouraging patients to bring their partners with
 19 them, to follow-up visits, and certainly to any
 20 discussions about testing.
 21 **Q.** And what, if any, knowledge do you have about
 22 seroconversions from heat-treated products for
 23 patients at the Royal Hallamshire?
 24 **A.** I don't think there were any. Though I am aware that
 25 there was an Armour product used in other centres that

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1 was withdrawn because some patients contracted HIV
 2 from those products, and I think that was the subject
 3 of litigation, but I don't think that involved
 4 Sheffield.
 5 **Q.** You were asked in your statement whether work was
 6 undertaken at Sheffield to establish the time period
 7 during which patients seroconverted, and you said in
 8 your answer:
 9 "Some stored samples were available in Sheffield
 10 from some but not all patients which enabled the
 11 approximate date of the initial infection to be
 12 determined. I recall that most had been infected in
 13 1982 to 1984."
 14 Do you know when that exercise of trying to
 15 establish the dates of seroconversion was undertaken?
 16 **A.** It would have been undertaken very early on, at the
 17 time of initial testing, possibly before the test was
 18 fully validated.
 19 **Q.** And do you have any further information about that
 20 process and what it showed?
 21 **A.** No.
 22 **Q.** Then in relation to the Children's Hospital, so you
 23 were at the Children's Hospital during that last part
 24 of '84 and first part of '85 when testing was becoming
 25 widespread.

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1 What, if anything, can you recall about the
 2 process of testing the children at the Children's
 3 Hospital for HTLV-III?
 4 **A.** I don't think they had any stored samples.
 5 Professor Lilleyman would have seen all of the parents
 6 individually and arranged testing.
 7 **Q.** So did you have any involvement in the process of
 8 informing parents that their children had tested
 9 positive?
 10 **A.** It's the sort of thing that I think John Lilleyman
 11 would have wanted to do himself.
 12 **Q.** Can I move on, then, to Liverpool, where you took up
 13 your post in 1987.
 14 Who was it that you succeeded as director at the
 15 centre?
 16 **A.** Dr BA McVerry.
 17 **Q.** Can you give us an outline of the facilities that the
 18 Liverpool centre offered in 1987?
 19 **A.** Well, the patients came along to the laboratory, which
 20 was in the Duncan Building, which is annexed to the
 21 main Royal Liverpool Hospital building, on the third
 22 floor, and there was a large clinical room in the
 23 middle of that laboratory, and that was the
 24 Haemophilia Centre.
 25 We had secretarial support, and I had a junior

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

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1 Q. Do you know whether it had been a user of DDAVP for
2 mild haemophiliacs and others?

3 A. I think latterly, yes.

4 Q. What, if any -- sorry, by the time you got there in
5 1987, were all the concentrates that were being used
6 heat treated?

7 A. Yes.

8 Q. Do you know whether any of the Liverpool patients had
9 seroconverted from heat-treated products?

10 A. Not as far as I'm aware.

11 Q. I think you raised a concern shortly after you arrived
12 at Liverpool, with Ms Spooner, I think, at Oxford,
13 that you discovered that there were quite a few
14 patients who were not registered with Oxford. Is that
15 right?

16 A. That's correct.

17 Q. Do you know how that had come about?

18 A. Well, I think they were just not very conscientious
19 about reporting patients. I think it was a voluntary
20 database, and I think patients commonly weren't
21 reported. When I took over the database in 2002,
22 there were only 16,000 registrants, and we now have
23 well over 30,000. And I don't think that that is
24 reflecting the birth of new patients; I think it's
25 reflecting previous historic under-reporting,

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1 particularly of the patients with mild bleeding
2 disorders.

3 Q. Do you have any recollection of what kind of
4 proportion of patients had not been registered with
5 Oxford prior to your arrival in '87?

6 A. Well, in the Liverpool centre I got the impression it
7 was over 50%.

8 Q. Over 50%?

9 A. Yes.

10 Q. And when you then completed I think you called them
11 notification forms or something like that in your
12 correspondence with Ms Spooner --

13 A. Yes.

14 Q. -- were those providing -- or what kind of information
15 was then provided about the patient to Oxford in those
16 notification forms?

17 A. Well, the basic notification form just reported the
18 patient's identifiers and their diagnosis and the
19 severity of the diagnosis.

20 Q. Did you report, either in relation to that cohort of
21 patients or more generally, to Oxford, the HTLV-III or
22 HIV positive status of your patients?

23 A. Yes, you'll come across all of this when you read my
24 still not completely written report that goes at the
25 end of this statistical report, but there was -- there

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1 were separate forms for reporting the details of HIV.
2 And as you've already observed, Dr Craske initiated
3 that process, and it continued for a number of years.
4 So yes, I filled those forms out as well.

5 Q. And did you tell your patients that you were providing
6 that information about them to Oxford?

7 A. I think that I did.

8 Q. What did you learn at Liverpool about how patients had
9 been told that they were HTLV-III positive?

10 A. Well, the patients told me. I had very little
11 information from Dr McVerry himself. They told me
12 that they had been informed by post.

13 Q. So they learnt they were HTLV-III positive by a letter
14 from the centre?

15 A. That's right.

16 Q. And in terms of the numbers of patients at Liverpool
17 who were found to be HTLV-III positive -- I've just
18 lost the reference to the numbers -- I think you've
19 said in your statement, in Liverpool 43 patients had
20 HIV, of whom four were children.

21 A. Yes.

22 Q. And you've taken that from the National Haemophilia
23 Database rather than any Liverpool records?

24 A. I have.

25 Q. Okay.

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1 **MS RICHARDS:** Sir, I note the time. Is that a convenient
2 point at which to stop?

3 **SIR BRIAN LANGSTAFF:** Yes, it is.
4 We take a break for lunch. Two o'clock, if you
5 please, professor. Two o'clock, everyone. I'll see
6 you then.

7 **THE WITNESS:** Thank you. Thank you.
8 **(1.01 pm)**
9 **(Luncheon Adjournment)**
10 **(2.00 pm)**
11 **MS RICHARDS:** Professor Hay, I was asking you about
12 Liverpool and your work there from 1987 onwards.
13 You were now, as director, responsible for decisions
14 as to what products to use. What were the existing
15 contractual arrangements, can you recall? Was it
16 something that the previous director had done directly,
17 or was it done regionally?

18 A. Well, it was what the previous director had done. It
19 was done originally because it was a regional
20 Haemophilia Centre. It covered Mersey Region and
21 parts of North Wales.
22 He contracted on -- well, through the hospital
23 purchasing manager, to purchase Factor VIII, and that
24 would have to be agreed -- or Factor IX -- and that
25 would have to be agreed with the commissioners.

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1 Q. And was that then an arrangement that you took over?
 2 So for the years that you were director at Liverpool,
 3 did you undertake the decision-making process and the
 4 arrangements for the acquisition of commercial
 5 products?
 6 A. Well, I agreed which products we should use, subject
 7 to the approval of the commissioners who paid for it.
 8 Q. And by "commissioners" you mean the hospital
 9 authorities, effectively; the fund holders?
 10 A. Yeah, the fund holders. We had a manager, and we
 11 would negotiate with each of the district health
 12 authorities what they would pay.
 13 Q. Your statement says you continued with the policy that
 14 had been operated at Sheffield, of using a single
 15 brand of concentrate per patient, if you could?
 16 A. Yes.
 17 Q. And what was the basis for the continuation of that
 18 policy?
 19 A. Well, it just seemed generally good practice. It made
 20 it easier to trace back if there was a problem with
 21 a specific batch of a product. It made it easier to
 22 handle any product recalls that might occur and also
 23 made it much easier to discuss with patients if there
 24 needed to be a change.
 25 Q. Were you --

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1 A. And we had to make changes from time to time, as
 2 newer, better products came along, or old products
 3 were withdrawn.
 4 Q. Were you able to ascertain, either from the patient's
 5 records or from your own discussions with patients,
 6 what kind of information they'd been given in the
 7 preceding years about the risks of non-A, non-B
 8 hepatitis?
 9 A. The medical records before I arrived appeared poor and
 10 were uninformative, so the short answer is no.
 11 Q. So did you then discuss non-A, non-B hepatitis from
 12 '87 onwards with your patients when you saw them?
 13 A. Yes, because we were monitoring for it, and, yes, we
 14 would.
 15 Q. In relation to risks of AIDS, HTLV-III, HIV, were you
 16 able to ascertain, again either from records or from
 17 your discussions with patients, what information
 18 they'd received before they were tested about the risk
 19 of AIDS?
 20 A. That was never very clear to me. I obviously spoke to
 21 the patients. They maintained that they didn't know
 22 very much about it and that when they had been
 23 informed of the result, they were not given very much
 24 support because there were very few staff. But
 25 nonetheless.

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1 Q. And you told us already that they had been informed of
 2 their result by letter.
 3 Did you ascertain or become aware of whether
 4 they'd even been told they were being tested for HIV?
 5 A. I can't remember.
 6 Q. Was there any system of stored samples at Liverpool?
 7 A. Before I arrived, there had been, apparently. And
 8 I made specific enquiries about that with Dr McVerry
 9 without any result. I suspect that some of the
 10 patients were tested from stored samples, but I was
 11 never able to obtain the results of those tests.
 12 Q. So it would follow, I think, from that that you don't
 13 have any information about the periods of time during
 14 which Liverpool patients seroconverted?
 15 A. That's right. I mean, that's why I made those
 16 specific enquiries. There was nothing left for me,
 17 and he didn't answer my letters.
 18 Q. Do you have any recollection as to how many, if any,
 19 family members, partners, wives and so on of patients
 20 were HTLV-III positive?
 21 A. I can't remember, but we certainly offered testing to
 22 all partners, and we encouraged partners to attend
 23 follow-up clinics with their husbands.
 24 Q. Now, how was the care and treatment of the patients at
 25 Liverpool with HIV, how was it organised from 1987

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1 onwards through to 1994 when you left?
 2 A. Well, I managed them largely myself, although,
 3 increasingly, I consulted with my STD colleague,
 4 Dr Carey, and occasionally with infectious diseases
 5 consultants, but they were based at Fazakerley
 6 Hospital, which was the other side of Liverpool.
 7 Q. What kind of support in terms of counselling or social
 8 work support was available?
 9 A. Well, when I first arrived, there was nobody but me,
 10 so I had a lot of -- initially quite difficult
 11 consultations with these patients who, as you might
 12 imagine, had many, many questions and required a great
 13 deal of support. It was a pretty awful time, and
 14 there was a great deal of uncertainty, and we all had
 15 a great deal to learn about HIV still.
 16 From 1988, AIDS money came along, and you'll have
 17 seen the article in the Haemophilia Bulletin about the
 18 team that they managed to put together, so we then had
 19 a counsellor, a social worker and a haemophilia nurse
 20 specialist, who was quite a senior nurse, and they
 21 also provided a great deal of pastoral support which
 22 was most certainly needed.
 23 Q. And in terms of the AIDS money, can you just tell us
 24 what that was and where it came from?
 25 A. Well, I think it was recognised by the Department of

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1 Health that a lot of Haemophilia Centres, particularly
2 those north of Watford, did not have the wherewithal,
3 in terms of staff and specialisation, to deal with
4 this new problem adequately.

5 You know, I only learned about the existence of
6 haemophilia nurses when the Haemophilia Society sent
7 me to one of their weekend annual residential
8 seminars. I'd never even met a haemophilia nurse
9 until I went along to one of those. So many
10 Haemophilia Centres didn't have haemophilia nurses or
11 the sort of full infrastructure that we now take for
12 granted.

13 So the Department of Health made some money
14 available which was distributed at a regional level for
15 that sort of infrastructure.

16 **Q.** And was that money made available on an annual and
17 continuing basis, or was it time limited?

18 **A.** My understanding was that it would be continuing.

19 **Q.** Do you know how the allocation was calculated?

20 **A.** I don't -- I can't remember. I do remember having
21 conversations with the regional Health Authority where
22 they said that they had received an allocation; what
23 was my shopping list? So I gave them a shopping list,
24 and they agreed to pay for it.

25 **Q.** Did you experience difficulties in obtaining funding

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1 for treatments for HIV and AIDS as those treatments
2 became available at Liverpool?

3 **A.** Not unduly. Whenever any new treatments came along,
4 you would always find that the regional Health
5 Authority or the local health authorities didn't have
6 the money, so there was often a delay. But HIV had
7 such a high profile that I don't remember having
8 inordinate difficulty getting the funding for that in
9 particular.

10 **Q.** Now, HCV testing became available whilst you were
11 still at Liverpool.

12 As far as you can recall, when did the process of
13 testing for hepatitis C start and for how long did it
14 go on?

15 **A.** It started when the second generation of hepatitis C
16 antibody tests became widely available, which would
17 have been during the course of 1991. Since the
18 testing was not clinically urgent -- and so the
19 patients weren't all brought in in a big wave but
20 tested at the next follow-up clinic, and then they
21 would be informed of their result at the follow-up
22 clinic following that, unless, of course, they wanted
23 to know the result more quickly.

24 **Q.** Had there been any use of the first generation of
25 tests by you at Liverpool?

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1 **A.** No.

2 **Q.** When the second generation tests became available and
3 you started the process of testing, did you tell
4 patients that you were going to test them for
5 hepatitis C and seek their consent?

6 **A.** Well, I think I did tell them, because the context of
7 testing them was in the clinic, and this was a new
8 test. And, you know, they would also have had
9 conversations before then about non-A, non-B
10 hepatitis. So those that had abnormal liver function
11 tests, or who had been treated with concentrate in the
12 past, we would have expected to have a positive test.

13 Because this is an antibody test, it doesn't tell
14 you whether you've got hepatitis C, only that you've
15 been exposed to the virus at some stage in the past.
16 So, you know, you'd say to them that you wanted to
17 test them for hepatitis C, and you would say to a lot
18 of them that you would expect the result to be
19 positive.

20 There were some where you didn't know whether it
21 would be positive or not, and those were the patients
22 who had been very infrequently treated in the past.

23 **Q.** You described that as being a process that was
24 undertaken at the regular outpatients appointment. So
25 a patient would come in for a scheduled appointment,

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1 you'd arrange the hepatitis C test, and then you'd
2 tell them the results at their next appointment.

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

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

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

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

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

23 **A.** Well, you would have already made some sort of
24 assessment of their liver disease. These are -- if
25 they had chronic transaminitis, indicating chronic

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

15 **Q.** The first treatment that was available was interferon.

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

19 **A.** Yes. Once it was licensed.

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

22 Were you involved in any clinical trials of
 23 interferon?

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

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1 **Q.** Can you recall what information you gave to your
 2 patients at Liverpool about interferon, both in terms
 3 of what was understood to be its prospects of success
 4 and in terms of side effects?

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

12 When you started to combine it with other drugs
 13 such as ribavirin, and then when you moved on to peg
 14 interferon, the side effects were generally much
 15 worse. And I would have a consultation with the
 16 patients, often several, and I would strongly
 17 encourage them to bring their wife along to the
 18 consultation so that they would hear about the side
 19 effects straight from the horse's mouth. And I would
 20 warn them that depression was an extremely common side
 21 effect and sometimes persisted for weeks or months
 22 after the treatment finished; that most patients
 23 suffered serious fatigue during the course of the
 24 treatment; some lost weight, and that it was extremely
 25 common, for the patient, however sweet natured they

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1 might have been before they went on to treatment to
 2 become extremely tetchy and get into arguments for no
 3 good reason.

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

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

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

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

5 They then moved to interferon alone for about
 6 12 months, and then it was combined with ribavirin.

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

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

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1 liver disease from developing. And also because the
 2 response rate was better in people that didn't have
 3 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 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 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 Transfusion
 15 Service, and only 50% employed by Manchester Royal
 16 Infirmary. They had used cryoprecipitate more than
 17 most centres for longer than most centres.

18 **Q.** Do you have any sense of how much commercial
 19 concentrates had been used? A rough proportion as
 20 between NHS and commercial in the early eighties?

21 **A.** I don't know. I'm not sure.

22 **Q.** Did you have any sense, when you arrived there, of
 23 what the Centre's approach had been to the response to
 24 the risk of HIV and AIDS?

25 **A.** Well, I get the impression that Dr Wensley was quite

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1 careful about this. He had, after all, been probably
2 the only clinician in the country to have used
3 porcine Factor VIII in a patient lacking an inhibitor
4 to minimise that risk, and he had -- their whole
5 approach to therapy was very conservative. And that
6 continued to be the case, to the extent that one of
7 the things that really worried me when I took over was
8 that I could see that, despite having the -- being the
9 third largest Haemophilia Centre in the country, its
10 budget was tiny, and the patients were using an
11 average of only 25,000 units per patient per year, for
12 severe haemophilia.

13 Now that compares with about an average of
14 300,000 units per patient per year today. But even back
15 in 1994, it was, by a margin, the smallest amount being
16 used.

17 **Q.** And was there any bank of stored samples, plasma
18 samples at Manchester?

19 **A.** None that I was aware. I believe that they had had
20 stored samples at some point, but I wasn't aware of
21 any when I took over.

22 **Q.** And what, if anything, did you learn about how
23 patients at Manchester had been informed of their
24 diagnosis with HIV?

25 **A.** Well, again, I was led to believe by the patients that

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1 they had been informed by post.

2 **Q.** And did you know, do you know whether those patients
3 had been aware that they were being tested for
4 HTLV-III?

5 **A.** I'm not sure about that.

6 **Q.** And you tell us in your statement, again -- well,
7 I don't know whether this figure is drawn from the
8 National Haemophilia Database or your own records, but
9 you've said that there were 83 patients HIV positive,
10 of whom ten were under the age of 18.

11 **A.** That's derived from the National Haemophilia Database.

12 **Q.** Do you know, of those patients in Manchester, the
13 proportion that were severe haemophilia A patients as
14 opposed to moderate or mild?

15 **A.** I couldn't tell you.

16 **Q.** Do you know how many haemophilia B patients were
17 infected with HTLV-III?

18 **A.** I'm not sure. But it would have been a smaller
19 proportion, given that they were treated only with
20 UK concentrate and HIV spread later into the British
21 donor population.

22 **Q.** Do you know whether any work had been undertaken in
23 Manchester to ascertain the dates of seroconversion?

24 **A.** Yes. This was in the notes, and it was apparent for
25 some patients, and when they were told about their

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1 HIV, their -- or had subsequent discussions with my
2 predecessors, they were told when they had been
3 infected.

4 **Q.** Do you know what the date range was?

5 **A.** It was mostly 1981 through to '84.

6 **Q.** And do you know whether there had been any
7 seroconversions at Manchester on heat-treated
8 products?

9 **A.** I don't think so but I would not swear to it. I don't
10 think any of the products that had been known to
11 transmit HIV after heat treatment had been used in
12 Manchester.

13 **Q.** Were there partners or other family members who had
14 been infected with HIV at Manchester?

15 **A.** Yes.

16 **Q.** Do you recall roughly how many?

17 **A.** A handful.

18 **Q.** When you arrived in 1994, how had the care and
19 treatment of the patients with HIV been organised?

20 **A.** In various different ways. Dr Wensley and Dr Lucas
21 looked after the bulk of them. Some patients had gone
22 to more -- a small handful had gone to North
23 Manchester, where they have infectious diseases
24 doctors with an interest in HIV.

25 **Q.** And what arrangements did you then follow over the

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1 next few years from 1994 as director?

2 **A.** Well, the patients who attended North Manchester
3 continued to do so. Patients left in Manchester,
4 I continued to look after, increasingly with input
5 from STD, as the subspecialty of HIV specialist
6 developed, and then we developed a joint HIV clinic,
7 particularly once HIV treatment became a little more
8 complicated. Because in the early days there were
9 only one or two drugs, and then more drugs came along
10 and -- to start with, they were all reverse
11 transcriptase, inhibitors, which -- you know, all
12 working in the same way, then other classes of
13 antiretroviral drugs were developed, with different
14 modes of action, which lent themselves to combination
15 treatments.

16 None of this was as effective as one might like
17 until triple therapy came along in 1995. Because a lot
18 of the patients who had had treatment in the early
19 years, because it was, by modern standards, suboptimal,
20 that developed some degree of resistance, and it was, as
21 much as anything, dealing with that resistance that made
22 it increasingly necessary to involve more specialist
23 help in their management.

24 **Q.** And what was available in Manchester in 1994, by way
25 of counselling or social work support?

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

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1 turned out that they hadn't been, so I didn't make any
 2 assumptions.
 3 As you've already pointed out, patients with mild
 4 bleeding disorders are seen less frequently and that,
 5 in its own right, may have led to them being tested
 6 later. So if I couldn't find a test, I'd assume that
 7 they hadn't been tested and I would test them.
 8 Q. And when would that patient be told their test
 9 results? Would it be at a special appointment or the
 10 next routine scheduled appointment?
 11 A. You would discuss that with the patient and at the
 12 consultation, because as I think you'll have noticed
 13 from my statement, when I arrived, I discovered that
 14 the mild bleeders were not followed systematically.
 15 This was quite a common practice back in the day. It
 16 was never my practice, nor the practice in any
 17 Haemophilia Centre I'd ever worked in. But in many
 18 cases, because they only need attention every few
 19 years, they would be told their diagnosis and said,
 20 "Well, you know, if you need surgery or you need
 21 advice, contact us and we'll see you."
 22 Whereas the problem with that was that we'd suddenly
 23 get a communication from a surgeon in some hospital
 24 without a Haemophilia Centre who wanted to operate on
 25 one of your bleeders whom you didn't know because they

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1 hadn't been seen for ten years. So I sent an
 2 appointment for all of these patients, and of course
 3 everyone moves an average of every seven years, and so
 4 we didn't have current addresses for a lot of these
 5 patients, so it was quite a struggle to bring those
 6 patients in.
 7 And they needed chasing up, partly because things
 8 had moved on, and partly because they needed to be
 9 tested, and in some cases you couldn't make any
 10 assumptions about HIV either. I don't think I picked up
 11 any new HIV positives in that way, but we certainly
 12 picked up some who had hepatitis C.
 13 When you asked those patients, "What have you been
 14 treated with in the past?", they'll say, "Well, I had an
 15 injection of some clear fluid back in 1972, but I can't
 16 remember what it was, or I never knew."
 17 So you couldn't make any assumptions about what
 18 they'd been treated with and had to assume that if
 19 they'd had any sort of treatment, it was potentially
 20 infectious, and so you just tested them all.
 21 Q. What information would you then typically give
 22 a patient who you were telling for the first time at
 23 Manchester that they had hepatitis C?
 24 A. Well, I would already have had a conversation when
 25 I tested them, particularly if they'd -- were one of

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

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1 their GP or not. Almost none of them would object to
2 you writing to the GP, and we would argue -- well, not
3 argue, but we would discuss with the patient that the
4 GP might attend them in an emergency and would really
5 need to know.

6 I did have one patient who lived in Wales who
7 explained to me that he lived next door to the doctor's
8 receptionist, and whilst they had very good relations
9 with their neighbour, he was understandably worried
10 about confidentiality, and we came to a special
11 arrangement for him because he could see the
12 intellectual reasoning for letting his GP know.

13 **Q.** And I think your statement says the special
14 arrangement was that the GP would keep the records at
15 the GP's own house so that the receptionist would not
16 have access to them?

17 **A.** That's right.

18 **Q.** Did you ever tell GPs of a patient's HIV status
19 without the patient's knowledge and consent?

20 **A.** Possibly. I don't know specifically.

21 **Q.** What about hepatitis C? What was the approach to
22 notifying GPs?

23 **A.** Well, we wrote to GPs every time a patient came to
24 clinic. So we would write to the GP. We would not
25 specifically ask the patient about that. The patients

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1 knew that we wrote to the GPs every time they came,
2 and I could not see why they would object to us
3 letting the GP know.

4 **Q.** What were the arrangements made at the Manchester
5 Centre for the care and treatment of patients with
6 hepatitis C from 1994 onwards?

7 **A.** Well, historically, Dr Warnes the hepatologist had
8 a close working relationship with the Haemophilia
9 Centre and indeed appears as one of the co-authors on
10 the Stevens paper and had conducted a lot of -- well,
11 he conducted all of those liver biopsies in that
12 series.

13 The non-serious liver disease we largely managed
14 on our own. Though, again, as with Professor Gilmore,
15 we regularly consulted with hepatology about the
16 criteria to be used in selecting patients for
17 treatment. And I would often send the patients to
18 Dr Warnes for hepatology opinion.

19 Now, back then -- and I've discussed this with
20 people from other Centres too. Back then, there were
21 not so many hepatologists. I don't think the Cardiff
22 Centre had one, at least until recently, for example, in
23 the whole of Wales, which is unimaginable. And because
24 there were not many hepatologists, what hepatologists
25 tended to do was offer an opinion, give you some

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1 instructions and send the patient back.

2 For those patients who had serious liver disease, my
3 desire was that they should be joint managed with
4 a hepatologist, and if there was any question about
5 whether they should be treated or not, I wanted
6 hepatological input.

7 Now, when Dr Warnes retired, he was replaced by
8 Dr Harry, I think, who was far more active. And
9 subsequently, she was replaced gradually by up to three
10 hepatologists, and they have basically taken over all
11 the therapy for hepatitis C. They do joint manage all
12 our patients who have serious liver disease.

13 And throughout that time, the Liver Clinic again was
14 immediately adjacent to our own follow-up clinic, so the
15 patients would often come along to both clinics the same
16 afternoon, and we had -- it was easy for us to have
17 joint consultations. Throughout that time, we had
18 a very close liaison with hepatology.

19 **Q.** I think if we put one document on screen. Soumik,
20 it's BART0000735, please.

21 This is a letter from you to Dr Rejman, the senior
22 medical officer at the Department of Health in 1985.
23 And we can see from the first two paragraphs a problem
24 with funding. You said:

25 "You were asking us yesterday to let you know of

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1 specific problems that we have encountered in relation
2 to health authorities paying for alpha interferon for
3 the treatment of hepatitis C. Since the
4 Secretary of State for Health has gone on record in the
5 House as saying that nobody suitable for interferon
6 therapy should be denied this.

7 "I have to tell you that we have encountered
8 consistent problems with two of our Health Authorities,
9 namely central Manchester and Trafford Health Authority.
10 These two Health Authorities take the rather paradoxical
11 view that they were paying for haemophilia services
12 before, and we should just absorb it within our costs,
13 despite the fact that no interferon was prescribed in
14 this practice before the product gained its licence."

15 It would seem from that that you did experience
16 difficulties at Manchester in obtaining funding for
17 interferon.

18 **A.** Yes.

19 **Q.** How long did those difficulties remain?

20 **A.** Well, we did eventually get it paid for, but we had
21 consistent problems with those two health authorities
22 because I think -- I mean, the hospital's actually in
23 the Manchester Health Authority, but partly because of
24 demand, and I guess the patient population, those
25 Health Authorities are always short of money.

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1 I had -- one of the first things I did when I took
2 over in Manchester was to move from a block contract to
3 a cost-per-case contract on the basis that it would be
4 more difficult for Health Authorities to refuse an
5 individual than a whole group, and because a block
6 contract was open to this sort of abuse.

7 If you have a block contract, they give you an
8 amount of money that is to cover everything. And then,
9 when a new pressure comes along, they say, "Well, that's
10 your problem." And of course, your block contract will
11 probably not cover all your expenses in relation to
12 therapy anyway. And the whole of this time, we were
13 trying to increase the intensity of treatment to manage
14 the haemophilia better, not to mention increasing
15 expenses in relation to HIV treatment and the treatment
16 of hepatitis C.

17 To give you some idea, a course of peg-interferon
18 and ribavirin would cost around £14,000 back in those
19 days. And we argued that, to be honest with you,
20 compared with the cost of the haemophilia itself, it was
21 a relatively small amount of money.

22 Now, what you have here is evidence of the Health
23 Authority still behaving as if you've got a block
24 contract, even though you haven't. So I was trying to
25 stir things up in the background, and we did eventually

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1 get funding. And in fact, when peg-interferon and
2 ribavirin came along, we were able to get funding before
3 the liver doctors were.

4 **Q.** I'm going to move on to look at a different issue now,
5 Professor Hay, and to ask you some questions arising
6 out of recommendations produced by UKHCDO in the late
7 eighties and early nineties.

8 Soumik, can we have on screen, please,
9 WITN3289044.

10 And if we zoom in on the first half of the page,
11 please. This is a set of recommendations exhibited to
12 your witness statement, professor. This from 1988 and
13 it's the UKHCDO's or the Reference Centre Directors
14 recommendations on choice of therapeutic products.

15 And I just want to show you a couple of passages and
16 then ask you a question about them. So in the first
17 paragraph, last sentence, it says:

18 "Whilst it is clear that risk can never be
19 completely eliminated, major advances have been made in
20 risk reduction and physicians are faced with the problem
21 of choosing between therapeutic products of possibly
22 differing risks."

23 "The purpose of this paper is to present a consensus
24 view of the UK Haemophilia Reference Centre Directors on
25 the relative merits of therapeutic products ..."

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1 And then it says the intention is to update
2 recommendations.

3 Then if we go to the bottom half of the page,
4 please. It says this:

5 "It must be emphasised that our opinions about the
6 risks and therapeutic efficacies of different products
7 are based on evidence which is often incomplete, and in
8 many cases unpublished. Despite these problems,
9 physicians necessarily have to make therapeutic
10 decisions in the best interests of their patients,
11 within the resources they have available. It has always
12 been the case in the UK that such decisions have often
13 had to be made without guidance from the regulatory
14 authorities. Whilst this situation is to be deprecated,
15 it is important for physicians to be aware of the legal
16 framework in which they prescribe therapeutic
17 products ..."

18 And then at the bottom of the page, last two lines,
19 it says:

20 "It is also important to remember that all
21 manufacturers, including those within the NHS, have an
22 [go over the page] interest in interpreting data
23 concerning their own products in the most optimistic
24 light, and vice versa."

25 I am not going to ask you about the detail of the

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1 recommendations that then follow, professor, but am
2 I right in understanding that this was the first time
3 the UKHCDO had formulated detailed recommendations of
4 this nature?

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

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

14 **A.** Well, not necessarily, because prior to the advent of
15 viral attenuation there really wasn't a great deal to
16 pick between the different brands of concentrate. It
17 may well have been that there were differences, but in
18 the absence of testing, you couldn't discern what
19 those differences were. That is to say, the products
20 that were available may have carried different risks
21 but that had been even less well quantified than it
22 was at that point, whereas here we finally have
23 concentrates that have been virally attenuated and
24 purified in different ways, and clinical trials have
25 been conducted to try to evaluate the safety and

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1 efficacy of those products, so there is far more
2 evidence on which to formulate a recommendation. And
3 even so, they are, I think quite rightly, stressing
4 the limitations of the data that they have available
5 to them.

6 In later evidence they would adopt an even more
7 evidence-based approach to guidance where each
8 recommendation would be given a scoring for the strength
9 of evidence upon which it's based.

10 One of the big problems assessing the safety and
11 efficacy of therapeutic products for haemophilia is that
12 it's a rare disease. If you look at clinical trials of
13 things like heparin, it starts with -- you take
14 10,000 people who are having hip replacement and they
15 all followed this regime. With haemophilia you're lucky
16 if you have a clinical trial with 100 people in it.
17 That would be a large trial, but in statistical terms
18 it's small.

19 So many of these trials were really small, and so
20 I wouldn't be overly critical that this is the first
21 guidance because, to be honest, this therapeutic
22 landscape had really only just emerged.

23 **Q.** This document deprecates the absence of guidance from
24 what's loosely described as regulatory authorities,
25 and certainly it could be said that the picture that

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1 emerges from the first half of the eighties is of
2 clinicians having to take their own decisions about
3 how to respond of risks, whether it be of hepatitis or
4 HIV.

5 Do you think it would have been helpful for there to
6 have been some form of central guidance, whether from
7 the Department of Health or the Chief Medical Officer or
8 some other authority or agent, rather than clinicians in
9 the hundred or so Centres across the countries being
10 left to make up their own mind?

11 **A.** Yes, I think it would have been helpful.

12 **Q.** Some of the documents that we've seen, and you've
13 touched on it in your statement, refer to a debate
14 about the use of high-purity products and the
15 availability of funding for such products. I'm not
16 going to go to any of the documents in relation to
17 that, but could you just briefly outline for us what
18 the situation was in relation to so-called high-purity
19 products and what the difficulty was in terms of
20 securing funding.

21 **A.** Well, in the early days of HIV, when we didn't have
22 a test for HIV, patients were being monitored
23 clinically, because it's a clinical diagnosis. But in
24 the laboratory there were one or two surrogate tests
25 you could do. You could test their CD4 count, the

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1 T-helper cells, and the lymphocyte count and the blood
2 count in general.

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

13 So when higher-purity products came along, they
14 noticed that they didn't seem to cause this problem.
15 The higher-purity products were developed partly because
16 we wanted the product to be as pure as possible anyway.
17 If you looked at an old-fashioned bottle of Factor VIII
18 from the days of intermediate purity, there would be
19 a bottle about this size, with 250 units in, a great big
20 cake of protein at the bottom, and if you were able to
21 take out all the spare bits that you didn't want, it
22 would look like an empty bottle. The Factor VIII in
23 that was just a trace. All the rest was fibrinogen and
24 immunoglobulin and goodness knows what else.

25 And the high purity was developed partly because we

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1 wanted purer products, but also because they realised
2 that one of the problems heat treating and so on was it
3 was a low-purity product. And if you had
4 a higher-purity product, you could virologically treat
5 it more aggressively. So that's why it was developed.

6 But then with all this background of immunological
7 abnormalities in people who didn't have HIV, we began to
8 wonder whether it would make a difference to the
9 progress of HIV. And there were one or two studies that
10 were done that suggested that patients treated with high
11 purity Factor VIII progressed in their HIV more slowly,
12 and so that was the bigger rationale.

13 There were a number of reasons for wanting to adopt
14 these products. We suspected that they might be
15 virologically safer. They were certainly easier for the
16 patients to use, being higher purity, smaller volume,
17 quicker to dissolve, the patients liked them. And
18 finally, they might have clinical benefits for people
19 with HIV. So I certainly canvassed for that.

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

23 **A.** Yes, yes. I was able to do that quite quickly. There
24 was very little resistance from the commissioners.
25 The difficulty was I think the first product that came

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1 on the market was Monoclote and Mononine from Armour.
 2 One other thing they did at the same time, which is
 3 of interest I think to the Inquiry, was that they
 4 obtained the plasma only from the American Midwest.
 5 They stopped obtaining plasma from California and
 6 New York because those were HIV epicentres.

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

12 **Q.** And without going into the detail of what we see in
 13 a number of the documents, some Centres had great
 14 difficulty, it seems to be suggested, in obtaining the
 15 necessary funding to use high-purity products or to do
 16 so as quickly as they would like.

17 **A.** Yes, that's right. I think the difficulty is that, to
 18 be honest with you, the evidence that influenced the
 19 rate of progression of HIV was not strong. Some of
 20 the evidence, if you'd taken it to its logical
 21 extreme, would have implied that we should give this
 22 high-purity Factor VIII concentrate to people who had
 23 acquired HIV in other ways and who didn't even have
 24 haemophilia because they seemed to progress more
 25 slowly than any other group.

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

4 **A.** Well, in all of those Centres, we had a handful of
 5 chronic carriers. I actually needle stuck myself from
 6 one of them and had to have immunoglobulin. There
 7 were not many because although a high proportion of
 8 the patients, particularly with severe haemophilia,
 9 had been exposed to hepatitis B through their
 10 concentrate -- I think in my report, I quote the
 11 figures from my MD thesis where I found that 80% of
 12 the patients in Sheffield with severe haemophilia had
 13 been exposed to hepatitis B, and 40% of the non-severe
 14 patients.

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

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

23 **A.** Yes. At least one of them underwent liver
 24 transplantation in Manchester. Treatment -- we used
 25 interferon and various other agents with hepatitis B

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1 started probably earlier than with non-A, non-B
 2 hepatitis. But I referred all of those patients to
 3 the hepatologist because the treatment was different,
 4 and there was never likely to develop much experience
 5 in hepatitis B therapy.

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

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

14 90% of the adult population have already been
 15 exposed to parvovirus. It causes fifth disease,
 16 characterised by the classic slapped face rash,
 17 I remember I got it along with my two children when
 18 I was already a senior lecturer. It can be a nasty
 19 illness if you get it in adulthood because you can get
 20 transient arthropathy.

21 The significance of this in the haemophilia story is
 22 that parvovirus is a protein-coated virus, and it's
 23 relatively resistant to viral attenuation techniques,
 24 and so those isolated outbreaks of parvovirus are
 25 clinically unimportant, but they illustrate the

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1 limitations of the viral attenuation techniques, and
 2 this, along with various other agents like prions, are
 3 also extremely resistant to viral attenuation. It's
 4 probably impossible. These sort of things form
 5 a cornerstone of the argument for recombinant
 6 Factor VIII.

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

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

13 (3.09 pm)

(A short break)

15 (3.38 pm)

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

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

25 **A.** Well, I used it in clinical trials both in Liverpool

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1 and in Manchester. Those were Phase III clinical
2 trials, so there would have been Phase I and Phase II
3 before then. And that would have been 1993 and '94
4 and '95.

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

11 **Q.** And we've certainly come across experiences in other
12 centres with patients who were part of that trial and
13 receiving recombinants and then, because of the
14 absence of funding, were expected to revert back to
15 plasma-based concentrates. Is that what happened with
16 your patients as well?

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

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1 for financial reasons.

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

4 **A.** That's correct.

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

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

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

12 **A.** Yes.

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

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

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1 Understandable.

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

12 **Q.** And I think the way you've put it in your statement is
13 that UKHCDO argued there'd been an outbreak of
14 hepatitis A, that there was evidence of parvovirus
15 transmission, and there were concerns about prions,
16 and that there may be other unknown pathogens
17 resistant to heat treatment.

18 **A.** Yes. The physical treatment required to inactivate
19 prions would completely denature Factor VIII. So it's
20 theoretically more or less impossible to attenuate
21 that.

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

25 **A.** That's correct. Though, interestingly, they did not

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1 -- they still didn't concede the viral safety
2 argument. They said that they were only doing this to
3 allay the concerns of the parents, so that allowed
4 them to climb down in a limited way whilst still not
5 changing the argument. And so, under the age of 18,
6 by the time the next stage came along, those
7 18-year-olds were in their early 20s.

8 **Q.** And that was, I think, 1998, and there was now
9 recombinant Factor IX available, so children with
10 haemophilia A and haemophilia B were able to access
11 recombinant from around 1998 onwards.

12 **A.** That's right.

13 **Q.** There was an issue that arose, I don't know whether
14 you can assist us with this, about non-availability of
15 recombinant because of shortages of supply due,
16 I think, to circumstances in a manufacturing plant in
17 the States. Can you recall when that was?

18 **A.** Yes, I can. I mean, firstly, it's worth remembering,
19 because it speaks to the issue of the adequacy of
20 supply, that when the children went on to recombinant
21 in 1998, we were unable to do it fully for a period of
22 six months because it took that long for the
23 manufacturers to wind up the supply to this country,
24 because any supply that we were getting was in
25 competition with other countries. And one of the

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1 problems that we've had negotiating lower prices until
2 relatively recently has been that it's been
3 a suppliers' market. There has been a shortage of
4 manufacturing capacity. That's no longer the case,
5 but it was the case for quite a long while.

6 Now, I think the specific episode that you're
7 referring to is the recombinant shortage starting,
8 I think, about 2001 and lasting for two years when Bayer
9 had an inspection of their Berkeley plant in California
10 and their paperwork was not adequate. There was no
11 suggestion that the product was unsafe. But whilst they
12 sorted out their auditing processes, they were not
13 allowed to issue a new product. Because a product
14 licence is not just licensing the end product. You also
15 licence the process which is then set in tablets of
16 stone, and that process involves, amongst other things,
17 auditing each step of the process, and that's where they
18 were a little lacking.

19 So this was a huge problem because at that time the
20 only suppliers were Baxter and Bayer and Wyeth, who were
21 marketing ReFacto at that time, and so the supply of
22 recombinant Factor VIII effectively halved to the whole
23 world overnight. And this, amongst other things, is
24 a reflection of why so many of us have a policy of not
25 putting all our eggs in one basket, because there were

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1 some Centres that only used Kogenate which was that
2 Bayer product, so their supply wasn't cut in half
3 overnight; they had no supply at all.

4 And the other manufacturers would naturally favour
5 their existing customers. So I, as Vice-Chairman of
6 UKHCDO, organised a system of supply swaps which had to
7 be agreed with both the clinician and the supplier, who
8 would often have an existing contract, so that we could
9 shift supply from one Centre to another, to at least
10 enable the younger children to remain on the
11 recombinant. Because, otherwise, you would have had the
12 situation where you'd have whole Centres where all of
13 their kids would have had to go back to plasma derived.
14 It was a compromise, obviously. One would have
15 preferred to have kept all of them on recombinant, with
16 that supplier. And we also negotiated as fast as we
17 could for the other suppliers to increase their supply.

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

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

23 **Q.** Now, your statement explains that in 2003, the
24 Department of Health finally decided to make available
25 funding for patients to switch to -- now adult

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1 patients to switch to recombinant products; is that
2 right?

3 **A.** That's correct.

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

7 **A.** Well, we were all a bit puzzled. I don't know why it
8 happened at that point, to be honest, because nothing
9 much had changed. We were just very grateful, though
10 with slightly mixed feelings because, as you know and
11 I guess we're going to talk about it, the funding for
12 that was staged.

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

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

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

7 And we had to devise a system to prioritise the
8 patients. But, of course, naturally that gave rise to
9 trouble. Because we and the Department of Health, you
10 know, we'd have preferred not to have been in that
11 position. We would have much preferred to have switched
12 all the patients at once. But the Birchgrove Group,
13 I think it was, objected to us prioritising younger
14 patients, and they felt that those patients with HIV
15 should start on recombinant first. We felt that the
16 patients least likely to have been exposed to viruses
17 should logically start first, and that was the
18 Department of Health view. And so we segregated
19 according to age.

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

23 **A.** By 2006.

24 **Q.** And you've said in your statement that towards the end
25 of the recombinant roll-out to adults, it became

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1 apparent that funding might not be secure. What can
 2 you recall about that?
 3 **A.** Well, what I think we were told was that the funding
 4 was separate; it was a separate uplift. We negotiated
 5 special contracts with all the suppliers that actually
 6 reduced the unit price and enabled us to roll things
 7 out slightly quicker. It was a very complex process.
 8 But towards the end, the Department of Health
 9 indicated to us that the money was going to be handed
 10 over to regional and district Health Authorities but
 11 that it might be bundled with other items of spending.
 12 Now, the problem with bundling is that they might
 13 take three separate items of expenditure each costing,
 14 say, 10 million, and tell people to buy all that with
 15 25 million. It's often a mechanism for actually cutting
 16 the funding. And we were very worried that that would
 17 cause us to have to revert to plasma derived which would
 18 have caused a storm of protest from everybody, not least
 19 the medical profession.
 20 **Q.** You were asked in your statement the question, "Should
 21 recombinant blood products have been made available to
 22 all earlier than they were, and if so when?"
 23 I'm just going to read out your answer and see if
 24 you have anything to add. You said in your statement:
 25 "Yes. It was UKHCDO policy that we wished to treat

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1 all our patients with recombinant Factor VIII from 1996
 2 and for haemophilia B from 1998, when recombinant
 3 Factor VIII and then recombinant Factor IX became
 4 available. We wanted to give the patients the benefit
 5 of the doubt about safety based on the unknown virus
 6 hypothesis. Having been at least thrice bitten by
 7 previously unknown viral pathogens and knowing that some
 8 pathogens were difficult (protein-coated viruses such as
 9 parvovirus and HAV) or impossible (prions, the cause of
 10 vCJD and classical CJD) to inactivate, we wish to treat
 11 the patients with a product that should theoretically be
 12 free from all human pathogens."
 13 Is that right, and is there anything that you would
 14 add to that?
 15 **A.** The only thing I would add to that was, whilst you're
 16 reading it out it occurred to me that, actually,
 17 I think prions were the final nail in the coffin, as
 18 far as the Department of Health's argument that we
 19 should not change over to recombinant, because there
 20 could be no certainty about the clinical significance
 21 of variant Creutzfeldt-Jacob disease at that point in
 22 time.
 23 **Q.** You've also said in your statement that the
 24 department's position which you described -- in other
 25 words, that they didn't accept that recombinant

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1 Factor VIII or IX was not safer than plasma derived
 2 Factor VIII or IX -- has never changed to your
 3 knowledge; is that right?
 4 **A.** Well, as far as I'm aware, that's the case.
 5 **Q.** Professor Hay, that leads us on to vCJD. There are
 6 quite a few documents I might need to ask you to look
 7 at.
 8 I'm going to start, sir, with a couple and then
 9 perhaps leave the rest until tomorrow morning.
 10 **SIR BRIAN LANGSTAFF:** Yes.
 11 **MS RICHARDS:** So, in terms of the vCJD notification
 12 process, I just wanted to start in 1997 with --
 13 I think this is the right reference, Soumik --
 14 HSOC0015148.
 15 Yes, I think I might have put in an extra digit.
 16 HSOC0015148.
 17 So this is a letter dated 26 November 1997. It's
 18 co-authored by you, and it reads as a letter sent to
 19 patients. You say:
 20 "I'm writing to you following the recent Panorama
 21 programme and in anticipation of further press reports
 22 to outline the current situation in relation to this
 23 condition [ie new variant CJD]. I would also like to
 24 keep you informed of the measures which we've decided to
 25 take at the Manchester Haemophilia Centre and the

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1 reasons for these."
 2 You then talk in the next paragraph about what CJD
 3 is, and the infective agent being thought to be a prion.
 4 You say in the last two sentences of that paragraph:
 5 "There is no evidence that CJD can be transmitted by
 6 blood or blood products. Furthermore, there have been
 7 no reports of classical CJD in patients requiring
 8 regular blood transfusion or in patients with
 9 haemophilia."
 10 If we then go over the page, second paragraph, you
 11 then talk about new variant CJD. You explain it's
 12 different from classical CJD, appears to affect young
 13 people, and you describe how it's caused.
 14 And then in the next paragraph, you go on to say
 15 that:
 16 "There's a very small theoretical possibility that
 17 new variant CJD might be transmitted by blood
 18 transfusion, although experience would suggest that only
 19 a small number of susceptible individuals would be at
 20 risk. In light of this, the Government has been advised
 21 to consider the possibility of filtering out all the
 22 white cells from whole blood and is currently
 23 commissioning an independent risk assessment which will
 24 take six months to report.
 25 "Three weeks ago, BPL withdrew a batch of 8Y

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1 Factor VIII concentrate because two of the donors had
 2 developed new variant CJD. Neither of the Manchester
 3 Haemophilia Centres have used these batches."
 4 Then you say this:
 5 "Last week, the executive committee of the UK
 6 Haemophilia Centre Directors met with experts in CJD and
 7 plasma fractionation to consider the problem. Blood
 8 products like Factor VIII are already made from plasma
 9 with white cells removed and do not transmit infections
 10 associated with white cells like glandular fever or
 11 cytomegalovirus and may not therefore transmit new
 12 variant CJD."
 13 Then you talk about the possibility of inactivation.
 14 Then this:
 15 "The Haemophilia Centre Directors concluded that
 16 there was most likely to be little or no risk of
 17 infection with [new variant] CJD from blood products.
 18 Since there can be no absolute certainty about this for
 19 some time it was felt that until the results of the DOH
 20 risk-assessment were known, that blood products of UK
 21 origin should be temporarily phased out. In their
 22 place, products manufactured from plasma taken from
 23 areas free from BSE and [new variant] CJD such as the
 24 USA will be used. There are currently inadequate
 25 supplies of these American products in the UK and so we

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1 plan to replace Replinate and Replinine with alternative
 2 products as stocks run out."
 3 Then you offer patients the opportunity to call the
 4 Centre and then you say you've arranged for a meeting at
 5 the main lecture centre at the Manchester Royal
 6 Infirmary on 11th December "to present the evidence and
 7 discuss the matter, to which you are invited".
 8 Was this, in 1997, the first main action taken by
 9 UKHCDO and then directors such as yourself in response
 10 to the developing knowledge about new variant CJD?
 11 A. Yes.
 12 Q. Did the meeting you've described in that last
 13 paragraph take place?
 14 A. Yes.
 15 Q. And what can you tell us about that meeting?
 16 A. To be honest I can't remember that meeting but it
 17 certainly took place. I think it was well attended,
 18 and we would have had a question and answer session.
 19 I would have made a presentation about what we did and
 20 did not know.
 21 Q. Can you recall what the reaction of patients was to
 22 news of a further potential threat to their wellbeing,
 23 and the news that there was going to be a reversion
 24 from UK-sourced blood products to US-sourced blood
 25 products, in some respects, the reverse of what had

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1 previously happened. How did patients respond to
 2 that?
 3 A. Well, as you might imagine, their responses were very
 4 varied. We always -- well, we knew, because of the
 5 way that prions work, that only perhaps a third of the
 6 patients would be susceptible. Those are the ones who
 7 are homozygotes. And so -- of course, we didn't know
 8 who was homozygous or heterozygous, but we did know
 9 that it was unlikely that it would be like hepatitis C
 10 or HIV and infect people indiscriminately. There were
 11 theoretical reasons for thinking that in this
 12 particular instance, the risk of transmission by
 13 clotting factor concentrates would be low. But having
 14 learned from past experience, I felt that it was
 15 important to emphasise what we did not know. Patients
 16 understand that. And in my experience it's much
 17 better to say, "You know, this is not known, it may
 18 take years to know", than to offer them some sort of
 19 speculation that they may take away as hard and fast
 20 fact which might turn out to be untrue.
 21 I go into my -- in my report I go into the reasons
 22 why we felt that concentrates would be much less likely
 23 to transmit this agent than a whole unit of blood. And
 24 I would describe that to patients, but I would also say,
 25 "You know, we'll just have to keep an eye on everybody

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1 that has had these products, because there may be no
 2 certainty about any of this for maybe ten or 20 years."
 3 And some of the patients got very distressed.
 4 Others were quite philosophical, and probably went away
 5 with the relative reassurance that they'd been provided.
 6 At the end of the day at this point we didn't even have
 7 any evidence that variant Jakob-Creutzfeldt Disease
 8 could be transmitted by blood, let alone the other
 9 products. This was in relation to discovering variant
 10 Jakob-Creutzfeldt Disease in donors of blood and the
 11 recognition that, histologically, one of the ways in
 12 which variant Jakob-Creutzfeldt Disease differed from
 13 classical Jakob-Creutzfeldt Disease is that you could
 14 demonstrate the prion protein in the lymph nodes and in
 15 lymphocytes, which are obviously elements of the blood
 16 system, whereas classical Jakob-Creutzfeldt disease is
 17 found in the central nervous system and you don't find
 18 it elsewhere. So that raised, at quite an early stage
 19 in our knowledge of the condition, the theoretical
 20 possibility that it could be transmitted by certainly
 21 whole blood, less certainly plasma.
 22 Q. This letter refers to the UKHCDO Directors Executive
 23 Committee having met with experts in CJD and plasma
 24 fractionation. At this stage, was there any
 25 particular involvement or direct involvement from the

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1 Department of Health in those deliberations?
2 **A.** I don't remember so -- but they were certainly very
3 much involved from an early stage thereafter.
4 **Q.** I want to pick up a document trail from 2004 onwards
5 with you, and I'll do that tomorrow morning, because
6 there are then a range of notifications from 2004
7 onwards with which you were closely involved in your
8 capacity as vice chair and then chair of UKHCDO.
9 But before we do that, can you recall, for
10 after 1997 and prior to 2004, what further processes
11 there were involving patients and providing
12 information to patients?
13 **A.** Well, the reason for doing this by letter, and then
14 following up with a meeting rather than to do it
15 individually, was because the press were finding out
16 about it, and we needed to get to speak to the
17 patients as quickly as we possibly could. As many of
18 the consequent conversations as possible were done on
19 an individual basis, mostly in clinic but sometimes in
20 the Centre.
21 Many of these conversations were quite protracted
22 because some of the concepts involved, for example the
23 concept of the public health risk, were very difficult
24 for doctors to understand, let alone laypeople. And
25 I think caused a lot of confusion. So, yeah.

1 **MS RICHARDS:** Sir, I'm conscious of the time. There are
2 quite a few documents I think it will be useful to
3 look at with Professor Hay on the CJD notification
4 process from the UKHCDO perspective, but it might be
5 more sensible to pick those up in the morning.
6 **SIR BRIAN LANGSTAFF:** Well, I think it's important
7 evidence. It's late-ish in the day. I'm sure,
8 professor, you've had a longish day. Can we meet
9 again at ten o'clock in the morning?
10 **THE WITNESS:** Sure. Certainly.
11 **SIR BRIAN LANGSTAFF:** And the same rules apply as applied
12 at every break during the day, but have a good evening
13 and stay safe, and the same to everyone else.
14 I look forward to meeting you, Ms Richards,
15 tomorrow at ten. You heard what I had to say earlier
16 this week about the attendance of others at the
17 hearing centre following what I imagine will be the
18 acceptance of Parliament of the Government's proposals
19 today about coronavirus.
20 Thank you very much.
21 **MS RICHARDS:** Thank you, sir.
22 **THE WITNESS:** Thank you.
23 **(4.08 pm)**
24 **(The hearing adjourned until 10.00 am the following day)**
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