

Tuesday, 6 October 2020

1
2 (10.00 am)
3 **SIR BRIAN LANGSTAFF:** Today we have Dr Colvin.
4 **MS RICHARDS:** We do, sir.
5 **SIR BRIAN LANGSTAFF:** Dr Colvin, may he be sworn.
6 **DR BRIAN TREVOR COLVIN (sworn)**
7 **Questioned by MS RICHARDS**
8 **Q.** Dr Colvin, you provided a detailed CV to the Inquiry
9 along with your statement. I'll just go through some
10 of the elements of your career most relevant to the
11 Inquiry's investigation.
12 You undertook your medical training at what was
13 then known as The London Hospital. When did it become
14 The Royal London Hospital?
15 **A.** It became The Royal London when the Queen came to see
16 us on our 250th anniversary. The hospital was founded
17 in 1740, so 1990 was the 250th anniversary.
18 **Q.** So you were trained there. Then you worked as
19 a junior doctor there from 1969 to 1975, I think, in
20 general medicine, cardiology, and then haematology?
21 **A.** Yes. I was a junior doctor really up to 1977, when
22 I was appointed a senior lecturer and honorary
23 consultant at The London. So my general training was
24 up to about '73 or '74, but I became a consultant
25 in '77.

1

1 a laboratory-based path, scientific path, and those
2 whose path was through general medicine?
3 **A.** Yes, if you look at the content of the so-called
4 Reference Directors in the time that I was about to
5 qualify in haematology, some were physicians, not
6 haematologists; some were haematologists who were
7 clinical haematologists; some were haematologists who
8 were laboratory haematologists, and we had one
9 paediatrician. There was a number of different ways
10 of being a Haemophilia Centre Director. I think the
11 fact that juniors like myself or like Mark became
12 members of the Royal College of Physicians and of the
13 Royal College of Pathologists was key in our desire to
14 be physicians and pathologists, and I think this will
15 come out quite a bit later.
16 **Q.** Then your post as a lecturer in haematology, which
17 I think your CV identifies as being from 1975 to 1977,
18 what did that comprise?
19 **A.** Well, really it was being a senior registrar, to be
20 honest. It happened at the London Hospital Medical
21 College that all appointments in pathology were
22 academic. But you will have seen from my CV that
23 I was never primarily academic. I was primarily
24 a physician and pathologist.
25 **Q.** You refer in your statement to having undergone some

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1 **Q.** What did the haematology training, the specialist
2 haematology training, comprise prior to your
3 appointment as a consultant?
4 **A.** It comprised mostly what can only be described as
5 an apprenticeship. There were one or two lectures
6 that took place at the Hammersmith. There was really
7 no formal training. I think it was to do with
8 apprenticeship and reading.
9 **Q.** In terms of training in relation to matters relevant
10 to the care of patients with bleeding disorders, was
11 that something that you did during this time under
12 Professor Jenkins?
13 **A.** Yes, indeed. I might just make a brief point,
14 perhaps, about what Mark Winter said last week.
15 I began my training in '69/'70 with the absolute
16 intention of being a physician as well as
17 a pathologist. So although Mark was saying that he
18 was the first generation of people who were physicians
19 and pathologists, I'd like to claim four years
20 earlier. That's exactly what I wanted to do, and he
21 was quite right to emphasise it.
22 **Q.** So would you accept, whatever the precise timing, the
23 broad point he was making, that there may be
24 a difference between those whose path to specialising
25 in the care of patients with haemophilia was

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1 training in blood transfusion at the Brentwood
2 Regional Transfusion Centre. What did that comprise?
3 **A.** This was absolutely obligatory for -- and I've said
4 that the training programme was an apprenticeship, and
5 it was an apprenticeship, but part of that
6 apprenticeship was to be seconded to the Brentwood
7 Blood Transfusion Service. There, one was introduced
8 to aspects like fractionation, blood cross-matching,
9 nitrogen frozen blood (which happened to be
10 a particular feature of Brentwood), and the general
11 practice not only of blood transfusion in its
12 administration but in really practical matters.
13 I mean, when I qualified in '69 and then was in
14 the laboratories in 1970, I would actually do all the
15 blood tests for the entire hospital during the night
16 without any training in haematology, chemistry and
17 microbiology in a way which is unthinkable, thank
18 goodness, today. Even into my time when I was a
19 consultant, I was still capable of performing
20 Factor VIII assays with my bare hands in the middle of
21 the night which nobody would think of doing today.
22 **Q.** You then took up your consultant post in 1977 at The
23 London Hospital, and you became effectively the
24 consultant responsible for the haemophilia service
25 there, albeit I think Professor Jenkins remained the

1 nominal director until the mid-'80s?

2 **A.** Yes. I mean, George (who is still alive in his 90s)

3 was the consultant haematologist and the director of

4 the non-haemophilia centre, and we had a physician

5 called Dr Adam Turnbull, who is unfortunately

6 deceased. George and Adam together, really as

7 a physician and as a pathologist, were in charge of

8 haematology, but Frank Boulton, who actually has been

9 referred to in this Inquiry, was going to look after

10 haemophilia, but he then left after a year or two of

11 being in post. That was my opportunity to be promoted

12 to the position of senior lecturer, and that was when

13 I was given the task of, if you like, looking after

14 people with haemophilia and building a haemophilia

15 centre.

16 **Q.** Then you remained a consultant and director of the

17 haemophilia service until your retirement in 2007?

18 **A.** Yes.

19 **Q.** I think you carried on with some clinical

20 responsibilities until 2009?

21 **A.** All that happened was when I retired, John Pasi (who

22 is now director of the centre) was appointed in 2003

23 really as a kind of preparatory to my retirement,

24 I suppose. When I retired in April 2007, there was

25 a great shortage of clinicians to do the work, and

5

1 form for the hospital. We addressed issues like

2 whether it was possible for unconscious patients in

3 great difficulty to really be offered research

4 projects which definitely needed to be done by

5 somebody, and whether it was possible for anybody to

6 give valid consent in an Emergency Department for, for

7 instance, some kind of clot-busting procedure when you

8 had a heart attack. I'm just giving an example, but

9 there were a number of issues like that.

10 Occasionally, there were ethical issues which

11 were to do with individual patients and, occasionally,

12 somebody would come to me or to Len and say, "I've got

13 this really difficult problem. Could you come up to

14 the ward and have a look at what's happening?" Then

15 Len and I would discuss together and would try to

16 reach an advisory conclusion as to what should be done

17 in a particular difficult position.

18 **Q.** That's distinct from the role a research ethics

19 committee which has a much more structured remit and

20 process.

21 **A.** A completely different function, and I think it's very

22 important to draw that distinction. I think that when

23 we started not many hospitals had clinical ethics

24 committees and I think that it was an American

25 concept. I think it was because Len was an American

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1 I was asked if I would come back to do one session

2 a week in the clinic without any administrative

3 responsibilities. At that time, I was still digging

4 for students at the London Hospital Medical College

5 because, although I had retired, my senior colleague

6 the warden had asked me not to leave my post as Dean

7 for student affairs. So I continued for a year

8 until -- two years really -- doing one clinic a week

9 just sitting in the clinic until, in 2009, I retired

10 completely from clinical practice.

11 **Q.** Between 1997 and 2007, you were chair of the Clinical

12 Ethics Committee at the Barts and London NHS Trust

13 which was what the trust was now known as. What did

14 that entail?

15 **A.** Well, Len Doyle was an American ethicist who decided

16 that it would be a good idea to have a clinical, as

17 opposed to research, ethics committee. My mentor,

18 Dr Alistair MacDonald, was Chairman of that committee

19 until he retired, and then I was persuaded by Len, who

20 was a very good friend of mine -- and he will also

21 appear later in these discussions, I think -- he

22 persuaded me to take the chair of the committee, and

23 the committee was there to address difficulties of

24 a clinical nature in an ethical context.

25 I mean, for instance, we designed the consent

6

1 that he brought in the Clinical Ethics Committee idea

2 so early to the London. Whether there is still

3 a Clinical Ethics Committee, I wouldn't know.

4 **Q.** Did that ethics committee exist prior to 1997, or was

5 that when it was --

6 **A.** Yes, because I think Alistair MacDonald was Chairman

7 before me, so, yes, I think it must have done.

8 **Q.** Do you have any idea as to when it first --

9 **A.** No, I don't know when it was founded, although

10 I imagine that could be discovered, but I don't know.

11 **Q.** Then you were chair of the Ethics Committee of the

12 Royal College of Pathologists between 2003 and 2008.

13 What did that entail?

14 **A.** Well, when -- I think the College of Pathologists

15 realised that there was all sorts of areas of

16 importance in pathology which needed to be thought

17 about in an ethical framework, and there was also

18 a need for a lay adviser for the college in this

19 context. So I was asked by the then president if

20 I would form a clinical ethics committee to look at

21 pathology, procedure and ethics, and we did. We

22 published one or two leaflets, and we tried to bring

23 the idea of ethics into pathology.

24 I'm not sure how much real business that we were

25 able to do in the period that I was actually Chair,

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1 but we certainly created the Ethics Committee, which
2 continues to the present day, and it certainly had
3 a strong lay influence to make sure that lay people
4 had the opportunity to advise the Royal College.

5 **Q.** You had a role with the Safety Committee of the
6 Scottish National Blood Transfusion Service. Henry,
7 could we just have up on screen, please,
8 GRAM0000006_002, please.

9 So we can see here it's referred to as the
10 Scottish National Blood Transfusion Service
11 Factor VIII and Factor IX Safety Committee. This is
12 a draft remit. The tasks are there set out:

13 "Reviewing clinical trial protocols, reviewing
14 data generated in the course of clinical trials,
15 reviewing serious adverse events, reviewing unexpected
16 or ambiguous events, commenting on trends identified
17 during clinical trials, commenting on interim analyses
18 of clinical trial data, and then providing similar
19 services in respect of post-marketing surveillance
20 studies and general pharmacovigilance."

21 What was the nature of the committee, and when
22 were you on it?

23 **A.** I was asked by Professor Ludlam if I would be willing
24 to chair this committee and was flown up, at very
25 short notice actually, to Edinburgh to, I think, its

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1 remember actually seeing the parents of one of my
2 patients in '75 at that meeting. So I was clearly
3 involved in haemophilia care as early as '75. But
4 I've explained that the haemophilia centre in '75
5 really didn't exist. The first thing we did, I think,
6 was for me to go over to the Royal Free Hospital to
7 see the late Katharine Dormandy, who was actually on
8 her death bed at the time -- I went to her home -- and
9 decided what we could do about haemophilia in North
10 East Thames region in addition to the great work that
11 the Royal Free were doing.

12 So, at a national level -- I'm sorry, I'm
13 diverging slightly -- but on a national level, I had
14 no status whatsoever; I was just a minnow in the
15 haemophilia care system. So I would be invited to
16 meetings or the annual meeting of Haemophilia Centre
17 Directors, but my influence was zero and, indeed, that
18 influence remained at zero until 1993 when I was
19 called on the telephone -- I can remember the
20 conversation now. Dr Rizza phoned me and said,
21 "Brian, would you like to take over the chair of
22 UKHCDO?" Which was a very great surprise to me.

23 Why that happened I think you would have to ask
24 other people. But it was right at the time when we
25 were trying to improve the management of UKHCDO in

11

1 first meeting. I'm not sure that it ever actually did
2 anything very much because I can't recall making
3 a significant contribution. You'd need to remind me
4 the exact year that I was Chairman.

5 **Q.** I was hoping you would be able to tell me that --

6 **A.** I can't remember, but it was quite late in the day and
7 I don't recall our making a significant contribution
8 because I think that the Safety Committee was founded
9 when essentially most of the problems had already been
10 dealt with.

11 **Q.** During your time as consultant at The Royal London and
12 director of the service, you were a member of UKHCDO.
13 We'll come on in more detail to UKHCDO's role, but
14 I think you attended your first AGM in 1977, having
15 taken over the service at the Royal London?

16 **A.** Yes.

17 **Q.** You were Chair of UKHCDO between October 1993 and
18 October 1996?

19 **A.** Correct.

20 **Q.** You were not, during the '70s and '80s, a Reference
21 Centre Director?

22 **A.** Perhaps I should explain that for you. When I started
23 my work in haemophilia, which I suppose was probably
24 1975 -- I still have on my desk a little marble
25 paperweight of the meeting in '75 in London. I can

10

1 a number of different ways, which we may, I guess,
2 come on to, and I think there was a feeling -- maybe
3 there was a feeling. Once again, I think you would
4 have to ask others. But maybe there was a feeling
5 they needed a new-ish broom to look at what UKHCDO was
6 doing in an independent way, and so I found myself
7 suddenly, having been nobody, chairing the
8 organisation.

9 **Q.** We will come back later in a little more detail to
10 UKHCDO's role.

11 You were also a member, and you touched on it
12 a moment ago, of the North East Thames Region
13 Association of Haematologists, and we're going to look
14 at some of the documents generated by that, so I'll
15 ask you more about that in due course.

16 You were a member of the Medical Advisory Panel
17 of The Haemophilia Society.

18 **A.** Well, I began to be involved with Haemophilia Society
19 really quite early on, and I think I referred in my
20 statement to one or two meetings where I gave talks.
21 I can remember on one occasion taking part in a debate
22 at The Haemophilia Society at one of their weekends,
23 "I have the right to go skiing", and made
24 a presentation about it.

25 So I used to support The Haemophilia Society.

12

1 They used to ask me to do things. But I was never
 2 really aware of the time when I ceased to be the
 3 medical adviser. I think that they didn't ask me
 4 after a while to do any more for whatever reason, but
 5 they never wrote to me saying, "You're not a medical
 6 adviser anymore."
 7 **Q.** Then you're -- lastly, by way of introduction, you
 8 gave evidence to the Lindsay Tribunal in Ireland, the
 9 Archer Inquiry, and the Penrose Inquiry in Scotland.
 10 **A.** So I gave evidence at the Lindsay Inquiry I think
 11 largely because a friend of mine had a relative who
 12 was a haematologist in the Republic, and I think I was
 13 asked to go to the Lindsay Inquiry to support her.
 14 I know she's deceased now, so I can't give you any
 15 detail. I just think it was through that route that
 16 I was asked to go to Lindsay through the route of
 17 somebody who was practising haematology in Ireland at
 18 the time.
 19 **Q.** Would that have been Dr Daly?
 20 **A.** No, it wasn't. I can tell you who it was if you need
 21 to know.
 22 **Q.** Unless it's a UK-based haematologist, we don't
 23 particularly need to know.
 24 **A.** Okay. My presence at the Archer Inquiry was entirely
 25 determined by the late Reverend Alan Tanner. Alan

13

1 **Q.** I understand from your statement that you were
 2 involved in relation to a number of legal claims
 3 brought against what then, I suspect, had been the
 4 health authority responsible for The London Hospital
 5 as part of the HIV litigation?
 6 **A.** Well, in 1990, there were 30 lawsuits on my desk, and
 7 I think this was related -- perhaps it's not for me to
 8 judge -- but I think these were related to The
 9 Haemophilia Society's campaign for compensation or
 10 whatever you'd like to call it. Compensation is
 11 impossible for these circumstances, but some kind of
 12 financial recognition of what had happened.
 13 So I began to look and to defend these cases
 14 with the Trust's solicitor, who happened to be the
 15 biggest Trust standard at the time. Then, of course,
 16 when John Major came to the premiership, he introduced
 17 what became the Macfarlane Trust, and the cases were
 18 dropped.
 19 **Q.** I want to ask you a little more about the facilities
 20 and services at The London Hospital.
 21 Could you start by describing what the staffing
 22 and facilities were in 1977 when you took up your
 23 consultant post.
 24 **A.** So there is an 18th century hospital with a 19th
 25 century out-patients. There was no day ward. There

15

1 rang me up during the Inquiry and said, "Brian, would
 2 you be willing to attend the House of Lords to give
 3 evidence yourself because we would like you to do so."
 4 That's another example, really, where I always tried
 5 to help society, and certainly Alan Tanner, whenever
 6 I could because I had a huge respect and affection for
 7 him, and when he asked me to do this, I willingly did
 8 so.
 9 I think my relation with the Penrose inquiry is,
 10 I think, probably rather more formal.
 11 **Q.** In relation to the Penrose Inquiry, you were asked to
 12 address two particular issues. One was the care of
 13 one of the deceased individuals who the Penrose
 14 Inquiry was considering, and the other was an issue
 15 about whether certain products should have been
 16 available in Scotland between 1985 and 1987.
 17 You didn't give wider evidence I think to the
 18 Penrose Inquiry?
 19 **A.** No. I think I actually gave what was effectively
 20 medico-legal evidence on two or three patients, rather
 21 than just one, but there were these two separate
 22 issues: one, the medico-legal issue, if you like, in
 23 terms of looking at an individual person's course; and
 24 the other was, as you said, the issue of a particular
 25 concentrate.

14

1 was nowhere to see patients other than really in my
 2 office, I think. There were -- there was a laboratory
 3 which I was certainly competent to do all the
 4 haemophilia tests personally. There was no nursing
 5 staff, no physiotherapy staff, no social work or
 6 counselling staff. We had cryoprecipitate and
 7 a little bit of NHS, and I think at that time even
 8 then commercial concentrate.
 9 So if patients wanted to come to see me with
 10 haemophilia, or see the hospital with haemophilia,
 11 they would just simply turn up I think in the
 12 Emergency Department, and then somebody would go and
 13 see them and, if they needed treatment, we would treat
 14 them with cryoprecipitate. So I would get the
 15 cryoprecipitate out of the freezer, put it in the
 16 water bath for half an hour, draw it up myself into
 17 a horse syringe, or my junior staff would. I mean,
 18 there were certainly junior staff around. So the
 19 whole thing was done absolutely on a basis which is
 20 unthinkable today.
 21 **Q.** We're going to look at a document from 1977, just to
 22 get a sense of the number of patients at that time and
 23 the geography of the area. Henry, it's HSOC0022537,
 24 please. This is a document authored by you, regional
 25 co-ordinator for haemophilia in domiciliary care --

16

1 sorry, co-authored by you, along with others including
2 Professor Jenkins and Dr Katharine Dormandy published
3 in the British Medical Journal in 1977.

4 We can see there reference to the North East
5 Thames region -- and we'll look in a moment at what
6 that comprised:

7 "Having appointed a nursing sister to
8 co-ordinate the organisation of care for haemophiliacs
9 in the region, and as a result of that, it's recorded
10 that facilities for home treatment have expanded
11 rapidly. Several associate centres providing care to
12 haemophiliacs had been set up around the region, in
13 addition to the four main haemophilia centres, which
14 are all in the south-west corner of the region. As
15 well as providing support and supervision of patients
16 on home treatment, the co-ordinator helps to place
17 haemophiliac children in suitable schools, maintains
18 the regional register of haemophiliacs, and has a more
19 general role in ensuring that services are available
20 where they are needed throughout the region."

21 If you just go two pages further on, Henry, to
22 page 3, we can see a map there. Could we just zoom in
23 on the map, please? So this is the North East Thames
24 region; is that right?

25 **A.** Yes. You'll also, I think, see on the left-hand side

17

1 to all of these centres?

2 **A.** Brentwood. But, yes, absolutely. Obviously, it was
3 geographically in the middle of the region, therefore
4 quite well placed, geographically, to distribute the
5 concentrate. But, of course, it was also in a rural
6 area, so in some ways, that wasn't so convenient.

7 **Q.** We'll see in a little while when we look at some of
8 the North East Thames Region Association meeting
9 minutes how things were organised as between, in
10 particular, The London Hospital and the Royal Free.

11 But just dealing with the associate centres for
12 the moment because we may not hear evidence directly
13 from consultants or doctors at those centres, what
14 autonomy did those associate centres have?

15 **A.** I think they had complete autonomy if they cared to
16 exercise it. I should add, perhaps, that Southend
17 became very important later because we sent
18 a consultant from the London who trained at the London
19 down to Southend, and Southend became an important
20 associate centre.

21 **Q.** Who was that doctor?

22 **A.** Dr Michael Mills went down to Southend. But I think
23 the answer was that we regarded this as being
24 completely shared care. So the consultants at these
25 hospitals had autonomy. They asked for our advice and

19

1 a white area which is the old North East Metropolitan
2 region. Now, this is very boring bureaucracy, but the
3 Royal Free used to be in the old North East
4 Metropolitan region, but I think was not in the North
5 East Thames region. When I began my career, it was
6 North East Metropolitan, which I think I actually --
7 perhaps it's the other way around. I'm sorry.

8 I think may have misled you because it's actually on
9 this slide that the Royal Free was not in the old
10 North East Metropolitan region but was in the North
11 East Thames region. I'm so sorry.

12 **Q.** That's all right. We see here the four main
13 haemophilia centres there referred to are the
14 Royal Free, University College Hospital, London
15 Hospital, and the Hospital for Sick Children; that
16 would be Great Ormond Street?

17 **A.** Yes.

18 **Q.** Then we can see there are then four -- these four
19 associate centres at Harlow, Colchester, Chelmsford
20 and Grays.

21 **A.** Yes.

22 **Q.** Then we see in the middle there the Brentwood Regional
23 Transfusion Centre. Am I right in understanding that
24 the Regional Transfusion Centre in Brentford(*sic*) was
25 the supplier of NHS concentrates and cryoprecipitate

18

1 our support, and the patients came to see us at the
2 London or the Royal Free, but they were autonomous.
3 Of course, the Royal Free had interests in north-west
4 London as well as north-east London. But my
5 perception, when I was appointed in '77, was that
6 there was a real need in Whitechapel and in Essex for
7 a proper haemophilia centre. This, of course, is the
8 case that the Royal Free, who are a famous and
9 brilliant haemophilia centre, originally admittedly
10 started in a caravan, but it had become a really
11 important and national leading centre. But
12 geographically, it was in Belsize Park, and so for
13 a patient to be looked after from Colchester going to
14 Belsize Park, not a terribly easy journey. Of course,
15 Whitechapel is also the extreme west of the area, but
16 I think it had some strength in terms of transport
17 links that the Royal Free didn't have.

18 I should also add that at that time Cambridge,
19 for all its many strengths, was not particularly
20 haemophilia orientated. So I think we tended to draw
21 patients from the north-east of the region -- and you
22 can see how wide that is on the map -- who might
23 geographically naturally have gone to Cambridge but
24 preferred in fact to come into London.

25 So when I was appointed, one of the first things

20

1 I did was to start outreach clinics. So I went out,
 2 actually with my wife, on a Saturday morning to places
 3 like Chelmsford and Colchester and Harlow to, if you
 4 like, fly the haemophilia flag, to say: look, we're
 5 trying to do better for people with haemophilia, we
 6 want to look after all your needs, we believe in the
 7 concept of, what later became, comprehensive care.
 8 There's the opportunity, perhaps for home treatment.

9 I would actually see patients in these hospitals
 10 on a Saturday morning, perhaps give a talk to the sort
 11 of, effectively, The Haemophilia Society community,
 12 and in that way we drew people in. We found all sorts
 13 of people with haemophilia who had not been looked
 14 after. I mean, there was one patient who, I suppose
 15 in his 60s when I first met him, literally had knees
 16 that were in fixed sections. All he could really do
 17 was to lie in bed, read The Times and watch the
 18 cricket on television. That was his life.

19 We tried to improve the lives of people who
 20 really didn't even know there was a haemophilia
 21 service.

22 **Q.** If we go over the page please, Henry, we can see
 23 a table -- if we zoom in on the second of the tables,
 24 please, Henry.

25 So we can see here this is obviously a snapshot

21

1 can see there a description of The London Hospital.
 2 This is in 1983:

3 "The London Hospital Haemophilia Centre has its
 4 largest catchment area in East London, but also cares
 5 for patients throughout Essex."

6 And then:

7 "Both the [Royal Free] and [The London Hospital]
 8 Centres operate comprehensive care programmes for
 9 haemophiliacs which include genetic counselling,
 10 diagnostic services, paediatric and adult out-patient
 11 and in-patient clinical services, home treatment,
 12 physiotherapy, social services, general and
 13 orthopaedic surgery, dental surgery and emergency
 14 care."

15 Also reference to having:

16 "... the facility to patients with inhibitors
 17 and problems related to hepatitis."

18 We'll come back to hepatitis.

19 Then:

20 "UCH and the Middlesex ... [are] designated
 21 Haemophilia Centres but only care for small numbers of
 22 patients, and offer less comprehensive services."

23 So it would seem that in the six years from 1977
 24 to 1983, the haemophilia service at The London
 25 Hospital changed and developed quite considerably?

23

1 in 1977:

2 "Numbers of patients cared for at each centre
 3 and treated at home according to type of haemophilia
 4 and preparation."

5 We can see The London Hospital is considered as
 6 having three treated at home with Factor VIII
 7 cryoprecipitate, eight on Factor VIII concentrate
 8 (that's in terms of haemophilia A), and then (in terms
 9 of haemophilia B) two patients on home treatment with
 10 Factor IX concentrate. So a total at that stage of
 11 13 patients on home treatment.

12 I think we see elsewhere -- oh, yes, if we just
 13 go up to the table above that, I think we've got
 14 a figure somewhere, I can't find it now, of the number
 15 of patients that were being treated under The London
 16 Hospital umbrella, as it were, and it was 190. I can
 17 find the reference to that if need be.

18 Just, again, a further snapshot in time,
 19 Dr Colvin, moving forward to 1983, could we have,
 20 Henry, BART0002284, please.

21 This is a document we may come back to, but we
 22 can see its co-authored between you and Dr Kernoff of
 23 the Royal Free in August 1983, "Haemophilia Services
 24 in the North East Thames Region".

25 If we could go, please, to the sixth page, we

22

1 can see there a description of The London Hospital.
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 4 largest catchment area in East London, but also cares
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 22 patients, and offer less comprehensive services."

23 So it would seem that in the six years from 1977
 24 to 1983, the haemophilia service at The London
 25 Hospital changed and developed quite considerably?

23

1 **A.** I certainly hope so but I'm afraid that the fabric
 2 hadn't changed very much. I mean, I think that one of
 3 the features of haemophilic care is it's really the
 4 people rather than the fabric that make a haemophilia
 5 centre. I think the Royal Free were very fortunate
 6 that they had a purpose-built haemophilia centre about
 7 the time of Katharine Dormandy's retirement and sad
 8 death, but we didn't have that facility.

9 So there's no doubt that the fabric of the
 10 Royal Free was much, much more sophisticated than the
 11 fabric at the London.

12 As you will realise from my statement, I relied
 13 very heavily on the Royal Free for advice. I was
 14 a single-handed, effectively -- I know there are other
 15 consultants at the London but I was -- in terms of
 16 haemophilia care, I was single-handed. I have
 17 occasionally said, and I think it's fair, that I was
 18 on call from 1977 to 2003, when John Pasi became
 19 a consultant at The London.

20 But I relied on the Royal Free for my advice,
 21 and they were extremely supportive. That work we did
 22 in the North East Thames region I think was absolutely
 23 the right way to have managed haemophilia.

24 Of course you could have said, "Well, don't
 25 bother with The London, the Royal Free can do it all

24

1 themselves, and they could have done, but I do think
 2 that the people of Whitechapel and Essex benefited
 3 from having a significant centre at The London,
 4 although it wasn't the same as the centre at the
 5 Royal Free.
 6 **Q.** If we just go further down the page, please, Henry, we
 7 can see it's said:
 8 "There are Associate Haemophilia Centres at
 9 Chelmsford, Colchester, Harlow, Orsett and Southend."
 10 So now Southend.
 11 "These Centres do not separately register
 12 patients or organise home treatment programmes and are
 13 not staffed or equipped to manage serious clinical
 14 problems, undertake major surgery or offer genetic
 15 counselling. Their main role is to offer local
 16 support to patients who are mainly managed at the
 17 [Royal Free] or London Hospitals."
 18 So, typically, if you had a patient whose local
 19 hospital was one of those five associate centres, what
 20 aspect of their clinical care would be your
 21 responsibility and what aspect would be the associate
 22 centres?
 23 **A.** It would depend a bit on how severely affected they
 24 were. If they were severely affected, then I would
 25 hope that they would come to The London for regular

25

1 prophylaxis when it happened in the 1990s, and things
 2 like genetic counselling when that became more
 3 important in later times.
 4 So things that required what you might describe
 5 as critical mass or expertise we tried to deal with at
 6 The London or at the Royal Free but things that were
 7 everyday were happily dealt with at a place like
 8 Southend or Harlow, and I was determined that those
 9 associate centres should not lose touch with my
 10 patients.
 11 Now, it was the case -- and this came up in the
 12 90s when we were managing the definition and the
 13 accreditation of the comprehensive care centres --
 14 what is the role of the associate centre? How do we
 15 police, if you like to use that word, the care
 16 provided in the periphery? It's extremely difficult.
 17 So it is a matter of personal relationships between
 18 the centre and the periphery to make sure that the
 19 patients get the expertise that's required at the
 20 hospital and yet they also have a contact with their
 21 local physician.
 22 **Q.** If we leave this up, Henry, because I'm going to look
 23 at the bottom of the page in a moment -- but just so
 24 I understand the position in relation to the different
 25 centres and the way they interacted in the late 70s,

27

1 review, probably every three to 6 months, that we
 2 would advise them on all matters related to home
 3 therapy. You will see from the previous paper that
 4 you showed me that in '77 we appointed the domiciliary
 5 sister; and this was a key part of our outreach
 6 programme because she travelled all over the region
 7 looking at our patients in the home, helping them with
 8 their home treatment, advising them on how they were
 9 getting on, and whilst I said to you that in '77 the
 10 associate centres were autonomous, and indeed they
 11 were, because I couldn't force them to do anything,
 12 but they very willing and happily, I think, allowed or
 13 instructed or requested me to look after their
 14 patients but with total shared care.
 15 I think it's terribly important that these
 16 patients were not lost to their distant -- for me,
 17 distant for me -- hospital. Because when things
 18 happen, you need to know where to go, what to do, and
 19 so it's no good having an ivory tower, if you like
 20 in -- no towers in Whitechapel are ivory -- but no
 21 point going to an ivory tower in Whitechapel when
 22 anything happens and you have to go to, say, Southend
 23 they don't know who you are. So the whole idea was
 24 shared -- shared -- care but we would be responsible
 25 for most supply, the home treatment programme,

26

1 early 80s, there were essentially, is this right,
 2 three types of centre: the reference centres?
 3 **A.** Yes.
 4 **Q.** The main centres that were not reference centres, of
 5 which The London Hospital would be one, and then the
 6 associate centres?
 7 **A.** Yes, that's perfectly correct.
 8 **Q.** The status of reference centre was, at that time, was
 9 a DHSS conferred status; is that correct?
 10 **A.** Well, it's probably more complicated than that.
 11 I think that in the 50s -- I don't want to go on too
 12 much, but in the 50s Macfarlane invented haemophilia
 13 care, really, for the United Kingdom, in Oxford. Then
 14 in the 60s I think half a dozen physicians,
 15 haematologists, got together, as part of the MRC
 16 I think, to create a system for managing haemophilia
 17 and, from that, grew UKHCDO.
 18 Although I'm sure we will be discussing later
 19 some of the data aspects of UKHCDO, it was
 20 a world-class arrangement for managing the national
 21 care of people with haemophilia on the basis of the
 22 centres who were most interested in delivering
 23 healthcare. This group of reference centres were
 24 actually self-appointed, if you like, and they
 25 represented those cities that had the greatest

28

1 interest in haemophilia care.
 2 Now, that meant that Sheffield was represented,
 3 but not Bristol; oxford had enormous influence over
 4 the whole of the middle of the country; nothing at
 5 Southampton, for instance; nothing at all in the
 6 West Country; manchester, yes; Birmingham, yes;
 7 Glasgow, yes; Edinburgh, yes; as I say, Sheffield; and
 8 of course St Thomas' and the Royal Free. But there
 9 was no sort of -- there was -- it's a brilliant
 10 organisation, but it was a self-invented organisation.

11 **Q.** Then we will just look at the numbers at the bottom of
 12 the page. So this, again, is a snapshot from 1983.
 13 We have there the figures of -- in terms of patients
 14 registered at The London Hospital: 201 with
 15 haemophilia A, 28 with haemophilia B, 109 with
 16 von Willebrand's, and then 36 patients on home
 17 treatment.

18 So you have gone from some 13 or so patients on
 19 home treatment in 1977 to 36 patients on home
 20 treatment by 1983?

21 **A.** I think it's important to appreciate that the
 22 Royal Free is actually bigger than this. I think that
 23 these figures may relate to the North West Thames --
 24 it may not relate to the North West Thames --
 25 influenced the Royal Free because the Royal Free has

29

1 haemophilia as a whole is, I don't know, perhaps
 2 20 per cent or something like that. Those patients
 3 you will know about. But there are people out there
 4 who don't know they've got haemophilia and, if you
 5 have an outreach programme, you pick up people with
 6 very mild haemophilia.

7 So you might find that at The London after this
 8 outreach initiative we had rather more mildly affected
 9 patients on our books than other centres who hadn't
 10 been out looking for patients. As I think I've
 11 mentioned elsewhere, there are occasions when one can
 12 diagnose a patient with haemophilia at the age of 70.
 13 I've certainly done that a couple of times, where
 14 somebody's come to the hospital bleeding to death,
 15 say, from a prostate operation, and I've been able to
 16 identify they have got haemophilia, despite they've
 17 spent the whole of their lives not knowing that they
 18 had anything wrong with them.

19 **Q.** In 1993 The London Hospital became a comprehensive
 20 care centre. What did that mean?

21 **A.** Well, I think what actually happened was that they
 22 wanted to me to chair the organisation, and the only
 23 way I could be chairman of the organisation is if my
 24 centre was a comprehensive care centre. So I think on
 25 one day they decided I was a Reference Centre Director

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1 enormous influence in North West Thames, which isn't
 2 actually, obviously, the North East Thames. We did
 3 have a north regional meeting from time to time but
 4 it's sometimes difficult to know whether the figures
 5 are actually all the Royal Free's figures or only some
 6 of them.

7 **Q.** I can clarify that with Professor Lee or Professor
 8 Tivnum in due course. But as far as your figures are
 9 concerned, this is a document authored by you in 1983,
 10 so it should be accurate?

11 **A.** Yes. Yes, of course. No, I've no problem with that.

12 **Q.** Without going to any further documents at the moment
 13 in relation to figures, your statement and I think
 14 your evidence to previous inquiries tells us, in terms
 15 of the growth of the centre, that by 1993 you thought
 16 you had around 500 patients, and by 2001 approximately
 17 600 patients?

18 **A.** If that's what I said, yes, I'm sure it's fine.

19 **Q.** You say in relation to patients of that magnitude it
 20 would be about 100 that you would see regularly?

21 **A.** Yes. I mean, one of the features of my outreach
 22 programme was that I tripped over, if you like, a lot
 23 of people who were quite mildly affected and, as
 24 you'll appreciate, the numbers of people who have got
 25 severe haemophilia compared to the people who have got

30

1 effectively in order to get me into the organisation,
 2 and the only way to do that was to say I was
 3 a comprehensive care centre. I think I met the
 4 criteria but that's I think how it really happened.

5 **Q.** Before we look in a moment at more detail at issues
 6 relating to hepatitis, just one further question on
 7 organisation and administration.

8 Your statement refers to a system of red or
 9 brown envelopes.

10 **A.** Yes.

11 **Q.** What did that refer to?

12 **A.** Okay. So when I started at The London as the
 13 director, or indeed when I was a junior doctor,
 14 somebody -- I think John Perrin, who was the person
 15 who looked after the few haemophiliacs before -- or
 16 people with haemophilia -- before Frank Boulton, had
 17 started a system of identifying people with
 18 haemophilia and keeping a little folder, in a brown
 19 envelope, in the department that was separate from the
 20 main hospital notes.

21 Now, I don't know whether The London is
 22 different from other hospitals, but getting hold of
 23 the main hospital notes was often a nightmare, and
 24 when people turned up in the hospital for treatment,
 25 if they had a bleed, you needed to know who they were,

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1 what their condition was and what they were treated
2 with.

3 I think John Perrin's idea was to have this
4 folder that would contain the main facts about the
5 patient in the department and that meant that if
6 somebody turned up in the middle of the night, or
7 indeed during the day for that matter, the person on
8 call could go to that folder and know they got the
9 right information and treat the patient quickly.

10 I don't believe, and maybe we will come on to
11 this, but I don't believe there was ever anything in
12 those folders that were not in the hospital notes.
13 Now the only difference between the brown envelope and
14 the red envelope was that they were originally brown
15 manilla envelopes and they tended to wear out and they
16 were eventually replaced by red plastic ones.

17 **Q.** Just so that I can understand, because you know,
18 I think, Dr Colvin, the issue of medical records, and
19 what has happened to medical records is an important
20 issue for the Inquiry, and we may come back to that,
21 but in this period, 1977 through to the early 1980s,
22 what would have been the various different types of
23 notes and records that you would have had access to?

24 **A.** So obviously no computer. The notes are all
25 handwritten, and there would be a system of

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1 described, where were those kept?

2 **A.** The red and brown envelope were kept in the
3 department. So when I --

4 **Q.** In the Haematology Department?

5 **A.** Yes. I mean, the department also was barely a real
6 department. What we had was, on the first floor of
7 the main block there was a secretary's office, and it
8 was in the same place as the laboratory.
9 Professor Jenkins had his office and maybe we young
10 physicians had a space where we could do things.
11 I think there was also a small area reserved for
12 patients who could be seen in what we might describe
13 as "the department", if they weren't in the
14 Emergency Department. The red and brown envelopes
15 were kept with my secretary's area, and there would be
16 access to them in the middle of the night presumably
17 by getting a key and opening the department to get to
18 the records.

19 **Q.** Then I understand that other notes may have been in
20 other locations within the hospital depending upon
21 where the patient might end up, but in terms of your
22 own clinic notes -- so the handwritten notes you would
23 make when you saw a patient and diagnosed them or
24 proposed a course of treatment and so on, took blood
25 for tests, whatever it was -- where would those notes

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1 handwritten notes for each clinic secured by star
2 clips. So you have a -- my service would be a big
3 thick file with star clips, and I would write in the
4 notes. For the rheumatology clinic there would be
5 a separate set secured by a star clip.

6 For in-patient notes, each individual in-patient
7 admission would be a paper copy separate from the next
8 admission. The results were in a separate file, also
9 secured by a star clip, and stuck onto sheets, which
10 often the glue failed, and so they tended to be less
11 than perfectly placed.

12 I'm afraid that -- there were secretaries in the
13 ward, and indeed I had a secretary whose job was to
14 try to control the avalanche of paper. I'm afraid
15 I was pretty obsessional and spent a lot of my time
16 trying to tidy up these dreadful notes. They, of
17 course, were being moved around the hospital, so often
18 you couldn't find them because a patient had been to
19 a clinic somewhere and they weren't available or had
20 been lost.

21 So I don't think The London was the worst
22 hospital in the world for making the notes tidy and
23 available but this difficulty used to trouble me
24 a great deal.

25 **Q.** In relation to the red and brown envelope that you

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1 be kept?

2 **A.** That would depend on how severely affected the
3 patients were, because I think we did keep the
4 severely affected patients' notes in the department in
5 a stack where we knew we could get hold of them. But
6 for a mildly affected patient who perhaps either came
7 once a year or didn't come up for years on end they
8 would be in the main hospital records and we would
9 call them up if we needed them.

10 **Q.** I want to move on, Dr Colvin, to consider your own and
11 the developing knowledge of risks of viral
12 transmission from blood and blood products.

13 Can I start by asking you what did you learn
14 about those risks during your general medical training
15 and your specialist haematology training?

16 **A.** So in '63 to '66, at university, that was just when
17 the Australia antigen was described, so hepatitis B.
18 I'm sure that in my general haematological training
19 and in my training at the blood transfusion centre at
20 Brentwood I would have been advised, and it would have
21 been explained to me, all about hepatitis B
22 transmission by blood and blood products. But of
23 course by the time I came to certainly a consultant
24 position, there was virtually no hepatitis B
25 transmission going on anymore. But we were fully

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1 aware of the fact that hepatitis B was a transmissible
 2 agent and was transmissible in blood products.
 3 **Q.** Other than what you learnt during your training, what
 4 was your -- what were your means of keeping up to date
 5 with knowledge? First of all, what journals or
 6 magazines would you read?
 7 **A.** So, I mean, very much like Mark Winter, I read the
 8 British Medical Journal, I read The Lancet and I read
 9 the New England Journal of Medicine as my weekly diet
 10 of information. In addition, I would read the British
 11 Journal of Haematology on a very regular basis. Of
 12 course I would see other journals as well but that was
 13 the core of my reading.
 14 **Q.** What other sources of knowledge were there? If we
 15 start with UKHCDO, in terms of the reports that might
 16 be generated for example by Dr Craske and the
 17 Hepatitis Working Party for either for Reference
 18 Centre Directors or for annual general meetings, if
 19 a report was simply going to the Reference Centre
 20 Directors, you presumably wouldn't see that?
 21 **A.** No, I wouldn't.
 22 **Q.** Were the minutes of Reference Centre Directors
 23 meetings disseminated more widely to other directors?
 24 **A.** I don't know but I doubt it. I really don't know.
 25 **Q.** Then in terms of the annual meetings to which all

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1 or information available to you -- I'm talking here
 2 really from 1977 through to the mid-1980s?
 3 **A.** I don't think so.
 4 **Q.** I'm going to look at an extract from your evidence to
 5 the Archer Inquiry.
 6 Henry, it's ARCH0000012, please. Henry, if you
 7 look towards at the bottom of the page, I don't know
 8 whether you've got the whole transcript. We need to
 9 go to page 140 for Dr Colvin's evidence. If we just
 10 go back to 138.
 11 We can see there, halfway down the page,
 12 Dr Colvin, this is the start of your evidence.
 13 **A.** Yes.
 14 **Q.** Then if we go over, please, Henry, to page 140 and
 15 picking it up halfway down the page, you said this:
 16 "The statement I really wanted to make was that
 17 I am aware of the fact that liver infection became
 18 a feature of blood transfusion in the 1940s, that from
 19 the 1970s, the beginning of the 1970s ... it was quite
 20 clear that the concentrates were capable of
 21 transmitting hepatitis and that by 1975, the
 22 haemophilia treating community was aware that there
 23 was at least a possibility of chronic liver disease in
 24 haemophilia."
 25 That is correct, is it?

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1 directors were invited, were the minutes of that
 2 circulated to the directors afterwards?
 3 **A.** I would think so, and I was a regular attender. There
 4 would be very few annual meetings of the UKHCDO that
 5 I didn't attend. I'd be surprised if I didn't attend
 6 any.
 7 **Q.** As far as I can tell from the minutes, there were
 8 reports produced, for example, by Dr Craske or by
 9 other working parties. It looks as though they were
 10 circulated in advance of the meetings for directors to
 11 look at?
 12 **A.** Yes, I mean, I think that the UKHCDO had a good record
 13 of information dissemination.
 14 Rosemary Spooner, who deserves a mention in any
 15 forum of the discussion of haemophilia care, was the
 16 data handler at Oxford, and was the most remarkable --
 17 a remarkable woman, who really was able to mastermind
 18 the data collection and the work of the UKHCDO and the
 19 dissemination of information about UKHCDO's work, and
 20 it was a very important work that she did.
 21 **Q.** So there's UKHCDO. You obviously had this close
 22 working relationship with, in particular, Dr Kernoff
 23 of the Royal Free Hospital?
 24 **A.** Yes.
 25 **Q.** Were there any other particular sources of knowledge

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1 **A.** Sure.
 2 **Q.** Then what do you recall learning, and roughly when,
 3 about non-A, non-B hepatitis? You have referred to
 4 hepatitis B.
 5 **A.** Well, I think that the term "non-A, non-B" gradually
 6 became adopted during the 80s particularly but very
 7 late 70s to 80s you would be able, perhaps, to inform
 8 me. But it doesn't make much difference really in the
 9 sense that we knew that there were abnormal liver
 10 function tests in people with haemophilia who had been
 11 treated by concentrates. In fact, of course, some
 12 people developed overt hepatitis. I mean, two or
 13 three of my patients, probably maybe up to half
 14 a dozen, had a significant attack of jaundice and
 15 hepatitis, which of course made them really quite
 16 unwell. They all always got over that. Obviously
 17 it's possible to die of acute hepatitis, even I think
 18 of non-A, non-B, but nobody -- very few did, not under
 19 my care.
 20 So we did have quite clear evidence of jaundice
 21 and liver infection in some patients, but it was also
 22 known that people who hadn't had acute clinical
 23 hepatitis had liver function tests that were not
 24 necessarily normal. Some of them were normal,
 25 but most of them weren't normal. That's what we were

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1 thinking about in -- perhaps particularly in the mid-
2 to late 1970s and then into the 1980s as to what does
3 this actually mean?

4 **Q.** So you were aware from probably the mid-1970s that
5 there was this further form of hepatitis?

6 **A.** Yes.

7 **Q.** In fact, I think the literature does start calling it
8 non-A, non-B hepatitis in the mid-70s?

9 **A.** Yes, sure.

10 **Q.** The issue appears to be, looking at your statement,
11 the question of how serious or severe it was
12 understood to be?

13 **A.** I agree.

14 **Q.** We're going to look at some documents in a moment,
15 but, first of all, what's your recollection -- picking
16 matters up really when you've become a director and
17 consultant in 1977, what's your recollection of your
18 understanding of this condition?

19 **A.** Well, I think you need to put this in the context of
20 the dramatic improvement in haemophilia care. I think
21 we heard from many witnesses, either on television or
22 in the last few days, how dramatic it was that
23 haemophilia care improved, and people could do things
24 they hadn't done before.

25 I think that physicians also were delighted that

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1 Lindsay Tribunal, it was more of a hope than based in
2 evidence.

3 **A.** Absolutely.

4 **Q.** I am going to ask you just to look at a small number
5 of medical articles from that time.

6 **A.** Yes, sure.

7 **Q.** They are materials that have been shown to you in
8 advance. The first, please, Henry, is PRSE001431.

9 I think I might have given you the wrong reference
10 there. PRSE0001431.

11 That's it. So this is an article in The
12 Lancet -- sorry, can we just have the date, please,
13 Henry at the top of the page? 3 August 1974. "Long
14 incubation post-transfusion hepatitis without
15 serological evidence of exposure to hepatitis B
16 virus."

17 So August 1974 in The Lancet -- I appreciate
18 this is before you are a consultant, but it's whilst
19 you're a haematologist. Would you expect to have read
20 it at the time?

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

22 **Q.** Then we can see it's by Prince and others, and if we
23 just look at the summary, first of all:

24 "An agent other than hepatitis B virus seemed to
25 be the cause of 36 -- 71 per cent -- of 51 cases of

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1 they were able to offer people proper haemophilia care
2 that changed their lives and I think people were
3 reluctant to contemplate the possibility that there
4 was "anything wrong" (in inverted commas) with these
5 treatments.

6 So when we had patients who'd got chemical
7 changes in their liver function tests that didn't make
8 them unwell, and when we had people who were very well
9 in themselves, I think there was the hope that this
10 wouldn't be a big problem, and that hope clearly was
11 misplaced.

12 However, the truth also is that it takes a very
13 long time for most patients to get ill with
14 hepatitis C or non-A, non-B alone, assuming they
15 haven't had an acute attack. So Eric Preston wrote
16 a paper -- I can't remember exactly when -- when he
17 was able to tell us how long it took to get ill with
18 serious liver disease, with non-A, non-B. It was --
19 something like 20 years was about the -- almost -- not
20 the minimum, but, I mean, most people would not be ill
21 for 20 years, in terms of things like cirrhosis or
22 hepatoma. So I think that there was an unjustified
23 but justifiable, if you like, feeling that it would be
24 all right.

25 **Q.** I think the way you put it in your evidence to the

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1 post-transfusion hepatitis identified during
2 prospective bi-weekly serological follow up of 204
3 cardiovascular surgery patients. The sera of the 36
4 cases showed no evidence of the antigen or antibody
5 response expected to accompany infection by HB virus
6 and to be detectable by the sensitive assays used.
7 Incubation periods and clinical and epidemiological
8 features were inconsistent with hepatitis A."

9 Then we see, if we go to the last sentence:

10 "The data suggests a large proportion of long
11 incubation post-transfusion hepatitis is unrelated to
12 hepatitis B and that control of post-transfusion
13 hepatitis will require identification of the hepatitis
14 viruses type C."

15 In fact, not properly named type C for another
16 decade or so. So there's the identification of non-A,
17 non-B hepatitis.

18 **A.** Sure.

19 **Q.** Then if we go to the last page of the report, please,
20 Henry, the sixth page. If we zoom in on the top
21 left-hand bit. Thank you. Just slightly further
22 down:

23 "The fact that non-B hepatitis cases are less
24 frequently associated with serious acute illness does
25 not imply that such cases are of lesser importance.

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1 Long-term complications of acute hepatitis B
 2 infection, such as chronic hepatitis, cirrhosis and
 3 hepatoma, have been reported to follow mild anicteric
 4 infections more frequently than severe icteric cases;
 5 consideration must thus be given to the possibility
 6 that non-B hepatitis may play a role in the aetiology
 7 of some forms of chronic liver disease."

8 So we can see there a distinction being drawn
 9 between hepatitis B and non-hepatitis B --

10 **A.** Sure.

11 **Q.** -- in terms of the acute phase, which I think touches
 12 upon what you have already said, that you didn't see
 13 the acute illness particularly frequently.

14 **A.** Sure.

15 **Q.** But would you accept this is identifying at least the
 16 possibility of longer term complications that may
 17 follow not just with hepatitis B but also with non-A,
 18 non-B hepatitis?

19 **A.** Yes, and of course, indeed, it also points out that
 20 there might be hepatitis C, D, E, F, G, H, I, J, K.
 21 That it wasn't necessarily one virus -- assume it was
 22 a virus which was very likely.

23 **Q.** Then if we look, please, at an article which you have
 24 referred to, Dr Colvin. It's PRSE0001794, please.

25 So we see on the right-hand side "Factor VIII

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1 moment?

2 **A.** I think it was very important.

3 **Q.** We'll just look at perhaps what's said on the second
 4 page of the report please, Henry, in the discussion.
 5 It's bottom of the page, please, under the heading
 6 "discussion" thank you:

7 "The measures now used by the National Blood
 8 Transfusion Service to reduce the incidence of
 9 transfusion hepatitis, such as the use of single
 10 donations and small pools of plasma, make the
 11 occurrence of more than one case of transfusion
 12 hepatitis as the result of contamination of a plasma
 13 pool by a single donor most unlikely. The risk is
 14 greatly increased with Factor VIII concentrates
 15 prepared from pools of more than a thousand donations.
 16 When blood for transfusion is prepared from commercial
 17 donations this increases the frequency of jaundice
 18 three to ninefold for single transfusions. The pool
 19 size however may be critical in Factor VIII
 20 concentrates, since transfusion hepatitis is a known
 21 hazard with large-pool products prepared from
 22 volunteer donors in the UK."

23 So am I right in understanding that one of the
 24 significant aspects of this paper is the attention it
 25 draws to the relative risks that may be associated

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1 concentrate". This is authored by Craske, Dilling and
 2 Stern and you have referred to this?

3 **A.** Yes.

4 **Q.** Presumably something that you saw at the time?

5 **A.** It's a key paper. I mean, it's a famous paper.

6 **Q.** What can you tell us about your understanding of its
 7 significance?

8 **A.** Well, I think what it says on the tin, in a way. What
 9 it says is there's an outbreak of jaundice in patients
 10 who have had freeze dried concentrate, and it wasn't
 11 hepatitis B.

12 **Q.** This was the -- an analysis of an outbreak that had
 13 happened in Bournemouth:

14 "Seven cases of non-hepatitis B, four of
 15 hepatitis B occurred within six months of the first
 16 use of this product."

17 So was this particularly significant for
 18 haematologists such as yourself because this is
 19 talking about patients who've received Factor VIII
 20 concentrates?

21 **A.** Yes. I think it's an important paper, and --
 22 obviously I don't remember the detail of it, but
 23 Craske, Dilling and Stern is a paper we talk about.

24 **Q.** Yes, and I think you described it in your evidence to
 25 the Lindsay Inquiry as something of a watershed

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1 with different pool sizes?

2 **A.** I think it does and I think it actually underestimates
 3 the reality because, as we will see later, the reality
 4 was that if you've got a large pool concentrate with
 5 a national prevalence of hepatitis C infection of
 6 something like 0.3 per cent (I quote, although other
 7 people quote slightly different values), you've got
 8 thousands of donations at a prevalence of
 9 0.3 per cent, hepatitis is inevitable. So I think
 10 this actually slightly underestimates what we now know
 11 to be the truth.

12 **Q.** The way you put it in your evidence to the Lindsay
 13 Inquiry -- we can look at it if need be -- but you
 14 talked about this as a moment, a watershed moment,
 15 after which it was known there was quite a significant
 16 problem for the future, at least in terms of numbers?

17 **A.** Yes, I think that's fair.

18 **Q.** So do I understand that to mean this was going to be
 19 a problem that might affect a significant number of
 20 patients?

21 **A.** Yes, I think that's fair. I think what wasn't known
 22 was what the problem was that would affect them. We
 23 didn't know what was going to happen next but I think
 24 we knew that it was going to happen to a lot of
 25 people.

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1 Q. So that was August 1975. We know, obviously, within
 2 the Inquiry and those listening of the World in Action
 3 documentary "Blood Money" broadcast in December 1975.
 4 Do you recall whether you watched it at the time?
 5 A. I don't recall that I watched it at the time. It's
 6 quite likely that I would have done. I've certainly
 7 seen it since.
 8 Q. Do you recall whether there was any generation --
 9 sorry, whether the programme generated any discussion
 10 amongst haemophilia directors at the time?
 11 A. I don't recall that actually, but I'd be surprised if
 12 it didn't. But I really can't recall.
 13 Q. Would you accept that by the mid-1970s hepatitis B was
 14 known to be a serious condition that could have severe
 15 long-term consequences?
 16 A. Of course.
 17 Q. What was the basis for assuming, if clinicians did
 18 assume, that this other virus (non-A, non-B hepatitis)
 19 would take a significantly different course?
 20 A. Well, you might say it was wishful thinking but the
 21 fact that one virus has one set of characteristics
 22 doesn't mean that another virus will have the same set
 23 of characteristics. So whilst I think the point was
 24 made that there was no reason to believe that non-A,
 25 non-B (hepatitis C) would have a different course from

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1 involve an acute phase, it might involve a chronic
 2 phase and it was generally understood that the chronic
 3 phase could result in long-term cirrhosis, long-term
 4 serious liver problems, including cancer. All that
 5 was known before --
 6 A. Yes.
 7 SIR BRIAN LANGSTAFF: -- the constituent parts of serum
 8 hepatitis were discovered, first of all, hepatitis B
 9 and then later on non-A, non-B, which became largely
 10 known as hepatitis C. So by the time that you went
 11 into training, it would have been appreciated that
 12 hepatitis caused after transfusion could result in
 13 very long-term consequences.
 14 A. Yes, of course.
 15 SIR BRIAN LANGSTAFF: So to think that -- was there
 16 a reason for thinking that by identifying hepatitis B,
 17 the serious part of what had been serum hepatitis had
 18 become known? That, I think, would be wishful
 19 thinking, would it?
 20 A. I think everybody used the expression "wishful
 21 thinking" and I think you've just used it and I would
 22 happily use it again. I think it's true.
 23 SIR BRIAN LANGSTAFF: So there would have been not only no
 24 reason to think that hepatitis non-A, non-B was less
 25 serious in its long-term consequences than hepatitis B

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1 hepatitis B, there was no reason to believe that it
 2 would have the same course. I mean, it's a matter of
 3 experience.

4 Now, of course, what then happens is what are
 5 you going to do about the abnormal liver function
 6 tests? There's no test for the virus. There's no
 7 valid test for the health of the liver in that time,
 8 I think, that is anything other than a liver biopsy,
 9 and you may want to come on to the question of, "Well,
 10 do we do liver biopsies or don't we?"

11 MS RICHARDS: Well, I note the time, sir.

12 We will come on to that after the break,
 13 I think, Dr Colvin.

14 Sir, is that a convenient moment to break?

15 SIR BRIAN LANGSTAFF: Yes.

16 Can I just ask you this: during the war, it
 17 became apparent that after transfusion hepatitis might
 18 result. That fact was a given.

19 A. Sure.

20 SIR BRIAN LANGSTAFF: The general understanding was, as
 21 I read it, that that was known as serum hepatitis, to
 22 distinguish it from hepatitis A, as it later became
 23 known, which was infectious hepatitis.

24 A. Yes.

25 SIR BRIAN LANGSTAFF: The course of serum hepatitis might
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1 had been or other forms of serum hepatitis, would
 2 there? It would be wishful thinking to think
 3 otherwise. You just said so, I think.

4 A. I think that many of the patients didn't have an acute
 5 phase.

6 SIR BRIAN LANGSTAFF: No.

7 A. Many of them had rather minimal abnormalities of liver
 8 function in terms of their transaminase levels. I
 9 don't think there was any evidence either for or
 10 against the long-term consequences. If you say to me,
 11 well, this form of hepatitis had long-term
 12 consequences, then surely this type of hepatitis,
 13 other form of hepatitis, would have long-term
 14 consequences, the answer is, well, maybe, maybe not
 15 but there's no evidence. There was no evidence either
 16 way until we get on to the points that may be asked
 17 after the break. But I --

18 SIR BRIAN LANGSTAFF: We will see where we go after the
 19 break nevertheless. Thank you very much.

20 MS RICHARDS: Sir, sorry, would you give Dr Colvin the
 21 customary advice about not discussing evidence. He
 22 knows already.

23 SIR BRIAN LANGSTAFF: Yes, I will.

24 We will take a break until 12 -- no, let's make
 25 it 11.50, because I think there are probably less

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1 people here today than there were last week.
 2 You're giving evidence. You must not discuss
 3 anything about your evidence, either what you have
 4 been asked or what you think you might be asked, with
 5 anyone, whoever it is, but you can discuss anything
 6 else you like.
 7 **A.** Thank you very much.
 8 **(11.12 am)**
 9 **(A short break)**
 10 **(11.50 am)**
 11 **MS RICHARDS:** Dr Colvin, I'm going to ask you to look at
 12 three further articles with me. They may or may not
 13 be materials you saw at the time, and that's one of
 14 the questions I'll ask you.
 15 Henry, could we please have PRSE0000381. We can
 16 see this is an article. It's in 1976 in the Yale
 17 Journal of Biology and Medicine. "Non-A, non-B
 18 hepatitis". Purcell, Alter -- one of the recipients
 19 of the Nobel Prize for medicine yesterday -- and
 20 Dienstag.
 21 Is it likely that this is an article you would
 22 have read at the time?
 23 **A.** Not at all.
 24 **Q.** If we just look at it, we'll just go, I think, please,
 25 Henry, to page 4, please. Picking it up halfway down

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1 Now, I understand that you wouldn't have seen,
 2 didn't see this article at the time. How would
 3 information and learning such as this, which would
 4 potentially be important for haemophilia clinicians to
 5 know at a practical clinical level, how would that be
 6 disseminated?
 7 How would you expect as part of the structure of
 8 medical learning for that kind of information to
 9 filter down?
 10 **A.** Well, obviously, if there are key papers in a journal
 11 that can be picked up within the medical literature --
 12 something like The Lancet or the British Medical
 13 Journal may pick up such a thing, but more likely The
 14 Lancet than the British Medical Journal.
 15 But really, you know, the best articles and the
 16 best information always came from the New England
 17 Journal of Medicine. I think that anybody practising
 18 any kind of medicine is well advised to read the
 19 New England Journal because it always contains the
 20 material which tells you what's really happening and
 21 has an enormous reputation for authoritative view on
 22 the current medical practice and the way medicine is
 23 going.
 24 So I think that, whilst UKHCDO might be expected
 25 to disseminate this kind of information, they probably

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1 the page with the passage beginning "Although type
 2 non-A, non-B":
 3 "Although type non-A, non-B hepatitis is
 4 associated with less severe acute illness than type B
 5 disease, as judged by frequency of jaundice and
 6 magnitude of SGPT elevations, the long-term prognosis
 7 for the two diseases may be similar. Thus, elevation
 8 of transaminase values persisting for six or more
 9 months has been observed more frequently following
 10 non-A, non-B disease and following type B hepatitis.
 11 Others have reported similar results. Transaminase
 12 elevations had been documented for several years in
 13 some patients. Three such patients at the NIH
 14 underwent liver biopsy. Two had histopathologic
 15 changes in the liver compatible with chronic active
 16 hepatitis, and the other was diagnosed as having
 17 chronic persistent hepatitis. Thus, chronic non-A,
 18 non-B hepatitis is not necessarily a benign infection
 19 and may be the cause of a significant proportion of
 20 chronic hepatitis not identifiable as type B disease."
 21 So we can see there, Dr Colvin, in this
 22 publication the warning, if I can put it that way, or
 23 observation that chronic non-A, non-B may have similar
 24 long-term consequences may not be a -- to hepatitis B
 25 may not be a benign infection.

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1 would over a period of time. I think that the best
 2 way to keep up is the New England Journal.
 3 **Q.** So for a haemophilia clinician such as yourself, not
 4 a liver specialist, your expectation at the time might
 5 have been that these kind of developments would be
 6 being picked up, say, by the Hepatitis Working Party
 7 of UKHCDO?
 8 **A.** Yes, I think so.
 9 **Q.** That would be a means of disseminating it more widely?
 10 **A.** Absolutely. Yes, of course. I agree.
 11 **Q.** Then if we just look at a couple of further articles
 12 before we turn to one which I'm fairly confident you
 13 will have seen.
 14 NHBT0000092_002, please, Henry. This is 1977.
 15 It's a publication, Vox Sang. Is that something that
 16 you would have seen?
 17 **A.** I didn't see Vox Sanguinis, no. Not on a regular
 18 basis.
 19 **Q.** We can see, again, it's Harvey Alter speaking or
 20 writing. This appears to be a text of something
 21 delivered as part of an international forum. "How
 22 frequent is post-transfusion hepatitis after the
 23 introduction of third generation donor screening for
 24 hepatitis B? What is its probable nature?"
 25 If we just go to the second page, Henry, really

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1 on a theme with what we've looked at so far. Last
2 paragraph on that second page, please, Henry. Further
3 down. No, that's not it. Could we go further down,
4 please. Sorry, Henry, to the next page. Do you have
5 a further page? There should be. Thank you.

6 So we look at the last paragraph:

7 "Although non-A, non-B hepatitis is, on the
8 average, less acutely severe than type B hepatitis, it
9 can cause severe acute disease, and more disturbing,
10 it appears to have considerable propensity to progress
11 to chronic hepatitis. The major thrust of
12 post-transfusion hepatitis research must now be
13 directed at developing detection methods for the
14 non-A, non-B agents, or developing some reliable
15 method of viral inactivation or removal which would be
16 independent of testing."

17 So, again, there appears to have been
18 a recognition here in 1977 of the potential for
19 progression to chronic hepatitis.

20 Again, you would expect, as a haemophilia
21 clinician, to glean that either from the more general
22 medical journals or through UKHCDO?

23 **A.** Well, yes.

24 **Q.** The final of these three documents, Dr Colvin, is
25 another 1977 publication.

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1 I think I would take the point of view that there were
2 similarities between hepatitis B and this entity, but
3 I wouldn't necessarily want to compare them in quite
4 that way, perhaps at intellectual level that there was
5 no evidence that this was hepatitis B and, therefore,
6 one would expect it to have some different
7 characteristics. I completely accept that some of the
8 characteristics were the same, but I wouldn't
9 necessarily assume that because there were
10 similarities that they were going to behave in the
11 same way. But I think one should be aware that it
12 might do.

13 **Q.** Yes, and I think in fairness to this paper, it's based
14 upon specific studies. I'm conscious they're not
15 studies you read at the time. So I think the first
16 point here may be more than an assumption by this
17 stage but based upon studies.

18 The second point then is:

19 "Second, non-A, non-B hepatitis appears to be
20 spread predominantly by the parenteral route."

21 Then most of the cases described an association
22 with transfusion, intravenous drug use, or serum
23 inoculation. That was, I think, was well understood?

24 **A.** I think that's a key point, really, that it's

25 a parenteral spread; that is, it's not spread by

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1 Henry, it's RLIT0000228.

2 So this is a publication in 1977 in the Annals
3 of Internal Medicine. Would that be something you
4 would expect to read?

5 **A.** I'm afraid not.

6 **Q.** We can see it's authored by Hoofnagle and an array of
7 others.

8 If we go, Henry, to page 6, please, right-hand
9 column. There's a paragraph beginning:

10 "Several clinical and epidemiologic features of
11 non-A, non-B hepatitis have become clear from studies
12 such as the present one."

13 I just wanted to go through the four features
14 and see the extent to which they reflected your
15 understanding, Dr Colvin, in the late '70s:

16 "So, first, non-A, non-B hepatitis closely
17 resembles type B hepatitis. The incubation period,
18 the clinical symptoms and signs, and the potential for
19 chronicity appear to be similar to type B hepatitis.
20 Undoubtedly what was once referred to as serum
21 hepatitis included both type B and non-A, non-B
22 hepatitis."

23 Would you say that was generally understood in
24 the late '70s by you and your colleagues?

25 **A.** I'm not sure I would quite take that point of view.

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1 mouth. So in that sense, of course, it's very similar
2 to serum hepatitis. That's the way it's spread.

3 **Q.** Then the third point is:

4 "Non-A, non-B hepatitis appears to be associated
5 with a chronic carrier state and chronic liver
6 disease. In this study, sera taken from
7 HBsAg-negative donors 149 to 385 days after an
8 implicated transfusion were found to be infectious.
9 These implicated blood donors were, for the most part,
10 asymptomatic, although liver function tests and liver
11 biopsy examinations frequently showed evidence of
12 underlying chronic hepatitis."

13 So, again, thinking of your state of knowledge
14 of what you would have expected you and your
15 colleagues to know in the late 1970s, is it fair to
16 say that you would, by this time, have been aware that
17 there may be an association between non-A, non-B
18 hepatitis and chronic liver disease?

19 **A.** I think that's fair.

20 **Q.** Then the fourth point:

21 "Non-A, non-B hepatitis appears to be common."

22 That, I think, was also increasingly or commonly
23 understood?

24 **A.** I think we didn't really know that until there were
25 studies of hepatitis from particularly cardiothoracic

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1 surgery from the blood transfusion risks in
2 cardiothoracic surgery. Then it became apparent that
3 the prevalence in the United Kingdom community might
4 be as high as 8.3 per cent. So I think that, in those
5 days, we didn't expect that hepatitis C would be so
6 common and prevalent in the United Kingdom community.

7 Of course, worldwide, there are huge differences
8 in the prevalence of hepatitis C. I think perhaps the
9 most prevalent area is -- perhaps Egypt is one of the
10 countries that's very prevalent. But I think we were
11 a bit surprised that it was as prevalent as it is.

12 **Q.** So if I understand your answer correctly, again,
13 looking at it in the late 1970s, you weren't
14 necessarily aware of its prevalence amongst the wider
15 population --

16 **A.** Yes.

17 **Q.** -- which would include the donor population --

18 **A.** Yes.

19 **Q.** -- but it was, I think, widely understood to be
20 a common consequence of blood transfusion and use of
21 blood products?

22 **A.** Exactly.

23 **Q.** Then if we can look next at the publication by
24 Professor Preston in 1978 in The Lancet. It's
25 PRSE0003622, please, Henry. We can see it's published

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1 importance of these abnormalities, percutaneous liver
2 biopsy was carried out on eight symptom-free patients
3 under Factor VIII cover. A wide spectrum of chronic
4 liver disease was demonstrated, including chronic
5 aggressive hepatitis and cirrhosis. The liver
6 pathology bore no relation to clinical history or to
7 biochemical findings. Hepatitis B virus markers were
8 common, but evidence suggests that this is not the
9 only factor contributing to the development of liver
10 disease. The high incidence of chronic liver disease
11 seems to be a recent development and is probably
12 related to factor concentrate replacement therapy."

13 So I think there are a number of things one can
14 draw from that summary.

15 **A.** Yes.

16 **Q.** First of all, this is work being undertaken by
17 haemophilia clinicians based upon studies on
18 haemophiliacs?

19 **A.** Yes.

20 **Q.** Including by biopsy, which as I think you already
21 pointed out was one of the few if not only methods
22 available to actually examine the liver at the time,
23 and it showed a wide spectrum of disease in a high
24 number of the patients examined, including cirrhosis.

25 Then what was your understanding or what would

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1 in The Lancet September 1978. "Percutaneous liver
2 biopsy and chronic liver disease in haemophiliacs."

3 You would expect to have read this?

4 **A.** Certainly.

5 **Q.** Do you remember reading it?

6 **A.** Oh, yes.

7 **Q.** So we can see it's authored by a number of clinicians
8 I think most, if not all, of whom were haemophilia
9 clinicians?

10 **A.** Well, Dr Underwood is a histopathologist. He
11 was Professor of Pathology and became president of the
12 Royal College of Pathologists.

13 **Q.** Professor Preston who we'll be hearing from --
14 obviously, a haemophilia clinician; likewise
15 Dr Mitchell who we'll be hearing from, and I think
16 Dr or Professor Blackburn was also a haemophilia
17 clinician.

18 **A.** He was certainly -- he was one of the early members of
19 the reference committees or the Reference Committee.

20 **Q.** Then we can see, if we pick it up, first of all, in
21 the summary:

22 "Systematic screening of 47 haemophiliacs in
23 Sheffield revealed abnormal liver function tests in
24 36 -- 77 per cent -- with a tendency for
25 these abnormalities to persist. To assess the

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1 have been your understanding of the sentence:

2 "The liver pathology bore no relation to
3 clinical history or to biochemical findings."

4 **A.** I think I already indicated that really in my answers
5 so far -- was that many of the patients had no
6 symptoms, and that didn't mean that there wasn't
7 development of liver disease. I think it's important
8 to understand that in many medical conditions there's
9 a reserve, if you like, of function, and you don't get
10 ill with liver disease until your liver really is in
11 a very poor state. Similarly, in haemophilia, if you
12 have a level of 5 per cent Factor VIII, you can get on
13 pretty well in your life, and only if you have
14 a serious problem do you get abnormal bleeding. So
15 there's a lot of reserve in biological systems, and
16 this is a good example where you can be potentially
17 unwell for many years without being actually unwell.

18 Of course, it is the case that we now know that
19 many people with hepatitis C suffer from fatigue
20 syndrome. I don't think that was an issue in the
21 '70s. Nobody somehow perhaps noticed. But I think
22 the main symptom of hepatitis C, or non-A, non-B, we
23 now know is probably chronic fatigue.

24 **Q.** So would it be fair to say that this would suggest
25 that clinicians could no longer work on an assumption

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1 that the fact that a patient was not presenting with
 2 any overt or acute signs of hepatitis or appeared
 3 clinically well was not a reliable indicator that they
 4 weren't going to develop non-A, non-B hepatitis?
 5 **A.** That's true. I would like, if I may, if I'm allowed
 6 to do so --
 7 **Q.** Absolutely.
 8 **A.** -- to introduce another paper from 1982. Now, this is
 9 a paper from Pierre Mannucci and Colombo and Rizzetto
 10 in Blood. I can give you the reference.
 11 **Q.** I am not sure whether we have it available to screen,
 12 but if you --
 13 **A.** The reference is Blood, 1982, volume 60, and it begins
 14 at page 655, and it's entitled "Non-progressive course
 15 of non A, non-B chronic hepatitis in multi-transfused
 16 haemophiliacs".
 17 So, as I'm sure you're aware, Professor Mannucci
 18 is one of the most distinguished international figures
 19 in haemophilia care. What he and his colleagues did
 20 was look at eleven people with haemophilia and what
 21 they found -- I won't go into the detail because it's
 22 not appropriate, but what they found was that there
 23 was evidence of non-progression or even improvement in
 24 hepatitis condition, including on biopsy.
 25 So I suppose for those who wanted to believe

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1 **Q.** The bit I was going to show you, but I'll just read it
 2 out. It's in a discussion of chronic hepatitis, and
 3 Dr Craske reported a visit to the Department of
 4 Medicine at the University of North Carolina during
 5 a visit to the States, and he says:
 6 "I had the opportunity to discuss the problem
 7 with Dr Roberts and his colleagues. They have carried
 8 out almost 100 liver biopsies on patients with
 9 chronically elevated serum transaminases in a
 10 collaborative survey, and nearly 50 per cent of these
 11 have histological changes compatible with cirrhosis,
 12 chronic active or chronic persistent hepatitis. These
 13 patients have had up to ten years of treatment with
 14 freeze-dried Factor VIII concentrates of different
 15 brands."
 16 Now I'm sorry we don't have that to actually
 17 show to you, Dr Colvin, and we can potentially rectify
 18 that later but that's a report of a much wider number
 19 of biopsies made by Dr Craske which he presented to
 20 a directors' meeting at which you were present in
 21 November 1978.
 22 Do you have any recollection of that
 23 information?
 24 **A.** No, I don't.
 25 **Q.** I appreciate I'm asking you about events over 40 years

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1 that it wasn't a problem, then they could try to rely
 2 on Mannucci's paper from '82. But the reality is that
 3 the Sheffield group, whether we think it was sensible
 4 to biopsy people with haemophilia or not -- and that's
 5 another issue -- the Sheffield group has very long
 6 history of achievement in identifying these problems.
 7 Of course, you will be hearing from Professor Hay
 8 later who is, I think, now the greatest expert in the
 9 United Kingdom on this issue, and it was in Sheffield
 10 that he began to really focus down on this problem.
 11 He's not on this paper, but it's Charlie Hay's work in
 12 hepatitis, initially in Sheffield and later wherever
 13 he went to practise, that really shone the main light
 14 on this issue.
 15 **Q.** If we just look at another document from 1978, Henry.
 16 It's CBLA0000831.
 17 That's towards the end of it. Do you have an
 18 earlier page, Henry? Is that the only other page you
 19 have? You don't have the whole document?
 20 We may come back to that. For present purposes,
 21 let me just tell you what it is rather than leave you
 22 and those listening hanging. It's a report from
 23 Dr Craske, and it's a report of the Haemophilia Centre
 24 Directors Hepatitis Working Party from 1978.
 25 **A.** Yes.

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1 ago. You would no doubt have read the report that was
 2 circulated in advance of the meeting?
 3 **A.** No doubt.
 4 **Q.** Do you think that's something that would at the time
 5 be likely to have struck you, that number of biopsies,
 6 with that level of --
 7 **A.** Well, I think I was struck by Professor Preston's
 8 information. I mean, I think I was -- I would have
 9 been struck by this as well. I mean, I think we
 10 appreciated that there was potentially a problem.
 11 I only introduced Professor Mannucci's paper to just
 12 give an explanation of why perhaps it was that some
 13 people didn't want to believe it.
 14 **Q.** Would you put yourself in that category in retrospect
 15 at the time of someone who didn't want to believe it?
 16 **A.** I don't think I would, but I would also put myself in
 17 the group of people who didn't know what it meant and
 18 didn't know what to do about it, because there was
 19 nothing to be done at the time.
 20 **Q.** We'll come on to that and what information could have
 21 been given to patients and so on in a few minutes.
 22 There are a couple of further documents, which
 23 are ones which I hope we will be able to bring up on
 24 screen, which are ones that you would have seen at the
 25 time.

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1 BART0002487, please.
 2 This is a letter dated 27 April 1979. It's from
 3 Dr Kernoff to you. We may come back to the letter
 4 when we look at your treatment policies in more
 5 detail, but if we just go, please, to the second page
 6 of the letter -- sorry, yes, I think it's the second
 7 page. Yes.

8 Under the heading, "Types of therapeutic
 9 material available", if you could just zoom in on that
 10 paragraph, please, Henry. As I say, we may come back
 11 to some of this, but if we go about halfway down that
 12 paragraph it says:

13 "Not only is commercial concentrate expensive,
 14 but there are both clinical and moral reasons for
 15 preferring the NHS material. The clinical reason is
 16 the growing awareness of the probability that
 17 commercial concentrates have a higher risk of
 18 transmitting non-A non-B hepatitis than NHS material.
 19 This is a serious disease with long-term consequences
 20 which, as far as is known, is at present much less
 21 common in the UK [et cetera]. We may, therefore, be
 22 introducing diseases which are not yet endemic in
 23 the UK."

24 So leaving aside that latter point, Dr Colvin,
 25 which I think you've already made, about not knowing

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1 Q. We'll see later that you met at this time on a regular
 2 basis and discussed a range of issues?

3 A. We did, yes.

4 Q. Then this is:

5 "Guidelines on the screening and investigation
 6 of hepatic disease in patient with congenital
 7 coagulation disorders."

8 Under the heading "Background" you say this:

9 "During the last few years it's become
 10 increasingly recognised that a high proportion
 11 (eg 50-75 per cent) of patients with haemophilia and
 12 Christmas disease having active replacement therapy
 13 have sustained abnormalities of plasma liver function
 14 tests. To elucidate the causes of these abnormalities
 15 several groups of investigators have recently carried
 16 out liver biopsies in selected patients."

17 That's a reference in the footnote to
 18 a publication by Spero and others in the New England
 19 Journal of Medicine, and then also to
 20 Professor Preston's that we've just looked at:

21 "A wide spectrum of histological abnormalities
 22 has been found (chronic active hepatitis, chronic
 23 persistent hepatitis, fatty infiltration, micronodular
 24 cirrhosis) but the type and severity of the
 25 abnormality correlates poorly with the results of

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1 the prevalence in the wider population, we can see
 2 here Dr Kernoff writing to you describing non-A, non-B
 3 hepatitis in 1979 as a serious disease with long-term
 4 consequences. So it's fair to say that would have
 5 represented your knowledge by that time in any event?

6 A. Of course, yes.

7 Q. Then if we could go, please, Henry, to BART0000684,
 8 please.

9 So this is -- if we just go to the third page,
 10 first of all, Henry -- we can see this is a document
 11 co-authored by Dr Kernoff and you on 16 May 1979.
 12 Then if we go back to the first page:

13 "NETR Association of Haematologists:
 14 Haemophilia Working Party."

15 Just before we look at the body of it, we
 16 mentioned this earlier and I was going to come back to
 17 what the Association was. Could you just tell us what
 18 was the North East Thames Region Association of
 19 Haematologists and what in particular was its
 20 Haemophilia Working Party?

21 A. So we had a group of consultants in the North East
 22 Thames region of the various different hospitals, and
 23 we just got together and the Association of
 24 Haematology itself nominated a working party of
 25 interested physicians.

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1 liver function tests."

2 So is that the mismatch that you described?

3 A. I think it is, yes.

4 Q. "The primary cause of liver disease in haemophiliacs
 5 is unknown, but thought to be most probably related to
 6 multiple transfusions. Infectious agents such as
 7 various hepatitis viruses have been particularly
 8 incriminated, but there are other possibilities such
 9 as immune complex disease and the effects of denatured
 10 proteins."

11 Then if we go on to look at the second
 12 paragraph, please:

13 "Of possible particular relevance to chronic
 14 liver disease in haemophiliacs is transmission by
 15 factor concentrates of the agents responsible for
 16 non-A non-B hepatitis. This group of disorders has
 17 recently come under close scrutiny because of the
 18 realisation that the majority of cases of
 19 post-transfusion hepatitis in some parts of the
 20 world -- in particular, the USA -- are not due to
 21 hepatitis A or B viruses or any other recognised
 22 infective agent. At present, there are no specific
 23 laboratory tests available for non-A non-B hepatitis
 24 and it seems likely that many cases are sub-clinical,
 25 or at least non-jaundiced. Recognition of the disease

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1 may therefore necessitate serial liver function tests
 2 being carried out after transfusion of possibly
 3 infectious material. For practical reasons, this
 4 could only be undertaken in patients at particularly
 5 high risk."

6 Just pausing there, what you seem to be saying
 7 there is that there may need to be serial, as in
 8 repeated, on an ongoing basis, liver function tests.

9 Why is it said there that for practical reasons
 10 that could only be undertaken in patients at
 11 particularly high risk?

12 **A.** Well, I think that's quite a difficult question to
 13 answer.

14 "Recognition of the disease may therefore
 15 necessitate serial liver function tests ..."

16 That makes sense. But liver function tests
 17 aren't difficult to perform. They are easy to perform
 18 and so, if it means that we should keep an eye on the
 19 liver function tests of people with haemophilia, then
 20 I don't think that that particularly relates to people
 21 at particularly high risk. So I find that quite
 22 difficult to understand.

23 **Q.** Okay. You share my confusion then, Dr Colvin. I was
 24 unclear as to who was this cohort of patients at
 25 particularly high risk.

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1 concentrates pose a greater risk than NHS material is
 2 uncertain. It is known that both commercial and NHS
 3 factor VIII and factor IX concentrates may transmit
 4 the disease."

5 So it would appear by this time, middle of 1979,
 6 you and Dr Kernoff understand that non-A, non-B can be
 7 transmitted both by commercial and by NHS?

8 **A.** Indeed. But you can also see, I think, in these
 9 sentences a degree of confusion and, indeed,
 10 inaccuracy, as we now know. I mean, I'm sure when we
 11 wrote these words we meant them and we believed that
 12 they made sense, but now we look back we can say,
 13 well, some of this isn't actually quite right.

14 **Q.** And, as it were, for the record, can we just identify
 15 what the bits that you would now say are incorrect
 16 are. The concept of immunity?

17 **A.** Well, I'm going to go back a bit further. I mean, one
 18 of the things that is clear, I think, is that either
 19 commercial or NHS concentrate will inevitably transmit
 20 non-A, non-B hepatitis C. That although serial liver
 21 function tests have got some value, there's no
 22 correlation necessarily with the progression of liver
 23 disease. It may be that we thought that people who
 24 had been given commercial concentrate had particularly
 25 high risk. That wasn't true. Maybe we wondered

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1 Would that have been potentially severe
 2 haemophiliacs?

3 **A.** I suspect it might have been.

4 **Q.** Is that the reference to "practical reasons" because
 5 they are the ones you are seeing on a regular basis
 6 and can follow up?

7 **A.** I think that is fair but the difficulty, of course, is
 8 that we now know that anybody who received the large
 9 pool concentrate, however often they received it,
 10 would have been infected with hepatitis C. So the
 11 other thing that might have been thought of in this
 12 context was maybe one should look at people carefully
 13 who had been treated with commercial concentrate
 14 rather than NHS concentrate. But the reality was, we
 15 now know, that whether it was commercial or NHS there
 16 was inevitable infection with HCV.

17 **Q.** This paper appears to recognise that broader risk. If
 18 we continue it says:

19 "Amongst haemophiliacs it seems likely that one
 20 risk factor is previously infrequent transfusions,
 21 since the patient will have been less likely to
 22 develop immunity to the disease. Another is probably
 23 a change in usual therapy from cryoprecipitate to
 24 concentrate, and perhaps a change from one type of
 25 concentrate to another. Whether commercial

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1 whether the subtype of hepatitis C, as it then became,
 2 transmitted in the United States was different from
 3 that in the United Kingdom. That may be true. Then
 4 we would have to ask ourselves whether that particular
 5 type of hepatitis C was more dangerous than the UK
 6 hepatitis C. That may or may not be true.

7 The idea was that if one had less frequent
 8 transfusion they would be less likely to develop
 9 immunity to the disease. Well, actually, I don't
 10 think it's got anything to do with immunity to the
 11 disease really. I mean, 10 per cent of people with
 12 hepatitis C do become immune and don't get into
 13 trouble with the liver. The other 90 per cent of
 14 course do and I don't think that's got anything to do
 15 with the frequency or infrequency of transfusion.

16 Maybe a change in usual therapy from
 17 cryoprecipitate to concentrates might be important.
 18 Yes, it is. Maybe a change from one type of
 19 concentrate to another might be important. No, it
 20 isn't and, no, commercial concentrates don't pose
 21 a greater risk than NHS material.

22 So I can now pick all sorts of holes in my words
 23 of years ago.

24 **Q.** Then if we go to the next paragraph, we can see you
 25 say this:

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1 "Despite the generally mild nature of acute
2 non-A non-B hepatitis it seems very possible that
3 there may be serious long-term sequelae and the acute
4 disease may sometimes be fatal. It is particularly
5 for these reasons that closer monitoring of patients
6 than has hitherto been the case as is now be,
7 advocated."

8 **A.** Yes, very fair.

9 **Q.** If we now go back to the main paper, please, Henry, we
10 see you go on to discuss the ethical problem of liver
11 biopsy and record a difference of opinion within
12 UKHCDO.

13 If we go to the second page, please, Henry.

14 As I understand it, Dr Colvin, the course
15 adopted at The London Hospital was not to undertaken
16 liver biopsies at this time?

17 **A.** There were very good reasons for that. Whether they
18 were valid reasons, of course, is not for me to
19 determine, but the Royal Free had done a liver biopsy
20 in a patient, either before or after this, I'm not
21 absolutely certain, but this patient had become ill
22 and died, of bleeding.

23 **Q.** Yes.

24 **A.** The view at the Royal Free was that it was dangerous
25 to perform a biopsy on the liver in a person with

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1 always have been a thought that if one was giving
2 a very large amount of concentrate for an
3 investigation which put a patient at risk and cost
4 a lot of money, it might not be a good idea. But of
5 course other people take a different view.

6 **Q.** Then we can see that under the heading
7 "Recommendations for routine management", you and
8 Dr Kernoff set out an ongoing management process. You
9 say:

10 "The general purposes of these recommendations
11 are (a) to provide a database which will help us to
12 understand and possibly contain a problem which at
13 present is of unknown magnitude and (b) to more fully
14 evaluate individual patients in order to aid better
15 short and long-term management."

16 Then we can see the plan is, at A:

17 "All patients having replacement therapy at
18 least once in any 6-month period should have plasma
19 liver function tests [et cetera] checked at least once
20 very 6 months."

21 Then B goes to set out where the liver function
22 test is found to be elevated, that the test will be
23 repeated on a monthly basis, and if this happens on
24 more than two occasions the patient will be referred
25 for further assessment.

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1 haemophilia.

2 Now, this reflects an interesting aspect of
3 medical practice in general, and that is if you get
4 your fingers burnt once, you are very reluctant to
5 have your fingers burnt again, even though, in the
6 overall scheme of things, this procedure might be
7 safe. Because of course the people at Sheffield
8 thought it was safe and the people in Italy thought it
9 was safe.

10 I was, as I explain, very much somebody who
11 believed in the importance of teamwork and I believed,
12 personally, and also in collaboration with the
13 Royal Free, that these biopsies weren't a good idea.
14 Now why might they not have been a good idea? Mainly
15 because once you've got the biopsy material, it wasn't
16 much use to you in making clinical decisions. Of
17 course you could say to people, well, you should try
18 to avoid excessive alcohol consumption, but you could
19 say that anyway. There wasn't any evidence of any
20 other particular benefit in knowing the answer since
21 there was no treatment.

22 Now, you might also ask me, "Well, were you
23 concerned, Dr Colvin, that it was expensive to do
24 biopsy the liver?" Because you need a lot of
25 concentrate to cover the procedure. Well, it would

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1 You say there:

2 "The Directors of the Centres at the Royal Free
3 and London Hospitals will be pleased to receive such
4 referrals and will be working in collaboration with
5 their local hepatologists."

6 At this point in time -- so in 1979 -- what
7 access for these purposes did you have to
8 hepatologists as opposed to the Royal Free?

9 **A.** Well, I would have had access to my own hepatologists,
10 and I detail some of them in my submission, and indeed
11 there are one or two others that I actually forgot.
12 But I don't think that we had any real evidence of
13 people who requiring referral at this time. This, of
14 course, is reflected from Professor Preston's work
15 where he showed that to get to the point where you
16 needed to have a hepatological opinion could take many
17 decades.

18 One of the things I think that this Inquiry was
19 puzzled about was my evidence I think to Archer, or it
20 may have been to Lindsay, that I saw very little
21 hepatological disease in my patients who were not HIV
22 positive. You sent me some information earlier,
23 I think yesterday, showing that I'd actually reported
24 that very clearly to Professor Preston.

25 So although I was willing to refer a patient to

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1 a hepatologist in 1979, I don't think I referred
 2 anybody to them.
 3 **Q.** Then we can see at C you say:
 4 "Particular importance is placed on a sudden
 5 change in LFTs, a marked change in LFTs and suspicion
 6 of acute hepatitis. In all these instances early
 7 referral should be considered."
 8 Does it follow from the answer that you have
 9 just given that you did not at this time or you do not
 10 recall seeing patients who had a sudden change in LFTs
 11 or a marked change or -- and suspicion of acute
 12 hepatitis?
 13 **A.** I think it's important to appreciate that the LFTs
 14 tended to come and go in a quite sort of unpredictable
 15 way. So the normal LFT AST is, say, sort of 30, and
 16 many of these patients sort of had values of, I don't
 17 know, 60, 80, 120, and fluctuate as the visits went
 18 on. Now if a patient suddenly had a value of 2,000,
 19 that would ring alarm bells. So you can see the scale
 20 of the potential changes because if you have a level
 21 of, say 2,000, it implies a lot of inflammation of the
 22 liver very suddenly. No, I didn't see that.
 23 **Q.** Then you talk at D about:
 24 "Patients considered to be at high risk of
 25 developing non-A non-B hepatitis (see above) should,

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1 patients, that we often tried to follow these patients
 2 carefully before the days of the anti-HCV test to see
 3 whether there really was any evidence that they had
 4 had liver inflammation or not. That became key in
 5 looking at the concentrates that were regarded as
 6 being safe, or at least safer, from a non-A, non-B
 7 hepatitis C viewpoint.
 8 **Q.** Leaving aside the issue of referral to the local
 9 hepatologist and leaving aside any question of liver
 10 biopsy, was this management programme that's set out
 11 here effectively the management programme that you
 12 implemented at this time at The London Hospital?
 13 **A.** I believe so. I mean, I saw my patients regularly.
 14 I believe it is the case that patients very rarely
 15 came to the hospital without seeing me personally.
 16 Even if my junior staff saw them, I would still go and
 17 see them to say hello and to make sure that their
 18 visit had been worthwhile, and I believe that I did
 19 monitor their liver function tests with care.
 20 **Q.** If we look at one further document from 1979, Henry,
 21 it's BART0000682, we can see this is an example of
 22 a set of minutes from the Haemophilia Working Party of
 23 the North East Thames Region Association of
 24 Haematologists. This is 12 December 1979, and you are
 25 there along with Dr Kernoff and others.

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1 where practicable, have blood samples for LFTs taken
 2 before and then at weekly intervals for 6 weeks after
 3 transfusion of the high risk material."
 4 Does that help in understanding who you were
 5 identifying as the high-risk patients?
 6 **A.** Well, I don't think it does very much. I think the
 7 main point is the attempts to identify people who were
 8 treated for the first time with a blood product as to
 9 whether they were getting into trouble. We now know,
 10 from 1985 anyway, onwards, that if you had a large
 11 pool concentrate you were bound to get hepatitis.
 12 I think that we began to look, and we'll perhaps
 13 come on to this, at all our patients who were being
 14 given treatment for the first time to look to see
 15 whether they had a normal liver function test or not,
 16 because -- because the liver function test
 17 abnormalities were both intermittent and remittent --
 18 by that I mean intermittent they were yes or no,
 19 remittent, coming and going, you could easily miss an
 20 episode of liver infection expression. So you could
 21 easily miss elevated LFTs if you didn't take samples
 22 very frequently.
 23 You will see in later discussions with the
 24 studies on people who had not been previously treated,
 25 either untreated patients or infrequently treated

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1 If we just go to the second page, please.
 2 Under the heading "Regional Study of
 3 post-treatment Hepatitis", it says:
 4 "Preliminary findings of the Regional Study of
 5 Hepatitis were discussed. Up to 70 per cent of severe
 6 Haemophiliacs have abnormal liver function tests at
 7 some time, with a wide spectrum of histological
 8 abnormalities.
 9 "The Non A/Non B types of hepatitis appear to be
 10 most common.
 11 "All types of Concentrate constitute a risk.
 12 There is, as yet, no evidence that imported
 13 Concentrates are more dangerous."
 14 What, if anything, can you recall about the
 15 regional study of hepatitis?
 16 **A.** I can recall nothing about this other than to say that
 17 I know, but I'm not sure of the dates, and you will
 18 have find out from Professor Lee, that she was
 19 recruited by Peter Kernoff to study hepatitis in this
 20 context.
 21 Now when she was actually doing her work I can't
 22 recall, but she will tell you I think anything that
 23 was to do with research in the field of non-A, non-B
 24 in the North East Thames region, but of course also
 25 included North West region, but I don't know the

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1 answer to that question. I'm surprised at this
 2 statement "with a wide spectrum of histological
 3 abnormalities", because I don't know where the
 4 histological abnormalities would be coming from,
 5 because I wasn't biopsying; I think neither was the
 6 Royal Free. So I think you need to ask Professor Lee
 7 that.

8 **Q.** Fine, I can do that.

9 Just still in March 1979, Dr Colvin, could we
 10 have BPLL0016050_003, please, Henry.

11 This is a report in The Lancet in March of 1979
 12 from, amongst others, Professor Zuckerman,
 13 "Transmission of non-A non-B hepatitis to chimpanzees
 14 by Factor IX concentrates after fatal complications in
 15 patients with chronic liver disease."

16 You would, I assume, have seen this at the time
 17 as it's a Lancet publication?

18 **A.** I must have done.

19 **Q.** We can see from the summary what the subject of the
 20 article was:

21 "6 cases of non-A non-B hepatitis which followed
 22 administration of four different batches of
 23 concentrates of coagulation factor IX and commercial
 24 and non-commercial sources are described. Of
 25 17 patients who received the concentrate on account of

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1 but I can certainly comment on it now if you would
 2 like me to do so.

3 **Q.** Yes, please.

4 **A.** So this paper is about people with chronic liver
 5 disease; it's not about people with haemophilia. The
 6 Factor IX concentrate was used to treat people who
 7 perhaps, when they are having a biopsy or something
 8 like that, I don't know exactly why it was used -- but
 9 we're not looking at people with haemophilia in this
 10 paper.

11 These physicians and pathologists are not
 12 haematologists. It's not a haemophilia paper. So
 13 I don't think we can necessarily extrapolate from this
 14 paper to haemophilia care, and I wouldn't support the
 15 last paragraph, in the sense that nobody in the
 16 haemophilia world, I don't think, thought that to
 17 limit commercial and non-commercial concentrates to
 18 life-threatening situations was remotely possible.

19 **Q.** We'll come on to that shortly because I want to ask
 20 you about your treatment policies.

21 Other than what you would have learnt from any
 22 discussions with Dr Kernoff and his colleagues at the
 23 Royal Free, and other than any analysis that may have
 24 been performed by the Hepatitis Working Party of the
 25 UKHCDO, are you aware of there having been at around

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1 chronic liver disease, 4 developed hepatitis, and in 3
 2 of these the illness proved fatal. The incubation
 3 periods ranged from 42 to 103 days (mean 65 days).
 4 3 chimpanzees were inoculated with concentrate from
 5 the same batch used on the above patients, a further
 6 commercial batch upon which no adverse reactions had
 7 been reported, and plasma from a known non-A non-B
 8 carrier. All developed hepatitis after 10 weeks'
 9 incubation."

10 Then if we go to the very end of the article
 11 please, Henry, so the last page.

12 If we look at the last paragraphs -- it's the
 13 left-hand side, please, Henry, left-hand column -- you
 14 can see in the last paragraph, the view of
 15 Professor Zuckerman and others:

16 "Until blood-donors can be screened for the
 17 non-A non-B hepatitis agent, it would seem wise to
 18 restrict the use of both commercial and non-commercial
 19 concentrates to life-threatening situations. In
 20 particular, their use in patients with chronic liver
 21 disease should be avoided, as the risk of a serious
 22 illness resulting appears to be increased."

23 Do you recall reading and considering that at
 24 the time, Dr Colvin?

25 **A.** I don't recall reading and considering it at the time

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1 this time, late 70s/early 80s, any form of systematic
 2 assessment by haemophilia clinicians of the risks and
 3 severity of non-A, non-B hepatitis?

4 **A.** Well, as far as the risk was concerned, it was being
 5 looked at by the Hepatitis Working Party, and
 6 eventually there were the publications from UKHCDO
 7 which showed the incidence and prevalence of
 8 hepatitis C.

9 So -- eventually, of course, there was
 10 Peter Kernoff's famous paper in 1985, when it became
 11 clear that all patients were infected. But there was
 12 another paper earlier than that, from Oxford, which
 13 showed very much the same thing. So there was
 14 activity going on to demonstrate the truth but it
 15 required, I guess, by then, quite a lot of
 16 co-ordination. We weren't doing any academic work
 17 ourselves at that time in the late -- which year are
 18 we in here?

19 **Q.** This is 1979.

20 **A.** So we weren't doing any academic work ourselves in
 21 1979 on this at The London.

22 **Q.** So you would, as I think you have already indicated in
 23 your answers, have been reliant in particular upon
 24 what UKHCDO and those involved in the Hepatitis
 25 Working Party were or were not doing?

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1 A. Yes.
 2 Q. And the advice that they were giving?
 3 A. Yes. The Fletcher paper, I think which is
 4 particularly important, which is part of your
 5 compendium.
 6 Q. Yes. I think you refer to that in your statement.
 7 A. Probably, yes.
 8 Q. Bearing in mind that by 1979 it was -- and I'm going
 9 to use your own words with Dr Kernoff's rather than
 10 any article you didn't read at the time -- it was
 11 recognised that non-A, non-B hepatitis could have
 12 serious long-term sequelae. Do you agree that that is
 13 information that should have been shared with patients
 14 at the time?
 15 A. Yes, and I think -- we did share with our patients the
 16 reality that they had normal liver function tests and
 17 that that could be important for the future, but
 18 I guess, in retrospect, we should have been, no doubt,
 19 more -- clearer about what we feared. But I think
 20 that in communicating with patients one perhaps
 21 doesn't always communicate one's greatest fears. This
 22 is a matter of communication and the importance of
 23 trying to get communication right, but I acknowledge
 24 that there may have been many occasions when we didn't
 25 get the communication as right as we should have done.

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1 Q. But does that mean you don't think you spelt that out
 2 to patients?
 3 A. I mean, it's 40 years ago.
 4 Q. I know.
 5 A. But I think it's possible that the patients didn't get
 6 the advice or the information that maybe they should
 7 have had. But I can't say more than that, really.
 8 Q. I may come back to that when we look at HIV again, the
 9 question of provision of information to patients.
 10 I want to turn to look at the policies in The
 11 London Hospital under your directorship in terms of
 12 the use of different products.
 13 First of all, I think your statement makes quite
 14 clear that once you became consultant in 1977 the
 15 decision as to what treatments to provide was
 16 a decision for you. There weren't others within the
 17 hospital who imposed any particular constraints upon
 18 you; is that correct?
 19 A. Yes, of course.
 20 Q. What role, as a matter of generality, again at this
 21 time, late 70s/early 80s, did the patients have in the
 22 choice of treatment?
 23 A. I think that we didn't give them that much choice
 24 because we or I had a clear view about what was the
 25 correct treatment. I can go into a lot more detail if

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1 Q. Without commenting on any individual patient, or
 2 indeed any particular patients that may have been
 3 patients of yours, a theme which has emerged from
 4 evidence received by the Inquiry on the whole has been
 5 patients saying that they were not aware at this time,
 6 late 70s/early 80s, of the risk of non-A,
 7 non-B hepatitis, and certainly there doesn't appear to
 8 be any guidance from UKHCDO saying, "Tell your
 9 patients".
 10 Doing the best you can, do you think you would
 11 have had any discussion about non-A, non-B hepatitis
 12 with your patients around this time?
 13 A. I probably wouldn't have necessarily called it non-A,
 14 non-B. I might have done. But I think I did monitor
 15 the liver function tests and we did discuss whether
 16 the liver function tests were normal or abnormal.
 17 Q. But bearing in mind you have already said that may not
 18 actually be the best indicator --
 19 A. No, of course not. I understand that.
 20 Q. Do you think you discussed with your patients the fact
 21 that the treatment they were receiving or may have
 22 been about to start receiving carried with it a risk
 23 of a hepatitis virus that wasn't hepatitis B and that
 24 that might cause long-term chronic liver problems?
 25 A. I think we could have done better.

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1 you want about why I chose particular treatments.
 2 Q. We will come on to that in just few minutes.
 3 So if we take it in stages, if we just deal with
 4 prophylaxis, first of all, because I think that
 5 there's probably very little to say about that, your
 6 statement says that prophylaxis wasn't fully
 7 implemented until the 1990s. Was there any
 8 prophylactic treatment at all in the late 70s, early
 9 80s?
 10 A. Not really. I think Mark Winter referred to this in
 11 his statement, perhaps in his interview.
 12 It was the case that if you had a patient with
 13 what is called a target joint, you might have a few
 14 days or weeks of attempted prophylaxis to sort of
 15 settle down a joint, but there really wasn't
 16 a concentrate for proper prophylaxis. I mean,
 17 Inga Marie Nilsson had thought of this years and years
 18 ago in Sweden, and I suppose we knew that it was
 19 a good idea to offer prophylaxis but there wasn't
 20 enough concentrate.
 21 Even when we get, of course, to 1988, when we're
 22 using heat-treated concentrates routinely, that's
 23 reduced the yield of the plasma source that is being
 24 employed. So there's a tremendous world shortage of
 25 Factor VIII in 1988, and I've referred to this I think

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1 in my paper, so that we didn't really start proper
 2 prophylaxis until the 1990s.
 3 What happened was even then we weren't using
 4 really good prophylaxis. What I think
 5 Inga Marie Nilsson was trying to propose was that the
 6 level of Factor VIII should always be kept above
 7 1 per cent, which is not very high, but actually we
 8 didn't achieve that. The result was a generation of
 9 young people with haemophilia who had been brought up
 10 in the 90s who had one or two target joints, pretty
 11 fit young people, but had one or two targets joints
 12 because they had been given prophylaxis that wouldn't
 13 really meet today's standards.
 14 **Q.** So let's come on then to home treatment which was
 15 a feature of The London Hospital's haemophilia centre
 16 policies at the time. We've seen the figures:
 17 a relatively small number in 1977, increasing over the
 18 following years. Can I ask, first of all, what were
 19 the categories of patients to whom home treatment was
 20 offered?
 21 **A.** Really people who were severely affected. There were
 22 one or two families where there was relatively mild or
 23 relatively severe haemophilia, with Factor VIII levels
 24 around sort of 1 or 2 per cent, who had significant
 25 repeated bleeding, and who were eventually selected or

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1 I wouldn't have expected to have been good at home
 2 therapy turned out to be quite brilliant.
 3 So it was really difficult to decide what
 4 families or which patients were actually the ones to
 5 give home therapy to when sometimes you had people who
 6 looked as though they were fine but were useless --
 7 perhaps that's not the right word to use -- sometimes
 8 you had people who you thought to be fine but actually
 9 weren't and sometimes you had people you thought
 10 wouldn't be able to cope but did. So it was quite
 11 a challenge.
 12 **Q.** So mostly those who were severe. Adults only or
 13 children as well?
 14 **A.** No, children -- children, if one possibly could.
 15 I mean, in fact, interestingly enough, this was
 16 where the domiciliary sister was so valuable. Because
 17 the domiciliary sister could go into the home and
 18 educate the families, and the children could surprise
 19 one very, very much. So you finish up with children,
 20 3 or 4 or 5, taking an active part in their own home
 21 therapy and the delivery of the concentrate, even
 22 performing venepunctures within the home. So that
 23 really the work of the domiciliary sister and the
 24 attempt to get people onto home therapy was very
 25 important.

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1 invited to perform treatment.
 2 The other big problem with deciding who was
 3 suitable for home treatment was also social
 4 circumstances. Now, as I'm sure you are aware,
 5 Whitechapel is one of the most deprived areas in the
 6 United Kingdom, with a huge immigrant community, many
 7 of whom speak no English, and so there was a challenge
 8 for me in deciding who was and wasn't suitable for
 9 home treatment within the severely affected group.
 10 Because if you're going to be on home treatment, you
 11 had to have a surface in your home, probably in the
 12 kitchen I suppose, where you could draw up and make
 13 the concentrates or the solution, and you had to
 14 record what you were doing, i.e. the actual treatment
 15 you were giving, and you had to be reasonably
 16 competent to give an intravenous injection and to
 17 understand when you would need to come to the
 18 hospital.
 19 Now, if you didn't have any of those
 20 characteristics, you might think, well, surely we had
 21 a surface. Well, I can tell you that they didn't, and
 22 they didn't always keep proper records and they didn't
 23 necessarily know how to give an injection. Then it
 24 was very difficult to deliver home therapy. But I was
 25 also very surprised to find that some of my patients

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1 Of course we've heard previously from other
 2 witnesses the dramatic effect of being on home
 3 therapy. Suddenly you could go to school. Suddenly
 4 you could go to work.
 5 I mean, I had three children, I think, who, as
 6 I became director, were at the Lord Mayor Treloar
 7 College, the college where there was the haemophilia
 8 centre for physically disabled children, and sadly all
 9 my patients who were there have died.
 10 But whilst that was an extraordinary service
 11 provided by the Lord Mayor Treloar, I know it had
 12 weaknesses that you may have wanted to identify, it
 13 was wonderful to have children who could live at home,
 14 in a way which had become almost impossible with
 15 severe haemophilia.
 16 Mark Winter made it very clear what a terrible
 17 disease haemophilia can be, and the provision of home
 18 therapy, of any kind, transformed people's lives.
 19 It's also important to appreciate you don't need
 20 to do very much to make a big difference. So if you
 21 look at the Indian experience, Bangalore, Srivastava
 22 reported not so very long ago that introducing
 23 a system of care, albeit with very low doses of
 24 Factor VIII, in India, could transform lives using
 25 doses that we would think were grossly inadequate.

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1 So there is a sense with haemophilia care, you
2 get a lot for your first few units. You don't get
3 much better from your last few units.

4 **Q.** In relation to home treatment, you began or the
5 programme had begun using cryoprecipitate?

6 **A.** Yes.

7 **Q.** I will come on later to the pros and cons of
8 cryoprecipitate, if I may, but then you moved on from
9 cryoprecipitate to Factor VIII concentrates.

10 **A.** Yes.

11 **Q.** As I understand your statement, your policy for home
12 treatment was to use NHS Factor VIII where possible?

13 **A.** If I could, yes.

14 **Q.** But sometimes it was not possible?

15 **A.** Yes.

16 **Q.** For supply reasons that we'll look at later.

17 **A.** Yes.

18 **Q.** And in those circumstances the family would have
19 commercial concentrates?

20 **A.** Obviously, I can't recall the detail but I think it's
21 almost inconceivable that I could have delivered
22 NHS concentrate to all my patients on the home
23 treatment for the whole of my career.

24 It's also important to appreciate -- and maybe
25 this is the right time to mention it -- that patients

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1 have this treatment if you do A, B and C, and if you
2 don't do A, B and C, you can't have the treatment. Of
3 course you can always come to the hospital to have the
4 treatment in the hospital, but it's not as good as the
5 home treatment."

6 So is there a sanction open to me, ethically if
7 you like, to withdraw home treatment if you won't
8 follow the rules?

9 I will leave that question open.

10 **Q.** Did the hospital also keep records of what particular
11 batches were being given to particular patients for
12 their home treatment therapy?

13 **A.** What happened was, we would record the home treatment
14 therapy that was sent out, and then the patients would
15 send back the information of what they'd used. But,
16 of course, the two weren't synchronous. So it was
17 actually very difficult in those days -- maybe it's
18 even difficult today -- to do a proper sort of stock
19 control of the treatment because it goes out and is
20 kept in the fridge for a month, and then you get the
21 results back one or two or three months later.
22 Particularly if you had a patient who wasn't on
23 a prophylactic regime, as they weren't to begin with,
24 depending on how often they bled as to how often they
25 -- they were meant to send the results in every month

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1 used to come in and out of my care, so that -- for
2 instance, let's take the Treloar boys. They were
3 partly in my care and partly not in my care.
4 I couldn't control what happened to them when they
5 were at the Lord Mayor Treloar College. I also had
6 children who came under my care who had been at
7 another centre whose treatment might or might not have
8 been the same.

9 Of course now, in 2020, I can't recall exactly
10 who got what in a way that I can reliably give you on
11 both.

12 **Q.** In terms of home treatment, were patients required to
13 keep their own records of the home treatment including
14 batch numbers?

15 **A.** Yes, they were. It was a requirement.

16 Now, of course, this is very difficult because
17 my view was that if you were going to have this very
18 important and, for that matter, expensive treatment,
19 you had to abide by the rules of the process. On the
20 other hand, I've also pointed out to you, which I'm
21 sure you will understand, that many of my patients
22 were from very deprived communities and might have
23 great difficulty in recording everything. They might
24 not even be literate.

25 So there's a challenge in saying, "You can only

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1 but, you know, stock control got dissociated.

2 **Q.** So patients were expected on a monthly basis to, what,
3 post the results to the hospital?

4 **A.** Yes, and we used to chase them.

5 **Q.** Did the development of the home treatment programme at
6 The London have an impact on the adequacy of supply of
7 NHS concentrate? Was more concentrate being used on
8 home treatment than it would have been if patients
9 were receiving their treatment in hospital?

10 **A.** Yes. I think that the truth is that the amount of
11 concentrate used in home treatment was probably --
12 I think it was probably going to be a bit more than
13 would have been used in the hospital because patients
14 had complete control over how much they gave, even
15 though they were given advice as to what dose they
16 should give. They could give it immediately, and they
17 could give it repeatedly if they wanted to. And
18 certainly, not my job and not my -- I couldn't say you
19 could only have one dose rather than three. If they
20 were in hospital, I would say how much they were going
21 to be given, and I would repeat it if I thought it was
22 necessary. But, obviously, in a home treatment
23 programme, you give people a lot of latitude, and that
24 would tend to, I think, increase the dose and
25 frequency, and of course, it would also increase their

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1 health.

2 I would also say if you are going out to play,

3 maybe -- and you've got a dodgy joint, maybe you

4 should have a dose before you go. So there was this

5 sort of rather limited sort of idea of sort of

6 occasional prophylaxis, not a full prophylactic

7 programme. But we tried to be sympathetic to the

8 patient's needs in home treatment.

9 **Q.** Then in terms of hospital administration of treatment,

10 so patients who were not on home treatment who were

11 getting their treatment through their visits to the

12 centre, is this right that they would receive, if they

13 were severe haemophiliacs or receiving concentrates,

14 predominantly commercial concentrates?

15 **A.** I don't think necessarily -- I think that the -- first

16 of all, the very small children I tried to keep on

17 cryoprecipitate right up to 1985. Now, it's very

18 important that the Inquiry doesn't think that I saved

19 the lives of all my children. I absolutely did not.

20 The idea was that if a child came into a hospital and

21 was an in-patient, then they would be given

22 cryoprecipitate -- particularly very small children.

23 The reason for that was that you don't need much

24 Factor VIII to treat a simple bleed in a child. But

25 if you have a child who's got a serious bleed or has

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1 Just dealing again with, in general, the

2 products that were used during this time. My

3 questions are focused I think largely on patients with

4 severe haemophilia.

5 **A.** Yes.

6 **Q.** In relation to patients with haemophilia A who were

7 mild haemophiliacs, what was the main or first-line

8 treatment for them?

9 **A.** Well, after '77 when Professor Mannucci produced his

10 paper on DDAVP, then for really simple things, then

11 one could rely on DDAVP and tranexamic acid and I used

12 it. I think you can see that from the returns that

13 you sent me a day or two ago, that I was using DDAVP

14 and tranexamics on a regular basis. But DDAVP has

15 many, many disadvantages which we can go into,

16 perhaps, and should do. It's not a satisfactory

17 treatment really for bleeding or for any important

18 kind of surgery and so, in those circumstances,

19 I think then we would probably be using concentrates.

20 **Q.** So for a mild haemophiliac who was having any kind of

21 surgery other than dental surgery?

22 **A.** Well, of course, even dental surgery is not that easy

23 because if you are having, say, a canine tooth

24 removed, it's right at the front of your mouth, and if

25 you use DDAVP and tranexamic acid for a patient with

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1 got a really bad knee joint, then it all becomes

2 unrealistic, and so a patient would then be treated

3 with a concentrate and, particularly if they were at

4 home, they would be treated with concentrate.

5 So the number of my children, small children,

6 who actually escaped any infection was actually

7 I think quite small, but there were one or two. As

8 far as whether they would receive commercial

9 concentrate, I think we tried to give NHS concentrate

10 if we could, and then for what I've described as

11 disasters or emergencies or perhaps inhibitor patients

12 or serious surgery, then that's when, probably, one

13 would have to use commercial concentrates. But it's

14 very difficult to have a precise rule about who gets

15 what on a particular day and, of course, it eventually

16 became very important.

17 But it's important for you to understand that

18 I was an enthusiast for the NHS. Now, not all my

19 colleagues were, and we tried to use NHS concentrates

20 whenever we could, and we all regarded the commercial

21 concentrates, which we did use, as a top-up for what

22 wasn't available, and I believed in the NHS.

23 **Q.** We'll come and look at some availability issues when

24 we look at some more of the North East Thames region

25 minutes.

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1 a level of, say, 5 or 10 per cent, then you will get

2 about threefold increase. From, say, 10 per cent you

3 get to 30 per cent. You're using tranexamic acid.

4 You might have just about two or three maximum doses

5 of DDAVP available to you because of what's called

6 tachyphylaxis, the level of response going off as you

7 go on giving 12-hourly DDAVP because you're using up

8 the limited resources of the body by using DDAVP.

9 DDAVP releases what you've got into the circulation,

10 and if you haven't got very much, you don't get much

11 out. Once you've released it, it doesn't reproduce

12 itself rapidly, and so you quickly run out of road

13 with DDAVP.

14 So if you are doing a simple dental

15 extraction -- I don't include, by the way, wisdom

16 teeth extraction in this -- if you have a simple

17 dental extraction, you can give DDAVP and tranexamic

18 acid, give two or three doses at 12-hourly intervals,

19 and then if the patient bleeds, you have a resource --

20 recourse, I should say -- to using a concentrate. But

21 if you are dealing with an operation of any

22 significance, or if you are dealing with a concealed

23 problem like a bleed into a muscle, then if it gets

24 worse when you're giving DDAVP, you've actually lost

25 a lot of ground.

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1 So I was never enthusiastic about using DDAVP
2 either for any kind of concealed bleed or for any kind
3 of serious surgery because I knew, from bitter
4 experience I may say, that if you operate on somebody,
5 or you give treatment for a muscle bleed, say, or
6 a joint bleed and you -- it doesn't work, you go down
7 a large snake, if you will forgive the expression --
8 in terms of snakes and ladders -- you go down a large
9 snake and finish up with a patient with a really awful
10 haematoma or a really serious bleed which then gets
11 infected, and you've lost all that ground you could
12 have gained by giving concentrate in the first place.

13 So, yes, DDAVP is wonderful. It's very useful
14 for very mild haemophilia and mild von Willebrand's
15 disease if you are not dealing with serious surgery or
16 a concealed bleed, or if you've got a small open bleed
17 that you can look at and deal with quickly, you know
18 you won't lose ground, it's got a lot of value.

19 **Q.** We may come back to DDAVP and an article in relation
20 to that after lunch. But just sticking with an
21 overview of the products you used, moderate
22 haemophiliacs, what was typically the way in which
23 they would be treated? Was there a typical way in
24 which they were treated?

25 **A.** Again, it depends a bit on the circumstances, but if

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1 Willebrand's disease -- I won't bore you with the
2 detail -- is not necessarily ideally treated in that
3 way with DDAVP. There's this thing called type 3 von
4 Willebrand's disease which mostly is due to
5 consanguinity in patients where their parents look
6 normal but have a genetic defect which is multiplied
7 by their consanguinity. Then you get very severe
8 bleeding tendency which is completely unsuitable for
9 DDAVP because it doesn't work.

10 Being in the East End, we had a large
11 consanguineous problem because of the immigrant
12 community, so I looked after I think
13 a disproportionate number of patients with type 3 von
14 Willebrand's disease who were not suitable for
15 anything other than replacement therapy.

16 **Q.** Then patients with haemophilia A with inhibitors, what
17 would the normal treatment have been for them?

18 **A.** So there is no normal treatment for people with
19 inhibitors to Factor VIII. They very rarely get
20 Factor IX inhibitors. I had one patient with a Factor
21 IX inhibitor who very sadly had a cerebral haemorrhage
22 and died early on in my career, so I can't really say
23 much, if anything, about treatment of haemophilia B
24 inhibitors.

25 But, as you will be aware, about 20 per cent of

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1 we're talking moderate haemophilia, we're talking
2 about one or two per cent Factor VIII which means
3 response to DDAVP is very inadequate, and I wouldn't
4 use it.

5 Then you've got a choice of either
6 cryoprecipitate or concentrate, and I think that we
7 would choose concentrate for patients who have got
8 significant bleeding or significant surgery who have
9 got moderate haemophilia. That really is the
10 treatment of choice. You may want to come on later to
11 what I tried to do in '84 with a few patients with
12 cryoprecipitate, and I'm happy to discuss that at some
13 point.

14 **Q.** Well, I will come on to that --

15 **A.** But the answer to your question, I think, is that if
16 you've got moderate haemophilia and you need
17 treatment, then you need concentrate.

18 **Q.** Then von Willebrand's disease would ordinarily be
19 treated with DDAVP?

20 **A.** Well, that's complicated as well because there are
21 various different types of von Willebrand's disease.
22 The majority are type 1, and they can be treated with
23 DDAVP and tranexamic acid -- except perhaps for major
24 surgery -- and even minor surgery or moderate surgery
25 may require factor treatment. But type 2 von

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1 people with severe haemophilia who, treated with
2 Factor VIII concentrate, develop an inhibitor.
3 Sometimes that inhibitor is weak, and sometimes it's
4 very strong, and you can't be sure whether it's going
5 to get very strong or not. If it's very weak, you may
6 be able to use Factor VIII to treat it. It probably
7 won't work. If it's fairly weak -- in the '80s, we
8 used to give porcine Factor VIII, and the reason that
9 worked was that the antibodies to human Factor VIII is
10 less potent -- I'm sorry, the antibody to human
11 Factor VIII is more potent against human Factor VIII
12 than it is against porcine Factor VIII because the
13 porcine factor has a slightly different configuration.
14 So what tended to happen was that the antibody to
15 human Factor VIII was perhaps ten times less active
16 against porcine Factor VIII. So if you had a low-ish
17 level of antibody to porcine -- if you had a low-ish
18 level of antibody to human Factor VIII, then the
19 porcine Factor VIII might actually work rather well.

20 **Q.** That would have been the Speywood porcine --

21 **A.** That would be the Speywood. That had a lot of
22 advantages. Unfortunately, it also tended to cause
23 very bad allergic reactions and also cause low
24 platelet counts. We used it, and it had a lot of
25 value before it was eventually withdrawn.

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1 Q. What else would be used for patients with inhibitors?
 2 A. The next thing you could use, if your human
 3 Factor VIII didn't work and your porcine Factor VIII
 4 didn't work (and you could probably predict from the
 5 potency of the antibody against human Factor VIII
 6 whether the porcine would work or not), then your next
 7 option was, in those days, FEIBA; that's Factor VIII
 8 Inhibitor Bypassing Activity. That was an activated
 9 Factor IX product produced in the United States.

10 So what was done -- oh, I don't know the exact
 11 technique, and it's probably a secret for all I know,
 12 and I think it was a secret -- they would take
 13 a Factor IX concentrate, and they would modify it in
 14 activating it in some way. What you were trying to do
 15 was to bypass the need for Factor VIII in the clotting
 16 mechanism, and it kind of worked.

17 Sometimes people used ordinary Factor IX for
 18 this purpose. So the ordinary Factor IX produced
 19 in -- either by, usually by BPL -- would have been
 20 activated a bit during its processing, and so it
 21 probably had some activated factor with it.

22 For instance, the ordinary Factor IX caused
 23 a lot of thromboembolism -- that is thrombosis -- in
 24 patients having orthopaedic surgery. If you had
 25 a patient with Christmas disease and you gave them

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1 what to do about people with inhibitors. If the human
 2 concentrate didn't work and if the porcine concentrate
 3 didn't work, then you were stuck with either FEIBA or
 4 later recombinant VIIa.

5 And it was always firefighting. It was
 6 extremely difficult and dangerous to initiate
 7 therapy -- for instance, surgery -- in somebody with
 8 an inhibitor and, of all the things I experienced in
 9 my whole career, the thing that kept me awake most at
 10 night was what to do about people with an inhibitor.

11 Q. Then Factor IX for patients with haemophilia B?
 12 A. We used NHS Factor IX and, as I've explained to you,
 13 that NHS Factor IX was an intermediate purity
 14 product -- it wasn't a particularly pure product to
 15 begin with -- and it was very successful in managing
 16 Christmas disease, except insofar as the tendency to
 17 produce thrombosis in people having surgery,
 18 particularly orthopaedic surgery.

19 Of course, we were self-sufficient. Because
 20 Christmas disease is a sixth as common as
 21 haemophilia A, and because the half-life of Factor IX
 22 within the circulation is twice or three times the
 23 duration (so it lasted in the body longer), we were
 24 perfectly self-sufficient in Factor IX from the
 25 beginning.

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1 Factor IX, ordinary British Factor IX, many of them,
 2 particularly with orthopaedic surgery, would develop a
 3 thrombosis (either a thrombose arm or a pulmonary
 4 embolism) and it could be life-threatening. But these
 5 Factor IX concentrates, the less pure ones that we
 6 used to use in this time, had the potential for
 7 causing difficulty with thrombosis, but that could be
 8 used to benefit for patients with haemophilia A with
 9 an inhibitor, but the FEIBA was more activated than
 10 the ordinary British Factor IX.

11 Q. When did the FEIBA become introduced?

12 A. In the early '70s. And, of course, it would have also
 13 had just the same risk of transmission of disease.

14 Q. Then last category for present purposes, haemophilia
 15 B. Were they invariably treated with NHS Factor IX
 16 concentrates?

17 A. Can I just complete the discussion on inhibitors?

18 Q. Yes, of course.

19 A. Because in the '80s, recombinant VIIa became available
 20 for the treatment of inhibitors, but it was extremely
 21 expensive. And the difficulty was that neither FEIBA
 22 nor recombinant VIIa which was, of course, not a blood
 23 product as such -- neither FEIBA nor recombinant VIIa
 24 could reliably stop the bleeding. So Haemophilia
 25 Centre Directors were in a terrible bind really as to

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1 MS RICHARDS: Sir, I note the time, and I'm going to move
 2 on to look at some documents that deal with issues of
 3 supply and shortfall in supply in the local area, so
 4 perhaps we could do that after lunch.

5 SIR BRIAN LANGSTAFF: Yes. Well, let's take a break then
 6 until 2.05.

7 (1.11 pm)

(Luncheon Adjournment)

9 (2.04 pm)

10 MS RICHARDS: Dr Colvin, I want to look with you at some
 11 minutes of the North East Thames Region Association
 12 Haemophilia Working Party from the late '70s/early
 13 '80s to look at some of the discussions that were
 14 ongoing about supplies of products.

15 Henry, could we have BART0000687, please. So we
 16 pick this up in February of 1978. We can see it's the
 17 Association of Haematologists (NETR), North East
 18 Thames Region Working Party in Haemophilia, and you're
 19 listed as present, along with the late Dr Dormandy,
 20 Professor Hardisty, Dr Tuddenham and others.

21 Can I just ask, who was Dr Carmichael?

22 A. Donald Carmichael was a consultant haematologist
 23 I think at Harlow but I'm not quite sure, and he was
 24 a sort of well-known figure in haematology in the
 25 region.

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1 Q. Thank you. Then if we look down the bottom of the
 2 page, we can see under the heading "Supply of
 3 Factor VIII concentrate", Dr WJ Jenkins -- now, that's
 4 not Professor Jenkins?
 5 A. No. John Jenkins was the director of the Blood
 6 Transfusion Centre at Brentwood.
 7 Q. At this time, and then I think Dr Jean Harrison took
 8 over later?
 9 A. Yes, she did.
 10 Q. So:
 11 "Dr WJ Jenkins said that Dr R Lane (now Director
 12 Designate of BPL) could increase his output by 25 to
 13 30 per cent with additional equipment and staff but no
 14 extension to premises. He and Dr Dormandy had written
 15 to the Department of Health supporting this proposal
 16 and asked for the support of the working party, which
 17 was unanimously given."
 18 So just pausing there. It would appear from
 19 this that there was a desire, supported by the working
 20 party, for BPL to be able to provide more Factor VIII
 21 for the region?
 22 A. Absolutely because the Factor VIII concentrate, which
 23 may not have been the highest quality technically,
 24 that came from British donors was regarded, by me
 25 anyway, as the product of choice, and I wanted as much

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1 working party, 29 November 1978. We can see that
 2 you're present, as is Dr Kernoff. If we go down
 3 towards the bottom of that page, we see under the
 4 heading "Central funding of commercial Factor VIII
 5 concentrate purchase" there's a suggestion there
 6 of central funding of commercial Factor VIII
 7 concentrate purchase for the NETR, (the North East
 8 Thames region).
 9 Can you recall why that was being recommended?
 10 A. I can't, although I have seen other correspondence you
 11 have provided for me on the subject. I think that the
 12 issue really is that if you have lots of little
 13 centres buying concentrate separately, they tend to
 14 have to pay more per unit than if you have a bulk
 15 purchase. I think Mark Winter mentioned this himself.
 16 The other concern, of course, is that if there
 17 are centres buying their own concentrate, you don't
 18 know what they are doing with it. If you've got
 19 a central purchasing system and if the commercial
 20 concentrate you have delivered is delivered centrally
 21 to either the Royal Free or The Royal London, you've
 22 got some sort of control over what happens to it. We
 23 were talking earlier about the autonomy of the
 24 peripheral centres, and they were autonomous. They
 25 could do what they liked, but they also appreciated

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1 of the NHS product as I could get hold of.
 2 Q. If we look over the page, we can see Dr Dormandy
 3 reporting that the region would need 590,779 units of
 4 Factor VIII per annum to replace commercial
 5 concentrate, and the estimated cost there is 82,705.
 6 Then she sets out if all home treatment patients were
 7 to be included what the total requirements would be.
 8 Then if we look in the next paragraph, there's
 9 a recommendation about central purchase. Then doubts
 10 were expressed about the fairness of allocation of
 11 Lister concentrate between regions because of
 12 differences in severity of patients.
 13 Do you know what that refers to?
 14 A. I'm not sure about the issue of the differences in
 15 severity of patients in regions, but I think
 16 Mark Winter mentioned that you got back what you put
 17 in, to some extent, and so if you had a region where
 18 you had plenty of donors, you tended to get more
 19 concentrate back. Whether that was equitable or not
 20 is another matter altogether. But I am not familiar
 21 with any particular relationship between the
 22 allocation of Lister concentrate and severity of
 23 patients.
 24 Q. If we move on to a later meeting in 1978. Henry, it's
 25 BART0000686, please. This is a meeting of the same

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1 the advice they got, I think, from the centre, and so
 2 the co-ordination would work better and more
 3 economically if there was a regional policy on factor
 4 purchase.
 5 Q. If we go to the next page, please, Henry, we can see
 6 that expressed at the top of the page is an aim for
 7 BPL to be able to supply all the Factor VIII
 8 concentrate required for the region.
 9 Then if we go down, please, Henry, to the third
 10 paragraph, you are recorded there as pointing out
 11 that:
 12 "Many home treatment patients were still on
 13 cryoprecipitate and that considerably more commercial
 14 Factor VIII concentrate was needed than used at
 15 present."
 16 Why was it that more commercial Factor VIII
 17 concentrate was being identified there, bearing in
 18 mind your policy, as I understand it, was that
 19 home-treated patients would receive NHS factor
 20 concentrate?
 21 A. Only that we didn't have enough NHS concentrate for
 22 our purposes. Obviously, we moved fairly soon after
 23 that, I think, to cryoprecipitate being replaced by
 24 factor concentrates in the community, and all I think
 25 I was trying to say, though perhaps it hasn't been

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1 very well put in the minute, was that if we weren't
 2 going to get NHS, we needed commercial concentrate.
 3 **Q.** I'll come back in a few minutes, if I may, Dr Colvin,
 4 to the question of continuing with cryoprecipitate.

5 **A.** Sure.

6 **Q.** But still with this document, if we go to the next
 7 page, we can see the top of the next page, Dr Lane
 8 there identifies three lines down:

9 "Supply of NHS factor concentrate is inadequate
 10 at present for two reasons."

11 The first reason he gave was substantial
 12 underinvestment in BPL.

13 Was that a concern that you and your colleagues
 14 shared?

15 **A.** Well, I think we all had that feeling. I mean,
 16 I remember going when I was a very young doctor up to
 17 visit Darcy Maycock in Elstree, I think it was, and
 18 I mean, I could see that this wasn't a terribly
 19 professional organisation in a way. I mean, it was
 20 part of the NHS but not locked into the NHS because it
 21 was the Lister Institute I think.

22 So I think that the feeling was that the
 23 commercial companies, particularly in America of
 24 course, were a bit ahead of BPL technically and in the
 25 capacity to produce the concentrate. David Owen was

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1 Was that a concern that you and your colleagues
 2 shared?

3 **A.** Well, I think the insufficient supply of FFP is
 4 obviously the source material. So if you haven't got
 5 enough plasma, you haven't got enough concentrate. It
 6 makes perfect sense.

7 The use of the plasma pooling process, I'm not
 8 quite sure what that means, but it is important to
 9 appreciate that every step you make in fractionation
 10 results in a loss of yield. So if you start with 100
 11 units, say, in your plasma, by the time you get to
 12 your cryoprecipitate, you have perhaps lost
 13 10 per cent. Then you get back to your concentrate,
 14 you have even lost more. If and when you get around
 15 to viral activation, you are going to lose also
 16 concentrate in the viral activation process so that if
 17 and when you decide on the capacity of the viral
 18 activation, you're going to have to have more plasma
 19 to produce the same amount of concentrate.

20 **Q.** Then just if we go over the page, please, Henry, the
 21 bottom of the next page, we can see the last paragraph
 22 says:

23 "Dr Jenkins was concerned about the possible
 24 increase of Australia antigen positivity in home
 25 treatment patients and their families. It was agreed

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1 clear about this himself. He realised that there
 2 needed to be investment in the preparation of
 3 concentrates in order to make us in any way
 4 self-sufficient.

5 The sort of principle of making concentrate is
 6 actually rather straightforward. You just take your
 7 plasma off the red cells by centrifugation, then you
 8 freeze it, then you thaw it, and you thaw it at
 9 temperature of 4 degrees Celsius so you can just lift
 10 off the cryoprecipitate. Then with the
 11 cryoprecipitate, you start using the fractionation
 12 process that was invented during the Second World War
 13 to create the lyophilised freeze-dried powder
 14 concentrate. So it's not fantastically complex in
 15 theory or perhaps in practice, but it needs to be done
 16 on an industrial scale. You can't do it with a very
 17 small organisation or a very small factory. It's
 18 a factory process. It's not a simple process like
 19 making cryoprecipitate.

20 **Q.** Then the second concern there identified by Dr Lane
 21 is:

22 "Insufficient supply of fresh frozen plasma from
 23 Regional Transfusion Centres, coupled with the use of
 24 5L plasma pooling providing source material of low
 25 potential yield."

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1 to ask Sister Mary George to look into this, with
 2 a full report and discussion at the next meeting."

3 Do you have any recollection as to what that
 4 particular concern was?

5 **A.** No. I suspect -- I mean, John Jenkins was a great
 6 man, but he was of another generation, and maybe when
 7 he was talking about Australia antigen positivity in
 8 home treatment patients, he was thinking about the
 9 past when hepatitis B, that is Australia antigen, had
 10 been a big problem. But by the time I qualified, and
 11 by the time I started practising haematology,
 12 hepatitis B -- although I had patients who had
 13 hepatitis B positive -- was not a big problem for the
 14 future. It's even conceivable that John Jenkins was
 15 actually worrying about non-A, non-B, rather than
 16 Australia antigen. But it is quite difficult to
 17 understand what that meant.

18 **Q.** Could we then go, Henry, to BART0002487. This is the
 19 letter we looked at briefly earlier from Dr Kernoff to
 20 you, 27 April 1979. I just want to look at some other
 21 parts of it now, please. If we go down to the second
 22 main paragraph, please, Henry, you'll see set out in
 23 the second main paragraph Dr Kernoff saying:

24 "The regional treasurer has recently refused our
 25 request to institute a system of central funding for

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1 Factor VIII."
 2 Then there's a compromised proposal and view set
 3 out there. Halfway down this paragraph, it says this:
 4 "It is also felt that there is a lack of
 5 understanding at regional level of the special
 6 problems of treating haemophiliacs and, in particular,
 7 the problem of obtaining adequate supplies of
 8 Factor VIII. This problem will not be solved by
 9 stop-gap measures and will be with us for at least
 10 several years to come."
 11 Do you know what was meant there by a lack of
 12 understanding at regional level of the special
 13 problems of treating haemophiliacs?
 14 **A.** I think Mark Winter really touched on this quite a lot
 15 in his discussion, and he said that haemophilia was
 16 a low-volume, high-cost condition which required a lot
 17 of investment for a rather small number of people, and
 18 of course that's true.
 19 I think that region didn't necessarily
 20 understand how difficult haemophilia was. This brings
 21 us back to what Mark was saying of how awful it was to
 22 have haemophilia without any treatment and that at
 23 regional level, I'm sure they were thinking about, you
 24 know, as we do today, about heart disease and cancer
 25 affecting the population at large, and they may have

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1 atmosphere maybe might have been around.
 2 **Q.** If we go on to the next page, please, we can see --
 3 this is the passage we looked at earlier under the
 4 heading "Types of therapeutic material available", and
 5 then reference made four lines down:
 6 "Three Factor VIII-containing preparations
 7 available: cryoprecipitate, semi-purified Factor VIII
 8 concentrate made by the NHS, and semi-purified
 9 Factor VIII concentrate made by commercial companies.
 10 Cryoprecipitate, although relatively cheap to produce,
 11 has clinical disadvantages."
 12 I am going to come on to those what you might
 13 say the disadvantages were:
 14 "And in the UK, as in all developed countries,
 15 is being superseded by semi-purified Factor VIII
 16 concentrates. Since the amount of concentrate being
 17 made by the NHS is at present quite inadequate to
 18 satisfy needs, the shortfall has to be met by buying
 19 commercial concentrate."
 20 Then it goes on to consider the issue we looked
 21 at earlier.
 22 What appears to be being set out here is
 23 a policy, a way of thinking, which is: cryoprecipitate
 24 is the past.
 25 **A.** Mm-hm.

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1 felt, well, what is this about?
 2 It is quite technical. The business of how to
 3 treat people with haemophilia is relatively technical,
 4 and maybe there just wasn't an understanding of what
 5 the real problems were for a person with haemophilia,
 6 and what the potential solutions were, and how
 7 important it was to address them.
 8 **Q.** Dr Winter's evidence in that regard suggested that
 9 there was, at an institutional Health Service level,
 10 perhaps a lack of priority accorded to haemophilia in
 11 terms of funding allocation. Was that your
 12 experience?
 13 **A.** I think that's entirely possible. Don't forget,
 14 certainly at this time -- at this time, there were
 15 perhaps 5,000 people with haemophilia in the
 16 United Kingdom -- A -- a thousand or a little bit less
 17 a thousand of people with haemophilia B in
 18 the United Kingdom. We were looking at about 6,000
 19 people in a population of 60 million. Those 6,000-odd
 20 people clearly were extremely important, and I spent
 21 the whole of my career trying to look after a small
 22 number of them. But you can see that if you were
 23 running the NHS or the region, you might say, wrongly,
 24 who are these 5,000 people? Why are we having to
 25 spend so much money on them? That's the kind of

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1 **Q.** Concentrates are the present and future. There isn't
 2 enough NHS and, therefore, the only answer is to buy
 3 commercial concentrate.
 4 Would you agree? That's a precis.
 5 **A.** Absolutely fair.
 6 **Q.** What consideration was given within the North East
 7 Thames region to, rather than making up the shortfall
 8 with commercial concentrates, making up the shortfall
 9 at least to an extent with cryoprecipitate?
 10 **A.** Well, now we come down to the issue of: what is
 11 cryoprecipitate; what's it useful for, and how does it
 12 work?
 13 So cryoprecipitate, as I've explained, is very
 14 easily produced from a bag of blood. You just freeze
 15 the plasma, thaw it at 4 degrees, take off the
 16 supernatant and refreeze. Each bag contains 1 unit of
 17 another person's blood, and you store the
 18 cryoprecipitate in a deep freeze. You have no idea
 19 how much Factor VIII is in it because there's no way
 20 of measuring it, and it's full of everything else.
 21 Admittedly, it hasn't got the red cells but it hasn't
 22 got the supernatant, but it's full of fibrinogen and
 23 Factor XIII and globulins and all sorts of stuff.
 24 It's very impure. It's also full of allergens, that
 25 is things that can create allergy.

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1 So when you're using cryoprecipitate, you have
 2 a large volume, perhaps only concentrated by a factor
 3 of 10 from the plasma itself. You have the likelihood
 4 of severe side effects. Okay, you can get minor
 5 allergic reactions, but they can be extremely severe
 6 and could potentially be fatal. You don't know how
 7 much factor is actually in the bag you're giving, and
 8 it's extremely inconvenient to make up. So that if
 9 you are trying to -- if you are a junior doctor in the
 10 middle of the night and you are not in the haemophilia
 11 centre because, you know, people go home, you will
 12 have a young doctor who's got to make up 10 even
 13 possibly 20 bags of cryoprecipitate in the middle of
 14 the night because the half-life of Factor VIII is only
 15 8 to 12 hours, so you can't go home and then not give
 16 any more until tomorrow morning if you've got a
 17 seriously affected patient.

18 It becomes quite impossible to use it in an
 19 effective way and in a reliable way when you've got an
 20 alternative that is easy to use with a known volume of
 21 Factor VIII in it and with a limited immediate side
 22 effect which is extremely attractive to use. You
 23 heard patients talking about this on film, saying
 24 their lives had been completely transformed by the
 25 concentrate.

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1 unpleasant experience and what, at worst, could be
 2 a very serious experience once they had experienced
 3 it. So it wasn't just an excuse. It was a reason for
 4 not giving cryoprecipitate. First, they had an
 5 allergic reaction, then I think it was time to move to
 6 concentrate.

7 **Q.** But in terms of maybe the scientific data that you are
 8 able to point to -- in terms your own clinical
 9 experience, very approximately to give us an idea,
 10 what proportion of patients on cryoprecipitate
 11 experienced a significant allergic reaction?

12 **A.** A third to a half. It's hard to say, but I think at
 13 least a third.

14 **Q.** You have also in your witness statement, where you
 15 have listed a number of disadvantages to
 16 cryoprecipitate, suggested that it was impossible to
 17 sustain in home treatment, and I want to suggest to
 18 you "impossible" might be overstating the position.

19 **A.** Well, I mean, you might say nothing is impossible.
 20 Maybe the word "impossible" is too great since I use
 21 it in home treatment. But I think it was impossible
 22 to sustain in the light of the advances that had been
 23 made in haemophilia care, and I don't think it was
 24 realistic to continue cryoprecipitate use in the home.
 25 It wasn't fair to the patients, and it wasn't the

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1 Now, the next thing you ask me is, well, you
 2 were able to give cryoprecipitate in the home. Why
 3 couldn't anybody else? The answer is: people could
 4 but it was very unattractive. You had to have the
 5 freezer, you had to have much bigger surface on which
 6 to make up the material, you had to worry about the
 7 allergic reaction, and you didn't know how much to
 8 give.

9 So I think we did give up on cryoprecipitate
 10 because -- not just because it was inconvenient, but
 11 because it wasn't as reliable, and it was more
 12 dangerous at an immediate allergic level.

13 **Q.** Can we just unpick some of those issues, Dr Colvin?

14 First of all, just dealing with the potential to
 15 give rise to an allergic reaction.

16 **A.** Yes.

17 **Q.** Is there any data on how common that was?

18 **A.** I'm not sure about scientific data, but if you look
 19 through -- as I recall, looking through my notes,
 20 I would often find that the person was known to be
 21 allergic to cryoprecipitate. It was extremely common.
 22 Of course, the level of allergy -- that is the
 23 seriousness of the allergic response -- varied from
 24 person to person. But I think there was a lot of
 25 reluctance to submit patients to what, at best, was an

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1 right thing to do.

2 **Q.** There are -- practically it takes longer --

3 **A.** Yes.

4 **Q.** -- and a freezer is required, but we're talking about
 5 an ordinary, domestic freezer. We're not talking
 6 about some special piece of scientific equipment?

7 **A.** No.

8 **Q.** We know that it was done at the Royal Free, in
 9 particular, under Dr Katharine Dormandy quite
 10 extensively in the course of the 1970s.

11 **A.** Yes, sure.

12 **Q.** The Inquiry has heard evidence from others in other
 13 parts of the country who were treated with
 14 cryoprecipitate in the 1970s.

15 I don't doubt that concentrates may have been
 16 more convenient, may have been quicker, but would you
 17 accept that those advantages would have to be balanced
 18 against risks, in terms of viral transmission?

19 **A.** Advantages always have to be balanced against
 20 disadvantages. It's quite right and, of course, it is
 21 the case that I used cryoprecipitate myself in home
 22 treatment. I wouldn't begin to deny it. I'm
 23 delighted to do so, to begin with, because it made
 24 such a big difference.

25 But I don't know how long the Royal Free went on

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1 giving cryoprecipitate to patients for home treatment.
 2 Maybe Professor Lee can tell you, although she wasn't
 3 perhaps there at the time when that decision was made.
 4 But I think you'd find that, throughout the
 5 United Kingdom, and probably throughout the developed
 6 world, people were "giving up" on cryoprecipitate to
 7 use concentrates. The analysis of the advantages and
 8 disadvantages at that time, in our view, in our world
 9 was that it was time to move on to cryoprecipitate --
 10 from cryoprecipitate to concentrate.

11 **Q.** All things being equal, if there were no difference in
 12 the risk of viral transmission, as between
 13 cryoprecipitate and concentrates, the clinicians'
 14 preferences for concentrates, or indeed the patients'
 15 preference for concentrate, may be entirely explicable
 16 for the reasons you have given. But wasn't the risk
 17 of viral transmission the elephant in the room; the
 18 factor you couldn't ignore in deciding whether to
 19 abandon cryoprecipitate or not?

20 **A.** Well, let's move on now to look at the risks of
 21 cryoprecipitate. If it is the case that the
 22 prevalence of hepatitis C in the British community is
 23 let's take the figure 0.3 per cent, that's 3 per
 24 thousand, if you use potentially 10 bags of
 25 cryoprecipitate for your treatment and if you might

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1 through concentrates?

2 **A.** Yes, of course.

3 **Q.** In relation to hepatitis, you may be right to say that
 4 you can't say that there is no risk of infection with
 5 hepatitis from cryoprecipitate, particularly if you
 6 are someone who is using cryoprecipitate a lot, but of
 7 course not every haemophilia sufferer would
 8 necessarily have been using cryoprecipitate in a way
 9 that builds that up?

10 **A.** I agree.

11 **Q.** We can put lots of different numbers into each side of
 12 the equation but would you agree that cryoprecipitate
 13 carried a lesser risk, didn't carry with it the
 14 certainty of infection with hepatitis C that you have
 15 pointed to in relation to concentrates?

16 **A.** I understand that. There's one other point I would
 17 make, though, and that is if you did get a bag of
 18 cryoprecipitate that was infected you could get a big
 19 dose of virus and could be quite ill.

20 There's a paper published by Peter Carr, from
 21 Christine Lee actually -- and she can refer to it, I'm
 22 sure, when she gives evidence -- where they
 23 specifically reported in Gart(?) a patient who was
 24 given a dose of cryoprecipitate who was extremely
 25 unwell.

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1 treat yourself two or three times a week, that would
 2 give you, I think, shall we say, up to 100 bags
 3 a month. I mean, I'm just -- I'm not doing the maths
 4 particularly now, but, I mean, you can see, it doesn't
 5 take long to build up a very large number of bags of
 6 cryoprecipitate.

7 Now, you might, of course, get the same person
 8 giving to the bag. So if you've got the same person
 9 giving to bags as time goes by, you are not exposing
 10 yourself to a new donor every time you get a new bag
 11 of cryoprecipitate. But it doesn't take long for you
 12 to get into the thousands of bags of
 13 cryoprecipitate. Then, of course, it is a matter of
 14 risk analysis. But you're really playing Russian
 15 roulette with a machine gun, that eventually if you
 16 have enough bullets one of them is going to hit you.

17 So, in that sense, with respect, in the end
 18 you're going to get hepatitis C.

19 **Q.** Let's look at it in a slightly different way. We
 20 haven't come on to talk about HIV yet because I'm
 21 asking you these questions in a chronological order
 22 largely, but would you accept that the risk of being
 23 infected with HIV from cryoprecipitate was far, far --
 24 you couldn't say it was non-existent but far, far,
 25 smaller than the risk of being infected with HIV

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1 So it's very important not to take the view --
 2 I know you don't take the view -- that there's no risk
 3 giving cryoprecipitate. It's not the case.

4 **Q.** What I'm seeking to explore with you, Dr Colvin, is
 5 when we look at, for example, this document, and we'll
 6 see it and a handful of further minutes in a moment,
 7 what we don't see is that risk analysis being
 8 undertaken, at least not expressly?

9 **A.** Yes.

10 **Q.** No-one appears to be asking themselves the
 11 question: what are the relative risks of
 12 cryoprecipitate and factor concentrates whether NHS or
 13 commercial?

14 **A.** Yes.

15 **Q.** Is that fair? That wasn't something that was
 16 expressly considered at that time?

17 **A.** I think it's fair to say that we didn't expressly
 18 consider the possibility of going backwards to
 19 cryoprecipitate use in a big way.

20 **Q.** Do you think the reason for that may have been in part
 21 what Dr Winter alluded to and what you alluded to
 22 yourself, a sense of wishful thinking and
 23 everything -- liking so much the effect of
 24 concentrates on the lives of your haemophiliac
 25 patients, you didn't want to think about going back?

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1 A. I'm sure that's true. The other thing, of course, is
 2 that if you had decided that cryoprecipitate was the
 3 answer, which it certainly was not, then what happens
 4 to the fractionation unit? Do you give up the idea of
 5 fractionated concentrates and freeze-dried
 6 concentrates?
 7 I think that there was a sense, and a true
 8 sense, in which cryoprecipitate was old hat. I take
 9 your point about the risk, and I think if you come on
 10 to some of the things I tried to do, you'll see that
 11 I was still using cryoprecipitate in certain
 12 circumstances, but in very, very selected
 13 circumstances, and that none of us really contemplated
 14 a return to cryoprecipitate as the first line of
 15 therapy.
 16 Q. Just going back to this letter, if we could go to the
 17 next page please, Henry, and just really to complete
 18 the factual position, we can see from the heading,
 19 "Financial arrangements", picking it up third line
 20 down:
 21 "NHS-produced cryoprecipitate and Factor VIII
 22 concentrate are distributed without charge to
 23 Haemophilia Centres in NETR ... either at Brentwood or
 24 Edgware ..."
 25 So you were, as a matter of fact, able to get

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1 A. I don't think it's to do with clinical freedom. You
 2 say -- are you trying to now refer to the "I know of
 3 no other instance" paragraph?
 4 Q. Yes.
 5 "... serious interference with the duties and
 6 rights of physicians to treat their patients in the
 7 most appropriate way they think fit."
 8 A. I mean, this is an anecdote, from my experience.
 9 Years ago I was asked, as we were trying to get
 10 funds for haemophilia care, for how long haemophilia
 11 had been treated at The London Hospital. As it
 12 happened, I knew that Sir Frederick Treves, in the
 13 late 19th century, had looked after a family of people
 14 with haemophilia and had published in The Lancet. So
 15 I was able to tell my district treasurer, who was
 16 saying to himself, really, "Why should I be doing
 17 this?" that we had been treating patients with
 18 haemophilia at The London since the 19th century.
 19 I think he rather -- he thought he was joking,
 20 but he wasn't, he said, "Well, perhaps Dr Colvin could
 21 treat all his patients for half the time or half his
 22 patients for all the time."
 23 I mean, that's a damning remark, I think you
 24 will agree, which is not far away from this statement,
 25 and was utterly unacceptable to anybody who was

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1 both cryoprecipitate and NHS Factor VIII without
 2 having to pay for it from --
 3 A. Yes, indeed.
 4 Q. Then if we go to the next paragraph, please.
 5 If we just look towards the bottom of that next
 6 paragraph, there's a sentence -- if you need to read
 7 the whole paragraph, Dr Colvin, do, but there's
 8 a sentence beginning:
 9 "Directors of these Centres ..."
 10 This was the smaller centres:
 11 "... have had considerable difficulties
 12 persuading their local administrations to purchase
 13 factor VIII."
 14 That's commercial Factor VIII?
 15 A. Yes.
 16 Q. "I know of no other instance where supplies of an
 17 essential drug have been withheld on the grounds of
 18 cost and in my view the refusal of local
 19 administrators to purchase commercial Factor VIII is
 20 a serious interference with the duties and rights of
 21 physicians to treat their patients in the most
 22 appropriate way they think fit."
 23 I wanted to ask you about that latter sentence
 24 there. Is this the concept of clinical freedom that
 25 other witnesses have referred to?

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1 a healthcare practitioner. So in that sense, it is
 2 true that district treasurers were very unhappy about
 3 the idea that they had to spend money.
 4 It's also important to appreciate, and we go
 5 back to the earlier part of the paragraph, that you
 6 have said that the cryoprecipitate and the NHS
 7 concentrate was a free good, which of course it
 8 wasn't, because it had to be paid for by the NHS. But
 9 we know the NHS is free at the point of delivery --
 10 thank heavens because the whole of my career was based
 11 on having the ability to give people of any social
 12 class exactly the same treatment -- enormous benefit
 13 for the whole of our community, which we've celebrated
 14 for all the years since '48. But the commercial
 15 concentrates had to be paid for with real money.
 16 Now as we moved on and it became apparent that
 17 NHS concentrate was going to get really expensive,
 18 because it became more and more difficult to produce
 19 it, because it was getting purer and purer -- the
 20 actual use of the fractionation industry got more and
 21 more complex -- so it became more and more expensive
 22 to make the product we required. That's when the idea
 23 of internal charging was introduced, with the idea of
 24 trying to make some sort of sense of the relationship
 25 between the NHS as a provider where treatment is free

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1 at the point of delivery, and the whole system works
2 in that way, and the import of commercial concentrates
3 that had to be paid for.

4 You will recall that during Mrs Thatcher's
5 premiership she described -- I think I'm just about
6 quoting -- the NHS is not a business run for profit
7 but it can be made more business-like. That's what
8 she said at the NHS review in her premiership.

9 That was, in a sense, what was happening at
10 these times, that it was recognised that something had
11 to be done to make the haemophilia service work at
12 a financial level. That's what I think these
13 treasurers were trying to achieve, albeit sometimes
14 with language which was unacceptable, and with
15 a policy which was not acceptable to us as clinicians.

16 **Q.** Could we then go on to one further set of minutes
17 from 1979.

18 Henry, it's BART0000683.

19 You can see this is a set of minutes from
20 1 August 1979. Again, you and Dr Kernoff and others
21 are present. If we go down towards the bottom of the
22 page, please, under the heading "Matters arising from
23 the minutes", the last paragraph says this:

24 "In the meantime Dr Carmichael stressed that the
25 Haemophilia Centres must demonstrate the best use of

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1 were using enormous quantities of Factor VIII
2 (particularly perhaps Dr Brachmann in Bonn) and
3 I think many people thought that, and in many ways
4 they were right, that we should be doing everything we
5 possibly could to make haemophilia care perfect and
6 that meant using a lot of Factor VIII concentrate.

7 Other people thought: Well, I'm not sure that's
8 necessarily the best strategy. If you look at the
9 usage figures, which I have and you have provided for
10 me, it looks as though, at The London, we were using
11 possibly about half the amount per person with
12 haemophilia as was being used nationally.

13 Now, why was that? It might have been because
14 I had lots of mildly affected patients. Maybe that
15 was part of the reason. But it might have been that
16 I was trying to be a good housekeeper. On the other
17 hand and this has been said to me by at least one
18 director in the past, "Brian, you should be using much
19 more concentrate and you are letting your patients
20 down by not using higher volumes". My view was that
21 I wasn't letting my patients down, that I was giving
22 them the appropriate treatment, but nevertheless in
23 the context of good housekeeping.

24 But I don't believe what Dr Carmichael said was
25 right at all.

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1 available resources. In the present financial
2 situation, there could be no point in competing with
3 other medical groups equally stressed by shortage of
4 funds. He repeated that 'good housekeeping', active
5 decisions when not to treat patients, using
6 cryoprecipitate where ever possible, and cutting out
7 expensive elective surgery, for example remedial
8 orthopaedic surgery, would all demonstrate a careful
9 and responsible use of available funds."

10 Now those are measures that are being suggested
11 on financial grounds. But they are all measures which
12 might have had an impact in terms of reducing risks of
13 viral transmission. There's --

14 **A.** But I think you have to understand -- sorry, I --

15 **Q.** No, no, please comment.

16 **A.** I think that the difficulty, therefore, is to contrast
17 the prudent, if you like, use of resources trying to
18 provide a high quality service and the profligate use
19 of resources trying to provide a high quality of
20 service. There were people in the United Kingdom in
21 haemophilia centres who really didn't care, I think,
22 what it cost and who believed that the more
23 concentrate you used the better, and they may have
24 been right.

25 You'll realise that the Germans, for instance,

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1 **Q.** So would it follow from what you've just said that you
2 yourself did not, whether for financial or risk-based
3 or other reasons, implement the measures that he set
4 out here?

5 **A.** I don't think I should have done.

6 **Q.** Then if we go over the page, we can see you saying in
7 the second paragraph and this is in the context of
8 a discussion about limitations of funding:

9 "Dr Colvin reported that he would be forced into
10 clinical decisions which no-one would wish to make.
11 There were genuine fears that patients would die due
12 to lack of treatment. The first sufferers would be
13 patients requiring remedial surgery, hip replacement
14 or repair operations, et cetera. If not offered
15 surgery, such patients would remain a drain on
16 available resources ..."

17 Et cetera, et cetera.

18 Then the next paragraph:

19 "After further discussion [it] was agreed to
20 conserve available Factor VIII resources as carefully
21 as possible and to encourage the expansion of the
22 Blood Products Laboratory, Elstree ..."

23 We can see therefore what your concerns were,
24 Dr Colvin. What do you understand that meant by the
25 agreement in the next paragraph to conserve available

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1 Factor VIII resources as carefully as possible?
 2 **A.** It is always, for any physician, the duty to conserve
 3 available resources within a proper use of those
 4 resources. So, as you will have seen from my CV,
 5 I was also Associate Medical Director. Now,
 6 I remember having another conversation with one of my
 7 colleagues who said, "What are you doing being
 8 Associate Medical Director at the same time as being
 9 a haemophilia doctor? You should be fighting your
 10 patients' corner, not thinking about your relationship
 11 with the hospital as a whole and being interested in
 12 the allocation of resources."
 13 Well, I can't really agree with that thesis. If
 14 we all -- I can see the idea that one should be
 15 fighting one's patients' corner, I tried to do that
 16 throughout my career, but it is essential that there's
 17 an organisation and that resources are allocated.
 18 It's a fact of life that the resources are not
 19 infinite and have to be allocated.
 20 So nobody should argue with the statement it was
 21 agreed to conserve available Factor VIII resources as
 22 carefully as possible. That's good housekeeping.
 23 What is not acceptable is to say that you're not going
 24 to be bothered with remedial surgery and people's pain
 25 and suffering when you know that remedial surgery will

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1 commercial products. By no means. But it was
 2 inevitable that if you had a big procedure then it
 3 might need to require commercial product.
 4 **Q.** If we go to the next page, paragraph 3, top of the
 5 page, it's then said, and this is part of, again, what
 6 is recorded as agreement:
 7 "Wherever possible, Hospital patients (including
 8 out-patients visiting for treatment) should be treated
 9 with cryoprecipitate or Commercial Factor VIII
 10 concentrate, the exception being Home Treatment
 11 patients previously exclusively treated with ...
 12 Factor VIII concentrate."
 13 So there doesn't appear to be any suggestion in
 14 this meeting that cryoprecipitate is somehow
 15 inherently not to be favoured or disadvantageous?
 16 **A.** No, I think that there was no reason why
 17 cryoprecipitate should not be used in occasional
 18 circumstances, and I can show that I was doing that,
 19 for instance, for very small children or -- until the
 20 mid-80s. There were still patients I was treating
 21 with cryoprecipitate.
 22 **Q.** Then if we go, please, to BART0000681.
 23 We move forward here to a meeting in April of
 24 1981 of the same working party. We can see again that
 25 you are there and Dr Kernoff is there.

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1 make the patient's condition better and will enable
 2 them to go back to work and be out of pain.
 3 So this is an ancient, no doubt, dilemma and
 4 it's with us today.
 5 **Q.** If we go down to the bottom of the page we can see the
 6 policy that appears to be agreed, but agreed on
 7 financial grounds rather than anything else. Point 2:
 8 "That all NHS Factor VIII concentrate should be
 9 allotted to Home Treatment patients as a first
 10 priority, and that the presently available 370 bottles
 11 of Factor VIII concentrate per month should be
 12 allocated to the London and Royal Free hospitals in
 13 proportion to the numbers of Home Treatment patients
 14 at each Centre."
 15 **A.** That sounds like good housekeeping to me.
 16 **Q.** So would it follow from that -- it picks up on what we
 17 were talking before lunch, Dr Colvin -- that in
 18 relation to those who were not on home treatment,
 19 commercial concentrates would now increasingly be
 20 filling that gap?
 21 **A.** Well, it depends on what's to be done. It's not
 22 sensible I think and I don't think we did devote all
 23 of our NHS treatment to home treatment. There was
 24 some NHS treatment available. We didn't spend all our
 25 hospital treatment or all our surgical treatment on

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1 If we go down towards the bottom half of the
 2 page, please, we can see in the penultimate paragraph:
 3 "It was agreed that all available NHS
 4 Factor VIII concentrate should be allocated to
 5 patients on Home Treatment ..."
 6 So the same policy still seems to be applied in
 7 April 1981.
 8 Then in the next paragraph we see, last five
 9 lines:
 10 "In-patients who require prolonged or intensive
 11 treatment should receive cryoprecipitate or commercial
 12 Factor VIII concentrate."
 13 Just pausing there, again, there doesn't seem to
 14 be any suggestion that cryoprecipitate is
 15 inappropriate or unsuitable for prolonged or intensive
 16 treatment.
 17 **A.** But it doesn't say anything other than the fact that
 18 one could consider using cryoprecipitate. It doesn't
 19 mean to say that cryoprecipitate is suitable for all
 20 intensive treatment. It isn't.
 21 **Q.** No, but there is nothing in here to suggest that it's
 22 inherently unsuitable?
 23 **A.** No, and I think -- I mean, I don't know if and when
 24 you want to discuss the very small paper I wrote in
 25 the 80s but I made quite clear that I was still

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1 selecting people to receive cryoprecipitate into the
 2 '85 period.
 3 **Q.** I will come to that when we get on to the mid-80s
 4 after we have looked at HIV.
 5 Then you refer there to:
 6 "... young children who react to cryoprecipitate
 7 may receive ... Factor VIII concentrate ..."
 8 If we just go over the page, we can see this it
 9 says:
 10 "Brentwood Regional Transfusion Centre wishes to
 11 decrease production of cryoprecipitate so that more of
 12 the available plasma can be sent to the Blood Products
 13 Laboratory, Elstree, as Fresh Frozen Plasma.
 14 Brentwood would continue to produce some
 15 cryoprecipitate and would be prepared to set aside
 16 cryoprecipitate on request for planned cases. Centres
 17 should be prepared to use commercial Factor VIII
 18 concentrate for in-patients ... in place of
 19 cryoprecipitate."
 20 Something of a tension between the suggestion on
 21 the previous page that in-patients should receive
 22 cryoprecipitate or commercial Factor VIII but here
 23 we're seeing a suggestion of a reduced production of
 24 cryoprecipitate. Do you recall any discussion about
 25 that issue?

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1 **A.** No, I think that is fair, that because of the lack of
 2 engagement on the non-A, non-B risk of factor
 3 concentrate, the potential advantage of
 4 cryoprecipitate for relatively infrequently treated
 5 patients with haemophilia might not have been
 6 addressed properly.
 7 **Q.** I suggest to you that's something that one can say not
 8 just with the benefit of hindsight but, looking at
 9 things at the time, there should at least have been an
 10 evaluation of the relative risks as part of the
 11 decision-making process?
 12 **A.** Well, what is and is not hindsight I can't judge,
 13 I guess that's for Sir Brian to judge, but I think
 14 that it is with hindsight that we appreciate that more
 15 attention should have been made to the potential of
 16 cryoprecipitate.
 17 **Q.** Can I just go back to the question of DDAVP, which we
 18 were talking about before lunch, and just ask you to
 19 look at a couple of documents in relation to DDAVP.
 20 Could we please have, Henry, MASK0000605_002.
 21 We can see that this is a report in The Lancet
 22 from 1 October 1983 entitled "DDAVP in Haemophilia and
 23 von Willebrand's Disease". Picking it up towards the
 24 bottom of the left-hand column it said:
 25 "For its ability [so that's DDAVP's ability] to

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1 **A.** I don't recall that particularly but I think that
 2 the -- I've been listening and watching for some days,
 3 and I think there's a sense in which, for perfectly
 4 understandable reasons, the Inquiry is -- are unable
 5 and unwilling, I think -- I perfectly understand
 6 this -- to realise that the haemophilia treaters felt,
 7 rightly or wrongly, that cryoprecipitate was
 8 a treatment of the past, that it was low tech, if you
 9 like, and that it would be replaced, in its entirety
 10 really, by concentrate. That eventually of course
 11 happened when effective virally-activated concentrates
 12 became available. So we are looking at 1988 really
 13 that -- that's the end of cryoprecipitate as
 14 a realistic treatment for haemophilia.
 15 But in this period in the late 70s, it
 16 nevertheless was the case that people felt, rightly or
 17 wrongly, and with some clarity, that the days of
 18 cryoprecipitate were over. Not just because of
 19 convenience but because it wasn't a good way of
 20 treating haemophilia.
 21 **Q.** Dr Colvin, it is clear that some people thought that.
 22 The question I'm seeking to explore with you is where
 23 into that decision-making process did an analysis of
 24 risk come? I think earlier you agreed with me it
 25 didn't really feature.

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1 raise the plasma concentration of Factor VIII, it is
 2 finding an increasing place in the treatment of
 3 haemophilia. In mild haemophilia A and von
 4 Willebrand's disease ... excessive bleeding usually
 5 occurs after trauma or surgery and can be effectively
 6 treated by cryoprecipitate or Factor VIII concentrate.
 7 The use of blood products, however, is not without
 8 dangers. Even with a modest number of factor VIII
 9 infusions, many patients or infected with hepatitis B
 10 or non-A, non-B and these infections may well progress
 11 to chronic active hepatitis and cirrhosis. If it
 12 renders transfusion unnecessary in selected patients,
 13 DDAVP therapy must be counted an important therapeutic
 14 advance."
 15 Is then if we just go to the next page, and then
 16 I'll ask you about it, Dr Colvin. So left-hand column
 17 please, Henry:
 18 "DDAVP can be used to treat patients with mild
 19 haemophilia, carriers of haemophilia with low
 20 Factor VIII concentrations, and patients with [von
 21 Willebrand disease]."
 22 Then it goes on to describe how it will be given
 23 and what its effect is. Then, if we can pick it up
 24 a few lines down:
 25 "Provided that the basal level of the most

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1 deficient Factor VIII activity ... is 7 per cent or
2 more, the resultant rise, which reaches a maximum
3 within 60 to 120 [minutes], should be sufficient to
4 stop external haemorrhage ... or to allow minor
5 surgery such as tooth extraction or lymph node
6 biopsy."

7 Pausing there, that, I think, is essentially the
8 observation you were making earlier about your usage
9 of DDAVP. Then it goes on to say, if we skip over
10 a sentence:

11 "Bigger surgical procedures [and a couple of
12 examples are given] ... may be possible with DDAVP if
13 the basal factor VIII levels or higher, particularly
14 in [von Willebrand's disease] ... A further injection
15 of DDAVP can be given after a few hours to boost the
16 Factor VIII concentration ..."

17 And so on, and it talks about different ways in
18 which the DDAVP can be administered.

19 So it would seem there, in 1983, it's being
20 suggested that DDAVP isn't necessarily limited to the
21 more minor forms of surgery that you referred to.

22 **A.** First of all, we don't know who wrote The Lancet
23 article, because Lancet articles are always anonymous.
24 Secondly, I can share with you my own view of the
25 value of DDAVP, which is not the same as this. I am

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1 out of your own resources. So it's no good for more
2 than two or three doses because it -- you lose the
3 effect.

4 So if you've got a simple small dental
5 extraction, give the DDAVP and tranexamic acid,
6 perhaps give another dose and wait and hope that
7 everything's fine, you're okay. But if you try to do
8 that when there's a risk of a haematoma forming, as
9 I explained this morning, you may actually do more
10 harm than good, because you're left with a haematoma
11 which you then have to try to resolve, which may take
12 days or weeks to resolve.

13 So also I pointed out some patients with von
14 Willebrand's disease are not suitable for DDAVP,
15 particularly types 2B and 3, and that means that
16 I have to work in my own mind when it's suitable and
17 when it's not. Here it says you can do
18 a cholecystectomy or a thoracotomy under DDAVP.
19 I completely disagree. I think it is a very foolish
20 thing to do. Personally. But as we discussed before,
21 there is this thing called clinical freedom and
22 different people have different views.

23 But I do emphasise that I'm a great enthusiast
24 of DDAVP but only in certain selected circumstances,
25 and I think my own use of DDAVP is more conservative

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1 happy to explain that to you.

2 So I have used a very large amount of DDAVP and
3 tranexamic acid in my time, and I think that's
4 demonstrable from my returns. It's an extremely
5 valuable treatment and it's very useful in people who
6 have Factor VIII levels of around 5 to 10 per cent,
7 because you get a three to five-fold increase.

8 So if your resting level is 5 per cent, you'll
9 get up to maybe, if you're lucky, 20 per cent. That's
10 not a very good level but it might give you
11 haemostasis or it might not.

12 Therefore, one links it with a drug called
13 tranexamic acid, which has become rather popular these
14 days, and it's often in the press, and tranexamic acid
15 helps prevent the dissolution of blood clots. So the
16 idea is that if you give a dose of DDAVP and
17 tranexamic acid you'll just about get a clot formed
18 and tranexamic acid itself may just about prevent that
19 clot from dissolving before you start bleeding again.

20 Now, DDAVP, as I explained earlier in this
21 discussion, is affected by a process called
22 tachyphylaxis, and that process of tachyphylaxis means
23 that DDAVP is delivering what you've got inside your
24 body to your circulation. If you give it every
25 12 hours or so, by the third dose you will have run

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1 than is expressed here, for the reasons I've given.

2 Also, DDAVP retains fluid because it's a brain
3 hormone which is fluid-retaining, and is therefore
4 unsuitable for neonates and, if you repeatedly give
5 it, having run out of your effect of stimulating
6 Factor VIII production, then you could cause fluid
7 retention which could be harmful. Also, of course,
8 it's completely useless for managing haemophilia B.
9 It doesn't work.

10 **Q.** I think the answer to this next question may be
11 obvious from what you have just said, Dr Colvin, but
12 did you yourself ever use or recommend DDAVP for
13 bigger surgical procedures than the ones you have
14 described?

15 **A.** No.

16 **Q.** Could I then just ask you some broader questions about
17 your approach to treatment.

18 We know you had a policy for how children would
19 be treated predominantly but not exclusively with
20 concentrates. What age of children did that policy
21 encompass?

22 **A.** Well, I think, as far as the use of cryoprecipitate in
23 the children's ward, it would have been rather young
24 children because once people were going to grow up,
25 they tend to get on to the home treatment programme,

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1 and then they were on concentrate. So what I'm
2 thinking about really was very small children.
3 There's one case that -- obviously, it's difficult to
4 talk about individual cases, but there was one child
5 who was referred to us I think in the early '80s from
6 Great Ormond Street, and we carried on with
7 cryoprecipitate until the -- sort of '85 or so, '86,
8 maybe '87 when what 8Y came in, and he avoided all
9 virus infections because we had insisted on his having
10 cryoprecipitate when he was a little child as an
11 in-patient in the hospital.

12 But that only -- that sort of happy outcome was
13 really quite rare for the reasons that I expressed in
14 my --

15 **Q.** Just, as a matter of fact, what age of children? You
16 said it was the younger children. Are we talking
17 under 6? Under 10?

18 **A.** I think probably more under 6 than under 10 because
19 I think once you get to a bigger, substantial child
20 we'd have had them on the home treatment programme, if
21 we could.

22 **Q.** And, thus, concentrate --

23 **A.** Yes.

24 **Q.** -- preferably NHS but in some circumstances for supply
25 reasons --

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1 erroneous view that the NHS concentrates had the lower
2 risk of causing hepatitis than the commercial
3 concentrate. I was wrong, but I think that that would
4 have been the reason that I would have thought in
5 those terms.

6 **Q.** Then if you wouldn't mind turning up your witness
7 statement, Dr Colvin, and going to paragraph 15, you
8 list in paragraph 15 a number of different products
9 that were used over the years at The London Hospital
10 for the treatment of haemophilia A and B.

11 I wondered if you could just assist me with --
12 in fact, maybe we'll put this up on screen. It might
13 be easier to follow. Henry, it's WITN3343007.

14 If we go to page 7, and we'll see bottom half of
15 the page, you have listed a number of products. Could
16 you assist me with an exercise of just ordering those
17 products by reference to safety considerations alone,
18 where -- obviously, these are all products available
19 at different times. They are not simultaneously
20 available to you, certainly not in the late '70s and
21 early '80s. If we leave aside recombinant on the
22 basis that presumably in terms of viral transmission
23 that is the safest, albeit in its initial form not 100
24 per cent safe, and I will be asking you tomorrow
25 a little bit more about recombinant.

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1 **A.** Yes, and paradoxically, if you were a child who lived
2 near The London and were perhaps socially deprived and
3 weren't suitable for the home treatment programme, you
4 modified be less likely to go on to the home treatment
5 programme, therefore more likely to be treated with
6 cryoprecipitate.

7 **Q.** Then I think as you told the Lindsay Tribunal,
8 although there was this policy in relation to the
9 treatment of children, as a matter of fact, you didn't
10 have a particular policy for the treatment of
11 previously untreated patients.

12 **A.** I don't think the policy -- since most of the
13 previously untreated patients would be very small
14 children, the policy would have been to use
15 cryoprecipitate. So maybe I didn't have a specific
16 policy at that time for the treatment of previously
17 untreated patients, but I think the effect of the
18 policy we had would be that they would be given
19 cryoprecipitate.

20 **Q.** In your witness statement, you say that the reason for
21 trying to reserve NHS Factor VIII for children not on
22 cryoprecipitate or for home treatment was partly
23 safety, and I wondered if you could just expand on
24 what you mean by "partly safety"?

25 **A.** Well, only that I think that at the time I took the

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1 In terms of safety, and I'm talking here about
2 viral transmission not possible allergic reactions, so
3 it's a limited question.

4 **A.** Yes.

5 **Q.** What is the safest of those products in your view?

6 **A.** From the point of view of viral transmission?

7 **Q.** In relation to viral transmission.

8 **A.** Obviously, desmopressin.

9 **Q.** Then after that?

10 **A.** Well, if you're talking about human infection, then
11 I suppose the answer's probably porcine Factor VIII.
12 The trouble with porcine Factor VIII was that it was
13 withdrawn because of potential contamination with
14 porcine parvovirus. So there's a kind of bracket
15 around that really.

16 If you then go on, the fresh frozen plasma and
17 cryoprecipitate are of equal risk, except insofar as
18 you couldn't give enough fresh frozen plasma to reach
19 the same number of units as you would use for the same
20 volume as cryoprecipitate.

21 Then the next most -- the next safest would be
22 the NHS Factor VIII heat-treated after 1988.

23 **Q.** Yes. So that would be 8Y?

24 **A.** Yes. Then -- are we only talking about Factor VIII
25 now, or are we talking about Factor IX as well?

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1 Q. By all means, talk about Factor IX as well.
 2 A. I think the Factor IX heat-treated after 1985 was
 3 demonstrably safe in the same way as 8Y was.
 4 Then probably Factor IX unheated because -- I'm
 5 sorry. We're on to virally -- I've got to go down to
 6 virally inactivated, haven't I? The next thing is
 7 virally inactivated concentrates. That would have
 8 been the NHS virally inactivated 8Y or 9A.
 9 Q. Yes.
 10 A. After that, we are in a degree of difficulty because
 11 the NHS Factor VIII really was an unknown quantity
 12 until we got to the 8Y because there was very small
 13 amounts of it. It's hard to interpret, which you may
 14 come on to later.
 15 Then I think of the -- if you're talking about
 16 hepatitis C and HIV together, which is quite difficult
 17 because they have slightly different levels of safety,
 18 the heated commercial concentrates whether 8 or 9,
 19 were very capable of transmitting both HIV and HCV.
 20 Eventually it perhaps was clear that the heated
 21 commercial concentrates had some benefit to begin
 22 with; it's difficult to be sure. Then I think the
 23 Factor IX commercial, I think we didn't have enough
 24 information really to judge.
 25 Then I think, equally, probably the Factor VIII

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1 clinical need, suitability of product for the
 2 particular patient, availability and cost -- were any
 3 of those factors, generally speaking -- did they carry
 4 more weight in your decision-making process than
 5 others, or were they all equally balanced?
 6 A. I think the most important thing is the suitability of
 7 the product for the individual patient and their
 8 particular problem at the time. That is, the
 9 overriding question is: what is the right thing for
 10 a patient?
 11 The issue of availability is obviously very
 12 important because if something isn't available, it's
 13 not available. I don't think cost was ever an issue
 14 in individual patients, but obviously cost cannot be
 15 ignored, as I explained in my discussion of the
 16 business-like nature of the way the NHS went after the
 17 '70s.
 18 Q. In relation to those with mild haemophilia, to what
 19 extent was an option of no treatment an option that
 20 you would contemplate and discuss with a patient, as
 21 opposed to a treatment which involved a risk of viral
 22 transmission?
 23 A. The answer to that, if you're talking about bleeding,
 24 is almost never because, as I've explained in my
 25 statement, mild haemophilia is not mild bleeding, and

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1 Inhibitor Bypassing Fraction that was heat-treated
 2 would have been much the same as the other commercial
 3 heat-treated. Then I think you'll see from the papers
 4 we've got that in the end it became clear that the
 5 commercial concentrates that were not heat treated
 6 were the least safe.
 7 Q. Thank you.
 8 A. That's my best bet at that particular process,
 9 off-the-cuff.
 10 Q. If we just go further down that paragraph, please,
 11 Henry, you say this:
 12 "My decisions on product use were made on the
 13 basis of clinical need, suitability of the product for
 14 individual patient and their particular problem at the
 15 time, availability and cost."
 16 Now, I understand each of those factors and what
 17 they mean. There's no reference there to safety.
 18 A. Well, it would have come in to the suitability of the
 19 product of the individual patient, I think. But
 20 I take your point. I haven't actually used the word
 21 "safety" there. I accept that. But I think safety
 22 would have been an issue. The only difficulty was
 23 that, having made those comments that I made earlier,
 24 it isn't always clear what is the safest product.
 25 Q. In terms of the factors that you have set out there --

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1 I can't say that often enough. I spent the whole of
 2 my career explaining to my juniors, and maybe even
 3 sometimes to my patients, that mild haemophilia does
 4 not mean mild bleeding.
 5 Let me give you a couple of examples. I have
 6 already given you one of a patient who nearly died,
 7 had a prostate operation at the age of 70 when his
 8 Factor VIII level resting was perhaps 15/20 per cent.
 9 I can also give you an example of a university
 10 student who was under my care who had a level of
 11 Factor VIII in, take, 15/20 per cent. He fell down
 12 the stairs I think in Aberystwyth and ignored his
 13 fall. He eventually realised he had to have some
 14 treatment, took a train from Aberystwyth to London to
 15 see me, and he had the most massive haematoma in his
 16 flank which had been developing over a week or so as
 17 he was trying to ignore it.
 18 One of the features of people with mild
 19 haemophilia, or maybe even moderate haemophilia, is
 20 that they, quite understandably, don't really know
 21 what bleeding badly from haemophilia is like and they,
 22 quite understandably, think that if they don't do
 23 anything it will get better. It is the case, I'm
 24 afraid, that for bleeding it won't get better. It
 25 will go on bleeding until something is done about it,

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1 and that's the history of ignoring or trying to avoid
 2 treatment for people with haemophilia. It is not
 3 a good strategy.
 4 Now, of course, if there's a question of
 5 surgery, then the issue is: how important is the
 6 surgery and what are the risks? That, clearly, is an
 7 important issue.
 8 **Q.** Other than through the continuation of your policy of
 9 using mostly cryoprecipitate for young children, did
 10 your approach to treating patients change at all in
 11 the years 1977 to '83 to reflect the risk of
 12 hepatitis?
 13 **A.** I don't believe that it did.
 14 **MS RICHARDS:** Sir, I note the time. I am going to move on
 15 to looking at materials relating to HIV, so that might
 16 be a convenient point at which to stop.
 17 **SIR BRIAN LANGSTAFF:** Yes. I think you want to break
 18 earlier for the afternoon than would otherwise have
 19 been the case. Is that still --
 20 **MS RICHARDS:** Not necessarily, sir. I think, if everyone
 21 is willing to keep going, we could keep going until
 22 4.15 to 4.30.
 23 **SIR BRIAN LANGSTAFF:** Shall we take a break for 25 minutes
 24 and come back then at -- let us make it 3.35.
 25 **(3.11 pm)**

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1 PCP among patients with haemophilia A and without
 2 underlying disease. Two have died. One remains
 3 critically ill."
 4 Would you have read and received the MMRWs?
 5 **A.** No, I wouldn't have seen that report. I was actually
 6 referring to the MMWR CDC when I said I wouldn't have
 7 seen the original report.
 8 **Q.** I don't think I have got a particular New England
 9 Journal article until the January, but would you
 10 expect to have become aware of that through some form
 11 or another in the weeks that followed?
 12 **A.** I would have thought so.
 13 **Q.** Then if we could have, please, Henry, HCDO0000556.
 14 We're in 1982 here. That report was July 1982. This
 15 is 13 September 1982.
 16 **A.** Sure.
 17 **Q.** It's a meeting of the UK Haemophilia Centre Directors
 18 Hepatitis Working Party. You, of course, were not
 19 a member of it, but we can see that Dr Kernoff was.
 20 **A.** Yes.
 21 **Q.** If we go, please, Henry, to the last page, we can see
 22 under the heading "Acquired Immune Deficiency
 23 Syndrome":
 24 "Following discussions at the annual general
 25 meeting of Haemophilia Centre Directors ..."

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(A short break)

(3.35 pm)

MS RICHARDS: Dr Colvin, I'm going to ask you now about
 the developing knowledge of risk in relation to HIV.
A. Yes.
Q. Your statement says you became aware of AIDS in 1982.
 When did you first become aware of reports of
 infection, AIDS, in haemophiliacs?
A. I think when a report would appear probably in the New
 England Journal. I think I may have said what I knew
 in my statement, actually, but I can go back to my
 statement. But it would have been -- as soon as it
 would appear in a journal like the New England, which
 would have been quite shortly after any announcement
 by the reports, I would know about it.
 What I wouldn't, I think, have done would have
 been to have read the original American report.
Q. We'll just look at that, and then we can go through it
 in a chronological sequence. So could we have,
 please, Henry, PRSE0000523, please.
 This is the MMRW from the Center for Disease
 Control, July 16, 1982. We can see the heading, and
 then we just need to look at the first two lines,
 I think -- two sentences:
 "CDC recently received reports of three cases of

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1 I haven't checked, Dr Colvin, to see if you were
 2 there. I'll check overnight, but I think you said you
 3 generally did attend.
 4 "... it was agreed by the working party that as
 5 the AIDS syndrome had similarities in its epidemiology
 6 to that of hepatitis B virus infection, enquiries will
 7 be made by members of the working party to ascertain
 8 the likelihood of transmission of the disease by blood
 9 or blood products."
 10 Do you recall any communications or discussions
 11 within UKHCDO or between you and Dr Kernoff around
 12 this time about the issue?
 13 **A.** No, I don't, but that doesn't mean to say it didn't
 14 happen because, you know, it's 40 years ago.
 15 **Q.** We know that in December of 1982 -- again, the initial
 16 source is the MMWRs -- there was a report of what
 17 we've been referring to as the San Francisco baby
 18 case.
 19 **A.** Yes, I know.
 20 **Q.** Do you recall learning about that?
 21 **A.** No, I don't.
 22 **Q.** Then we'll come, then, January 1983, to the
 23 New England Journal of Medicine, which I think you
 24 would have seen. Henry, PRSE0002410.
 25 We can see the date here at the top of the page,

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1 13 January '83, New England Journal of Medicine, "AIDS
 2 and preventive treatment in haemophilia".
 3 If we go to the second page, please, Henry, I'll
 4 just pick it up at the bottom of the page where it
 5 says this:
 6 "The fact that haemophiliacs are at risk for
 7 AIDS is becoming clear. If the use of cryoprecipitate
 8 will minimise this risk, the current home infusion
 9 programme needs to be revised."
 10 Then:
 11 "The studies reported in this issue in vitro
 12 abnormalities of immuno-regulation but the numbers are
 13 too small for definitive comparison of the risks of
 14 different modes of treatment. Unfortunately, the data
 15 are consistent with a greater potential for AIDS in
 16 the population treated with concentrate. Physicians
 17 involved in the care of haemophiliacs must now be
 18 alert to this risk. Preventing the complications of
 19 the present treatment may have to take precedence over
 20 preventing the complications of haemophilia itself."
 21 That's the article by Jane Desforges which you
 22 would have read?
 23 **A.** I would think so, yes.
 24 **Q.** Do you have any recollection of reading it at the
 25 time?

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1 second half, under the heading "Acquired
 2 Immunodeficiency Syndrome", it says this:
 3 "This was discussed in the after-lunch period.
 4 Dr Craske summarised the current position. He gave
 5 a clinical description of the AIDS syndrome."
 6 Then we see further information in relation to
 7 that set out in the second paragraph and then, if we
 8 keep going down, please, Henry, we pick it up towards
 9 the bottom of the page:
 10 "Up to 10 December 1982, some 800 people had
 11 been reported as suffering from the AIDS, and there
 12 was a 45 per cent mortality. Ten haemophiliacs in the
 13 US have been affected, and five have died. The
 14 youngest was aged seven. All cases have had prolonged
 15 treatment with Factor VIII, but there is no specific
 16 implication of one particular product or batch. Other
 17 cases involving blood and blood product transmission
 18 have included platelets transfused in three cases. In
 19 one of these cases, one of the donors was a young
 20 New York man in his 20s. A second case was
 21 a 20-month-old child with rhesus HDN who had received
 22 several units, including platelets known to have come
 23 from a homosexual donor who was asymptomatic at the
 24 time but who later died. The child has developed
 25 autoimmune haemolytic anaemia and a possible AIDS

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1 **A.** My main recollection is my wife's complaint that
 2 I used to read the New England Journal of Medicine in
 3 bed at this time before I went to sleep. So I think
 4 it's entirely possible and likely that I would have
 5 read this because I used to read the New England
 6 Journal of Medicine regularly, and this would be an
 7 important part. I can't really conceive that I
 8 wouldn't have read it, but I don't recall reading the
 9 actual article at all today.
 10 **Q.** Then in January of 1983, we know you attended
 11 a meeting at a London Airport hotel.
 12 The reference for that, Henry, is PRSE0002647.
 13 So if we just look at the top of the page to
 14 start with, we can see notes of meeting with Immuno at
 15 London Airport, 24 January, and the topic is
 16 "Hepatitis-reduced Factor VII and Factor IX
 17 concentrates for haemophilia therapy".
 18 Could we go to the last page please, Henry. We
 19 can see there the list of attendees, and we can see
 20 a few lines down it includes your name.
 21 Now, do you have any recollection of that
 22 meeting and how it came about?
 23 **A.** No, I don't.
 24 **Q.** If we look further up the page, please, Henry -- if we
 25 go to the previous page, sorry, and we go to the

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1 state."
 2 That's the San Francisco baby case. If we go on
 3 to the next page, please, Henry:
 4 "The incubation period for the syndrome appears
 5 to be six months to two years. In the UK so far, only
 6 one or two cases have been reported from the
 7 communicable diseases centre. The infectious
 8 precautions include discouraging homosexuals from
 9 donating blood or organs. Protocols from the US have
 10 been considered by the Hepatitis Working Party in the
 11 UK. Apparently, the American fractionation companies
 12 are very aware of the problem and are taking some
 13 unspecified measures to screen out such donors.
 14 The attention of the meeting was then drawn to
 15 the two articles [and we've looked at one of them,
 16 Dr Colvin] on the editorial in the New England Journal
 17 of Medicine on 13 January which, in summary, indicates
 18 that the T48 ratios among haemophiliacs receiving
 19 Factor VIII is greater among those who have been
 20 exposed to concentrates than those exposed to
 21 cryoprecipitate only. However, cryoprecipitate in the
 22 US comes from volunteer unpaid donors and therefore
 23 are presumably well motivated people. Final comments
 24 on the possible nature of the transmissible agents
 25 indicated that there may not be just one agent but

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1 a mixture, i.e. a barrage of viruses including
 2 hepatitis B, non-A, non-B, CMV and many others,
 3 possibly transmitted from asymptomatic healthy blood
 4 donors."

5 Now, I've read that effectively into your
 6 evidence because, clearly, on any view, by 24 January,
 7 you would have been up-to-date with this information?

8 **A.** Yes, sure.

9 **Q.** The attention of those present was expressly being
 10 drawn to the New England Journal of Medicine
 11 editorial.

12 Can you recall anything about the discussion at
 13 that meeting on this issue or any other?

14 **A.** I have already explained, I don't recall the meeting
 15 at all.

16 **Q.** Would you accept, seeing this material and the
 17 New England Journal -- and I know you have been
 18 following the evidence over the last couple of weeks,
 19 but by the beginning of 1983 or, in any event, by
 20 24 January 1983, you would have been aware that there
 21 was a risk to haemophiliacs of AIDS?

22 **A.** Yes.

23 **Q.** That the most likely route of transmission of AIDS for
 24 haemophiliacs was blood or blood products?

25 **A.** Yes.

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1 comment about the previous minute because one of the
 2 features of immunodeficiency in people with
 3 haemophilia was thought to be the exposure to factor
 4 concentrates of itself. Now, I never did any research
 5 in this area at all, but I was aware of those who
 6 believed, I think incorrectly, that the exposure to
 7 Factor VIII itself was immunosuppressive and might
 8 have been related to what had happened.

9 Now, of course, I've agreed entirely to what you
 10 asked me earlier, but I think there was a sense in
 11 which some people thought that there was an intrinsic
 12 tendency for factor concentrate to have an effect on
 13 immunity.

14 **Q.** But whether that explains the non-discussion of the
 15 issue at this meeting --

16 **A.** Only in the sense that if people believed that, they
 17 might have taken a different view to the one that
 18 we've just discussed, and in which case they wouldn't
 19 have thought it necessary to talk about this. I think
 20 that's unusual and unlikely, but you asked me to think
 21 of any reason I could possibly think of as to why this
 22 wasn't discussed, and that was the only one I could
 23 think of.

24 **Q.** But that wasn't a view to which you subscribed, and
 25 presumably at some time during the first half of 1983,

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1 **Q.** We then -- if we go to BART0000679, please. This
 2 is -- if we just zoom in slightly, Henry, thank you.
 3 This a further meeting of the North East Thames Region
 4 Association of Haematologists Working Party. It's
 5 9 February, so it's not long after the meeting that
 6 we've just looked at. You are there. Dr Kernoff and
 7 others are there.

8 If we just look down over what's discussed, we
 9 see there's a discussion about self-sufficiency for
 10 Factor VIII concentrate production. If we look down
 11 towards the bottom of the page, there's an issue about
 12 cross-charging and then, the end of the page, an aim
 13 to produce all Factor VIII in the region from local
 14 screened donors.

15 Then if we go to the next page, we can see
 16 there's then a discussion about designation of
 17 haemophilia centres. Then -- if we go further down,
 18 please, Henry -- collection of regional statistics,
 19 domiciliary, haemophilia nursing sister.

20 What is conspicuous by its absence is any
 21 discussion of AIDS at that stage locally.

22 Are you able to say why that wasn't by now at
 23 least on the agenda, even if not high on the agenda,
 24 for this working party?

25 **A.** I'm not able to. Perhaps I could make a very brief

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1 you must have had some of discussions with Dr Kernoff
 2 about AIDS?

3 **A.** That's very likely, but I can't remember the exact
 4 dates because we spoke together very often.

5 **Q.** No, I understand that, but presumably you would recall
 6 if he had come up with an unconventional theory about
 7 the link with AIDS?

8 **A.** I don't think that Peter particularly had such an
 9 unconventional link. All I'm saying is that I knew
 10 that around the country there were those who were
 11 studying the effect of concentrate on the body's
 12 immune system. That's all I'm saying.

13 **SIR BRIAN LANGSTAFF:** May I just ask, I suppose if one
 14 treats that as a possibility and one treats an
 15 infectious agent such as a virus as a possibility, the
 16 transmission on both cases would occur, on either
 17 theory, through blood products, would it not?

18 **A.** Sorry, could you explain that, sir?

19 **SIR BRIAN LANGSTAFF:** Yes.

20 The risk to which counsel has alerted you --

21 **A.** Yes --

22 **SIR BRIAN LANGSTAFF:** -- discussed at the meeting in
 23 January at Heathrow, which you can't remember,
 24 discussed in the New England Journal of Medicine, was
 25 a risk of blood products transferring some cause of

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1 AIDS to those who are haemophiliac.
 2 It doesn't much matter, for those purposes, for
 3 that analysis, whether the cause was viral or the
 4 abnormal proteins found in factor concentrate or
 5 whatever, does it?
 6 **A.** Well, it would -- I mean, let's just say for a moment,
 7 which clearly is not the case, that there was
 8 something about Factor VIII concentrate which
 9 inhibited the immune system, then that of itself could
 10 be the cause of an immunodeficiency condition, in
 11 which case a virus wouldn't necessarily be involved.
 12 I agree that that's not likely but it was considered.
 13 The other possibility is that if it was some
 14 kind of virus infection and people have been exposed
 15 to a very large amount of concentrate, it might be
 16 that those who had been very heavily exposed to
 17 concentrate might be more vulnerable to the immune
 18 deficiency illness than those who had not.
 19 But, I mean, I'm not trying to say to counsel or
 20 you, sir, that I don't believe and didn't believe at
 21 this point there was any transmissible agent, I think
 22 there was, it's just that counsel had asked me whether
 23 I could think of any reason why it wasn't discussed at
 24 the February meeting.
 25 **SIR BRIAN LANGSTAFF:** I think what I was putting to you

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1 was: On either view, what was doing it was getting
 2 the factor concentrate?
 3 **A.** Yes.
 4 **SIR BRIAN LANGSTAFF:** That was all I was asking.
 5 **A.** Yes, of course.
 6 **MS RICHARDS:** As well as the probability that this was
 7 a condition transmissible by blood products or by
 8 blood, would you agree that by January 1983, looking
 9 at -- even if one just looks at the New England
 10 Journal and the account given at that meeting at The
 11 London airport hotel, it was always known at that
 12 stage to have a very high mortality rate.
 13 **A.** Certainly the condition of AIDS was known to have
 14 a high mortality, yes, of course.
 15 **Q.** It seemed also to be apparent, and is expressly
 16 referred to in the notes of the meeting in
 17 January 1983, that there may be a significant lapse of
 18 time before the symptoms present themselves?
 19 **A.** Yes.
 20 **Q.** So the fact that there were only a few cases at that
 21 point identified wouldn't necessarily be a reliable
 22 guide to the true extent of the risk?
 23 **A.** Exactly.
 24 **Q.** Can we look at the 1983 returns that you made to
 25 UKHCDO.

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1 Henry, it should be at HCDO0000177_003.
 2 Thank you.
 3 So we can see this sample return. These are the
 4 annuals runs for 1983 of materials used to treat
 5 haemophilia A patients, carriers of haemophilia A and
 6 von Willebrand's disease patients. Centre is The
 7 London Hospital. You are identified as the director.
 8 As I understand it from Dr Winter, this is a return
 9 that would be filled in at the beginning of the
 10 following year?
 11 **A.** Yes.
 12 **Q.** So the aim is to give a picture of product usage
 13 during the 1983 calendar year?
 14 **A.** Indeed.
 15 **Q.** If we look at the figures for haemophilia A patients,
 16 total used at hospital in-patients and out-patients,
 17 for cryoprecipitate we've got -- well, we've got two
 18 figures. One is a figure in packs. Is the other
 19 figure that's written there the figure in units?
 20 **A.** It might be. I don't know who's written that figure
 21 because there's no exact figure that you can put on
 22 the number of units. But you might have expected
 23 something like 100 or just a bit less than 100 units
 24 per pack. So it's not very far off. Somebody's
 25 attempt to work out how many units it might be.

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1 **Q.** So that's your not handwriting anyway?
 2 **A.** I don't believe so, no.
 3 **Q.** So we can see that anyway you are using
 4 cryoprecipitate to that amount.
 5 We then have the figure, still in the column for
 6 hospital treatment, for NHS human Factor VIII
 7 concentrate, 336,645 units. Then we can see the
 8 figures -- in terms of commercial usage you're using
 9 Koate to the magnitude of 182,550 units, and Kryobulin
 10 108,052 units. So in terms of in-patient usage, it's
 11 a mix of NHS Factor VIII and commercial Factor VIII
 12 with some cryoprecipitate?
 13 **A.** Yes.
 14 **Q.** Then if we look at home treatment, we can see that
 15 in 1983 there's no cryoprecipitate there identified
 16 for home treatment?
 17 **A.** Of course.
 18 **Q.** We can see the majority then for home treatment is NHS
 19 human Factor VIII concentrate, 763,747, but there is
 20 some Factor VIII, some Koate, some Hemofil and
 21 a slightly larger amount of Kryobulin being used for
 22 home treatment?
 23 **A.** Yes.
 24 **Q.** Then if we just look across, for the sake of
 25 completeness, we've got for carriers for haemophilia A

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1 you're using DDAVP and tranexamic acid. I think that
 2 that's only one patient, we can see from the top of
 3 the page. Then for von Willebrand's disease patients,
 4 hospital provision is cryoprecipitate seems to be, in
 5 fact, the only treatment that's been used. Is that
 6 a correct reading?
 7 **A.** That looks correct to me.
 8 **Q.** Nine patients were treated but did not receive blood
 9 products. Do you know what that refers to?
 10 **A.** It might be patients who perhaps had menstrual
 11 difficulties who were given hormone therapy. It might
 12 be somebody who came up for something else and perhaps
 13 they had a wart on their hand and was given treatment
 14 for that. I mean, it could be almost anything. But
 15 I think it implies that we knew they had been to the
 16 hospital and been consulted but didn't actually get
 17 any particular haemostatic treatment.
 18 **Q.** Then if we look at --
 19 **A.** Sorry, haemostatic means things to stop the bleeding.
 20 **Q.** Then if we look at the top of the page, just in terms
 21 of the numbers of patients, we've got:
 22 "Total number of haemophilia A patients treated
 23 during the year: 78.
 24 "... carriers of haemophilia A ...: 1.
 25 "... von Willebrand's disease patients

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1 don't have returns I think in equivalent form for
 2 earlier years.
 3 If we just look towards the top of that page, we
 4 can see in terms of those with inhibitors, that's
 5 reference to two patients being treated.
 6 Then if we can just go to the return in relation
 7 to haemophilia B for the same year, HCDO0000177_005,
 8 and we can see here that you have treated
 9 11 haemophilia B patients during the year and one
 10 carrier of haemophilia B during the year.
 11 Then in relation to the haemophilia B patients
 12 both in hospital and for home treatment, the usage is
 13 NHS Factor IX concentrate, and then there's a small
 14 amount of fresh frozen plasma that's been used for the
 15 hospital treatment of a carrier of haemophilia B?
 16 **A.** That's a rather strange entry, actually, because --
 17 I'm quite pleased to see it because it implies that
 18 I realised that, for a carrier of haemophilia B, there
 19 was a risk of infection and that I was using fresh
 20 frozen plasma 3 bags which only contained the risk of
 21 three people's infection risk.
 22 So I might have decided, and it wouldn't have
 23 been the best thing to do, to give a carrier, for
 24 whatever reason I don't know, a Factor IX concentrate.
 25 It was much better to give those three bags of fresh

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1 treated ...: 16."
 2 Then if we go to HCDO0000177_004, please, Henry,
 3 we can see this is the annual return for 1983 of
 4 material used for the treatment of haemophilia A
 5 patients who have inhibitors.
 6 Although the unit has been written in the
 7 cryoprecipitate column, that's been crossed out and an
 8 arrow drawn?
 9 **A.** Yes.
 10 **Q.** So is it a fair inference that that should have been
 11 a record of NHS Factor VIII concentrate?
 12 **A.** Yes, I am sure it was, but it's a tiny amount. It's
 13 hard to know why anybody would be given that amount of
 14 NHS concentrate for an inhibitor because it wouldn't
 15 work anyway, but I mean, it's impossible to judge what
 16 that means, I think.
 17 **Q.** Then towards the bottom of the page we can see
 18 "Porcine Factor VIII [the] hyate C", 11000 units.
 19 **A.** At that time, if somebody had a very low titer
 20 inhibitor that was responsive to porcine Factor VIII,
 21 that's what we would have given.
 22 What's remarkable, in a way, in this record for
 23 1983 is that I had almost nobody with an inhibitor who
 24 was being treated.
 25 **Q.** Yes. Of course this is only a snapshot because we

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1 frozen plasma, however out-of-date such an idea was.
 2 **Q.** So that tells us the products that you were using
 3 simply in the calendar year of 1983. Other than the
 4 point you have just made about fresh frozen plasma,
 5 does what we have seen in those returns suggest any
 6 change of approach on your part or is that essentially
 7 consistent with how you had generally been treating
 8 patients?
 9 **A.** I think it's consistent, not least because it -- I'm
 10 relatively pleased to see that it was the case that
 11 the majority of my home treatment patients were
 12 treated with NHS concentrate and that we were using
 13 some NHS concentrate in the hospital, which was
 14 appropriate, but inevitably, because of the shortfall,
 15 we were using a significant quantity of commercial
 16 concentrate in the hospital.
 17 I can't explain the commercial concentrate in
 18 the home. It was, I think, about 10 per cent of the
 19 total usage. Of course, at this distance it's
 20 impossible for me to tell why that was the case. But
 21 it doesn't altogether surprise me.
 22 **Q.** Now having understood by January 1983 that there is
 23 this risk of AIDS potentially affecting haemophiliacs
 24 with high mortality rate and so on, as far as you can
 25 recall, did you, in the course of the year that

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1 followed, make any changes to your approach to
2 treating patients?

3 **A.** Well, if you look at the paper that I wrote about
4 cryoprecipitate, you will see that the patients who
5 were treated -- in a rather unusual way -- with
6 cryoprecipitate were treated between 1982 and 1984.
7 So I think the implication of that is that I was
8 thinking about the risk, and I think that I have to
9 rely on you to tell me when you want me to talk about
10 that paper.

11 **Q.** Let me see if I can find the reference to it,
12 Dr Colvin.

13 **A.** I mention it now only because it shows that I was
14 thinking about it.

15 **Q.** We have it somewhere. It may be I need to come back
16 to that in the morning, Dr Colvin, because I can't
17 find the reference currently. I can find a reference
18 to a study by you on heat treatment but I know there
19 is one in relation to usage of cryoprecipitate, so it
20 may be we can put that on screen tomorrow morning.
21 What, if any, recollection do you have of any
22 conscious rethinking of your approach to treatment
23 in 1983?

24 **A.** I think that, again, if one thinks about the little
25 work we did, I think it would have been to try to

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1 Would that have been your usual practice, in any
2 event, at that time?

3 **A.** Yes. Yes, it would.
4 I can give you the reference for the
5 cryoprecipitate study if you would like it now.
6 Perhaps you would rather tomorrow morning?

7 **Q.** Do you have the --

8 **A.** It's PRSE0003838.
9 But yes, it would have been.

10 **Q.** We will come back to the letter but I am happy to look
11 at the study.

12 **A.** May I -- oh, sorry.

13 **Q.** So this is the study that you were referring to?

14 **A.** Yes.

15 **Q.** "A prospective study of cryoprecipitate
16 administration: absence of evidence of virus
17 infection."
18 The summary of it is:
19 "In a prospective study of cryoprecipitate
20 administration to patients who had never received
21 large pool concentrates, no evidence of hepatitis or
22 HIV infection was detected in a follow-up period of
23 one year. Following the introduction of screening of
24 blood donors for anti-HIV in the UK in October 1985,
25 the use of cryoprecipitate in selected cases should be

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1 minimise the risk where it was sensible and possible
2 to do so. But it's very difficult at 40 years
3 distance to give you a clear view from my memory.

4 **Q.** Just going through the course of 1983, we can see that
5 in June 1983 you received a letter, as did other
6 directors, from Professors Bloom and Dr Rizza. It's
7 BART0000844.
8 We can see, Dr Colvin, this is a letter dated
9 24 June 1983. We've seen it in a similar form sent to
10 others but this is the version that's actually
11 addressed to Professor Jenkins and to you.

12 **A.** Indeed.

13 **Q.** It's headed "Acquired Immune Deficiency Syndrome". It
14 refers to a meeting of Reference Centre Directors on
15 13 May 1983 to discuss the problem in haemophilia.
16 Then in the second paragraph it says this:
17 "At the above mentioned meeting on May 13th, the
18 following general recommendations were agreed.
19 "1. For mildly affected patients with
20 haemophilia A order von Willebrand's disease and minor
21 lesions, treatment with DDAVP should be considered.
22 Because of the increased risk of transmitting
23 hepatitis by means of large pool concentrates in such
24 patients, this is in any case the usual practice of
25 many Directors."

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1 reconsidered."
2 I think you had an observation you wanted to
3 make about --

4 **A.** Can I explain what was happening --

5 **Q.** Yes.

6 **A.** -- because I think it is really quite important.
7 First of all, this is not really research. What
8 it is, is an analysis of a clinical decision that
9 I had made on clinical grounds, and you'll see later
10 in the paper, that I've said some patients are not
11 suitable for DDAVP. So I had considered using DDAVP
12 in these patients. It's very important because you
13 might say, are you, Dr Colvin, bringing people to the
14 risk of cryoprecipitate when they could have DDAVP
15 which wouldn't be a method.
16 But the position was that -- there was one
17 patient I think with a very severe haemarthrosis of
18 the knee with mild haemophilia, and another few
19 patients with von Willebrand's disease who were having
20 elective surgery that I didn't think was appropriate
21 for DDAVP for the reasons that I've explained.
22 So for these patients, I would have said to
23 them -- this is, I think, between '82 and '84. I
24 would have said to them, "I am concerned about the
25 safety of the concentrates that we need to use for

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1 your operation. My view is that for this relatively
2 minor operation, I can use cryoprecipitate to treat
3 you, that there is of course a risk of viral infection
4 with cryoprecipitate, and therefore, as we go in to do
5 this surgical procedure, I would like to have your
6 consent to take blood samples after the operation to
7 confirm that you haven't had an infection."

8 So this is not research that needs a research
9 ethics approval; it is a study of selected clinical
10 practice. Now, you might say, well, did you give your
11 patients the opportunity to have DDAVP? And the
12 answer is: no, I didn't because I didn't think it was
13 clinically indicated. I think it's very important for
14 you and Sir Brian to understand what this study
15 actually means.

16 But by the time it was published,
17 cryoprecipitate was dead because it's published
18 I think in '88 or '87, and it's sent to publication in
19 '86. So by the time it's published, it's actual
20 history. But it shows that I was interested in '82 in
21 trying to keep these particular patients with mild-ish
22 von Willebrand's disease and a bad haemarthrosis using
23 the concentrate that might be appropriate for this
24 advice before it was given.

25 Q. Yes. If we go back to the letter of advice, Henry, so

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1 imported concentrate. So that's not quite completely
2 untreated patients but patients who haven't previously
3 had commercial concentrates. Did you have any
4 particular policy or practice in relation to that
5 category of patients?

6 A. So this is where the word "circumspect" becomes very
7 important and the policy was that if we were going to
8 do major surgery on a patient at that era, then I only
9 had the option of using commercial concentrate.

10 Q. Would you agree with me that this is a document that
11 is very much leaving matters still to the judgment of
12 the individual Haemophilia Centre Director?

13 A. So we, of course, heard the discussion over the last
14 few days, including Mark Winter's discussion, about
15 the degree to which the UK Haemophilia Centre
16 Directors organisation, and the Reference Centre
17 Directors in particular, gave valuable advice and
18 I think, in retrospect, this advice could have been
19 clearer and more prescriptive.

20 But it is the case that guidelines or advice is
21 only ever guidelines and advice. From my medico-legal
22 experience over many years, I have noticed many of the
23 problems in medico-legal practice are because people
24 haven't perhaps read the guidelines or, more
25 importantly, when they have read the guidelines and

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1 it was BART0000844. We were looking at the paragraph
2 numbered 1, if we just go down a little, Henry. Thank
3 you. The mildly affected patients, von Willebrand's,
4 minor lesions treatment with DDAVP. Then if we go to
5 paragraph 2:

6 "For treatment of children and mildly affected
7 patients, or patients unexposed to imported
8 concentrates, many directors already reserve supplies
9 of NHS concentrates (cryoprecipitate or freeze-dried),
10 and it would be circumspect to continue this policy."

11 We discussed the existing policy you had in
12 relation to the treatment of children, Dr Colvin. In
13 terms of patients unexposed to imported concentrates,
14 I think your answer earlier was that, in your clinic,
15 that would have been largely children, in any event;
16 is that correct?

17 A. Sorry, say that again.

18 Q. Sorry. I had asked you about whether you had any
19 particular policy for patients who had previously been
20 untreated, and your response, I think, was that those
21 would generally be children?

22 A. Probably, yes --

(Overspeaking)

23 Q. The category here -- you have children, we have mildly
24 affected patients, and then patients unexposed to
25

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1 have a different view or take a view of
2 interpretation, they don't write it in the notes.
3 I have always been a very keen note writer, and
4 I think my junior staff in the past got rather tired
5 of me writing notes.

6 But I think it's very difficult, and I would
7 have appreciated more advice from UKHCDO, and of
8 course we haven't yet discussed it, but the Galbraith
9 letter becomes very important in this context, which
10 you may be about to show me.

11 Q. I may deal with that tomorrow, Dr Colvin.

12 But just whilst we're still looking at this,
13 would you agree that, in the second paragraph, for
14 children mildly affected, those who haven't previously
15 had commercial concentrates, this isn't even saying:
16 prioritise cryoprecipitate over factor concentrates.
17 It's saying: prioritise NHS whatever the nature of
18 whether it's cryoprecipitate or factor concentrates
19 over commercial.

20 A. Yes, it does say that.

21 Q. In your evidence to the Archer Inquiry about this
22 advice, you observed that the advice to give children
23 and mildly affected patients NHS products meant that
24 those who weren't children or weren't mildly affected
25 were probably going to be treated with commercial

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1 products. It might mean certain cohorts more likely
 2 to receive commercial products than hitherto?
 3 **A.** That, of course, is about resource allocation.
 4 **Q.** Did this advice have any effect upon your policy of
 5 using NHS concentrates for home treatment?
 6 **A.** I don't think so, no.
 7 **Q.** We can see from the return that we looked at, as a
 8 matter of fact, you did continue to use commercial
 9 concentrates not to the same extent as NHS
 10 concentrates but still to a reasonably significant
 11 degree.
 12 **A.** It looks like that. Obviously, I have no memory of
 13 how or why but this is the example of the statistics.
 14 **MS RICHARDS:** Sir, I note the time. I've got a number of
 15 further documents I need to explore with Dr Colvin, so
 16 it might be this is a convenient point at which to
 17 break and pick it up in the morning.
 18 **SIR BRIAN LANGSTAFF:** Yes, certainly. We'll do that.
 19 **A.** May I make a comment on that document?
 20 **MS RICHARDS:** This one here?
 21 **A.** Yes.
 22 **Q.** Yes, certainly.
 23 **A.** I mean, I have it in front of me. If we go to the
 24 bottom of page 1, item 2, it reads:
 25 "Another point concerns the proposed trials of

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1 cryoprecipitate or NHS freeze-dried concentrate. It
 2 actually says:
 3 "Many directors already reserve supplies and it
 4 would be circumspect to continue this policy."
 5 It could be read literally as meaning whatever
 6 the directors are currently doing, they go on doing.
 7 It doesn't say anything about recommending anything to
 8 anyone else.
 9 **A.** I think it also implies, sir, that if patients on home
 10 treatment were on imported concentrates, they should
 11 remain on imported concentrates.
 12 **MS RICHARDS:** Do you recall -- I know I should finish but,
 13 picking up on that point, do you recall whether that
 14 was the position for your patients?
 15 **A.** I don't.
 16 **Q.** Thank you.
 17 **SIR BRIAN LANGSTAFF:** The language is just a bit -- if
 18 I say "mealy-mouthed" it may be misunderstood, but
 19 it's not very clear.
 20 **A.** I certainly think it was less than helpful now that
 21 I think back 40 years.
 22 **SIR BRIAN LANGSTAFF:** Yes, thank you very much. Tomorrow
 23 morning, 10 o'clock in that case.
 24 **(4.16 pm)**
 25 **(Adjourned until 10.00 am the following day)**

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1 hepatitis-reduced factor concentrates. There is no
 2 evidence that the processes involved in the
 3 manufacture of these inactivate any other hypothetical
 4 viruses" and then it goes on over the page.

5 "It is still important that the effectiveness of
 6 imported hepatitis-reduced concentrate vis-a-vis
 7 hepatitis is subjected to formal clinical trials in
 8 mild haemophiliacs notwithstanding our general
 9 recommendation above. Directors are urged not
 10 [underlined] to use these concentrates randomly on
 11 a named patient basis."

12 That may become important if you were to want to
 13 discuss with me Dr Winter's evidence from his policies
 14 in 1984.

15 **MS RICHARDS:** Okay, thank you.

16 **SIR BRIAN LANGSTAFF:** Yes, the only other thing, perhaps,
 17 if we can just go back to the first page of that
 18 letter -- can we go back to the previous page please,
 19 Henry -- and look at the recommendation number 2,
 20 there may be a mismatch between what it says literally
 21 and how it was meant to be understood.

22 You have understood it, as I think it may well
 23 have been meant to be understood, that the guidance is
 24 for those who are mildly affected or previously
 25 unexposed to imported concentrates should have

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