

Thursday, 1 October 2020

1  
 2 (10.00 am)  
 3 **SIR BRIAN LANGSTAFF:** We have Dr Winter this morning.  
 4 Shall we have -- Dr Winter, would you come forward,  
 5 please.  
 6 **DR MARK WINTER (affirmed)**  
 7 **SIR BRIAN LANGSTAFF:** Dr Winter, I understand that you  
 8 don't always find it very easy to hear.  
 9 **A.** I'm very deaf, if that's what you mean.  
 10 **SIR BRIAN LANGSTAFF:** That's a better way of putting it.  
 11 I was being polite. We'll do what we can to help.  
 12 I'm raising it now so that everyone understands that  
 13 council will speak slowly, and that if you have any  
 14 difficulty in hearing, please indicate, and one way or  
 15 the other, we hope that you will hear everything. If  
 16 you don't, please let us know.  
 17 **A.** I've managed through my hearing aids to get on to your  
 18 loop-system, so you are very clear at the moment.  
 19 **SIR BRIAN LANGSTAFF:** I hope it continues that way, and  
 20 I hope the same is true for counsel, so thank you for  
 21 that.  
 22 **Questioned by MS RICHARDS**  
 23 **Q.** Dr Winter, I'm just going to ask you, first of all, to  
 24 give us an overview of your career. My understanding  
 25 is that you studied at medical school at Guy's

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1 around the whole experience of one day, you went out  
 2 on the vans and helped blood to be collected. You  
 3 spent some time in the laboratory. You spent some  
 4 time seeing how the fractionation, such as it was,  
 5 happened before it went off to Elstree and, you know,  
 6 the day-to-day workings of a blood transfusion  
 7 service.  
 8 **Q.** So you transferred, as you just referred, in 1979 to  
 9 Guy's Hospital as lecturer and honorary senior  
 10 registrar?  
 11 **A.** Yes.  
 12 **Q.** That was in the Haematology Department at Guy's?  
 13 **A.** It was.  
 14 **Q.** Then you remained there until late 1983, and on  
 15 1 December, you took up a consultant post at Thanet  
 16 General Hospital in Margate?  
 17 **A.** Yes. It was -- the post was -- the health authority  
 18 in those days was Canterbury and Thanet, and there was  
 19 a haemophilia centre there which, for historical  
 20 reasons, covered nearly all of the county of Kent and  
 21 was the sort of the biggest in the south-east outside  
 22 of London. So it was a curious arrangement because of  
 23 its geographical position.  
 24 **Q.** Then that centre relocated to Canterbury in the  
 25 mid-1990s and became a comprehensive haemophilia care

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1 Hospital between 1968 and 1973?  
 2 **A.** Correct.  
 3 **Q.** You then undertook, over the following three years,  
 4 various roles in general medicine?  
 5 **A.** Yes.  
 6 **Q.** Then between 1976 and 1979, you were a lecturer and  
 7 honorary senior registrar at the Middlesex Hospital.  
 8 **A.** (Nodded)  
 9 **Q.** Is that where you undertook your haematology training?  
 10 **A.** That's where I started, and then after four years,  
 11 I transferred sideways to a similar post at  
 12 Guy's Hospital where my training was completed in  
 13 1983.  
 14 **Q.** Whilst you were at the Middlesex Hospital, I gather  
 15 that you were seconded for six months to the Edgware  
 16 Regional Blood Transfusion Centre?  
 17 **A.** Yes. It was part of standard haematology training  
 18 that all trainees had to spend six months at  
 19 a regional blood transfusion centre to give them  
 20 experience of the way in which transfusion centres  
 21 work.  
 22 **Q.** What were your duties, in outline, at the transfusion  
 23 centre?  
 24 **A.** Nothing of any great significance, to be honest. It  
 25 was really observatory. I mean, you sat in. You went

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1 centre?  
 2 **A.** Yes. For the -- really because the centre had grown  
 3 so much and because the geographical access was so  
 4 poor and the facilities were not very good that the  
 5 service was put out to tender by the local health  
 6 authority and was eventually relocated into very good  
 7 facilities on the Canterbury site. So that was a big  
 8 step forward. Then shortly after that, we managed to  
 9 get accreditation as a comprehensive care centre.  
 10 **Q.** You retired from that post in 2011.  
 11 **A.** Yes.  
 12 **Q.** Then, in terms of your membership of or involvement  
 13 with other relevant organisations, you were a member  
 14 of the United Kingdom Haemophilia Centre Directors  
 15 Organisation from late 1983 until 2011?  
 16 **A.** Yes, as are all Haemophilia Centre doctors.  
 17 **Q.** I think, during that time, you were at various stages  
 18 on UKHCDO working parties of one kind or another?  
 19 **A.** I was.  
 20 **Q.** You became a designated HIV physician for the area --  
 21 was it the whole of Kent, or the Margate area?  
 22 **A.** It was for the health authority. This was really an  
 23 unusual step. As we'll doubtless discuss, we had  
 24 a particularly significant HIV problem, and the AIDS  
 25 Control Act, which I think was 1985, stipulated every

1 HIV -- every health authority had to have a nominated  
2 HIV physician. So they said to me, how would I like  
3 to be that person, as I seemed to be the only one who  
4 had any HIV expertise. So from that moment on, I only  
5 did haemophilia and HIV.

6 But that, I think, gave me different insights,  
7 because I think I was the only haemophilia doctor who  
8 was an HIV physician, so I had people with haemophilia  
9 and HIV, and some people with HIV who did not have  
10 haemophilia.

11 **Q.** You're right. We'll come on to that in more detail  
12 later.

13 You were a medical trustee appointed by the  
14 Department of Health for the Macfarlane and Eileen  
15 Trusts from 1996 to 2009?

16 **A.** Yes. I think that came out of the -- you know, the  
17 rather unique HIV situation. I was a choice to be the  
18 trustee which -- the dates you say.

19 **Q.** Again, I'll ask you some more about that at a later  
20 stage.

21 You had some involvement with The Haemophilia  
22 Society. As I understand it, you were on their  
23 treatment and care committee -- and I'm taking these  
24 dates from your CV -- from 1987 to 1991. You were on  
25 their General Services Committee from 1992 to 1996,

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1 Guy's was an accredited haemophilia centre, but  
2 a small one; is that right?

3 **A.** Well, it was because it was only barely a mile from  
4 St Thomas' which was a major centre. So, in a way, it  
5 was quite curious that it was seeing people with  
6 haemophilia at all, but there were some haemophiliacs  
7 who historically had gone there and chose to stay  
8 there. Neither of the consultants had an interest or  
9 expertise in haemophilia; so, together with another  
10 senior registrar, I started to get involved and that  
11 would be the first time really that I got involved  
12 with haemophilia patients.

13 **Q.** Roughly how many patients were registered with Guy's  
14 -- haemophilia patients -- during that period?

15 **A.** Well, there probably was sort of 30 or 40 registered,  
16 but there was a hardcore of sort of ten to 15 severely  
17 affected patients of all ages.

18 **Q.** I think your statement suggests mostly adults, but  
19 there were a small number of children.

20 **A.** There were.

21 **Q.** The director of the Haemophilia Centre was Dr Percy  
22 Barkhan?

23 **A.** He was an expert in vitamin K metabolism.

24 **Q.** Yes. You have said in your statement, in practice,  
25 the haemophilia patients were managed by the senior

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1 and their Medical Advisory Panel from 1999 to 2005?

2 **A.** I was. I was particularly involved with them when we  
3 were trying to pressurise the Government to set up  
4 what became the Macfarlane Trust. So I acted with  
5 them as a sort of media liaison and medical support,  
6 and we went around -- we went to the House of Commons  
7 a few times and made presentations and lobbied  
8 politicians. So, yes, I was actively involved with  
9 the Society.

10 **Q.** Then you were one of the founders of an organisation  
11 called the Haemophilia Alliance. Again, I'll ask you  
12 a little more about that later. That was established  
13 in 1999?

14 **A.** It was.

15 **Q.** Now, you also have given evidence to both the Archer  
16 Inquiry and the Penrose Inquiry?

17 **A.** I did.

18 **Q.** I'm going to take your evidence to those inquiries as  
19 read, Dr Winter. I'm not going to go through it.  
20 Although, inevitably, my questions will cover some of  
21 the same ground, and we may look at a handful of  
22 extracts from your evidence.

23 I want to start, if I may, by asking you about  
24 the four years or so that you were at Guy's Hospital,  
25 so from 1979 to 1984.

6

1 registrars. I think one of the other registrars would  
2 have been Dr Clarke; is that right?

3 **A.** No. He was the other consultant. He was also not an  
4 expert in haemophilia.

5 **Q.** Can you recall who the other registrars were?

6 **A.** I can. They were a husband and wife team, Dr Hugh and  
7 Yvonne Williams.

8 **Q.** Now, your statement explains that, as a registrar at  
9 Guy's, you weren't involved in the procurement of  
10 blood products.

11 Can you help us with whose decision it was as to  
12 what products to source and use at Guy's? Was it  
13 Dr Barkhan's?

14 **A.** Well, I was certainly not part, in any way, of the  
15 procurement, as you say, because I had no role in sort  
16 of day-to-day managerial functions as, effectively,  
17 a trainee. My recollection was that we received from  
18 a transfusion centre supplies of such NHS-derived  
19 Factor VIII concentrate as was available, and that  
20 almost certainly was never enough. So to top that  
21 up -- I'm sure they supplied to nearly all centres --  
22 we had to purchase some commercial concentrate to meet  
23 needs.

24 There was a particular issue in the south.  
25 Every health authority was supposed to have its own

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1 Blood Transfusion Service, but for reasons that were  
 2 never clear, the south-east Thames did not have its  
 3 own Blood Transfusion Service. So the Tooting centre,  
 4 the Tooting Blood Transfusion Unit, covered two very,  
 5 very large regional health authorities. It covered  
 6 the south-east, and it covered the whole of the  
 7 south-west, and that really led to a lot of problems  
 8 because that service was inevitably under a great deal  
 9 of pressure, in terms of clinical demand.

10 I don't recall, I think, that some -- you know,  
 11 we went to the pharmacy and said, you know, we're not  
 12 receiving enough Factor VIII concentrate that is  
 13 NHS-derived. We're going to need to buy some  
 14 commercial concentrate. I can't remember which one we  
 15 used, and, as I say, I was not part of the contractual  
 16 arrangement.

17 **Q.** The way you've put it in your statement is your  
 18 recollection that you received an allocation of NHS  
 19 concentrate, and then a shortfall was covered by the  
 20 usage of commercial concentrates?

21 **A.** Yes.

22 **Q.** I'm going to ask you more about cryoprecipitate in  
 23 a while, but just dealing with the use of it as  
 24 a matter of fact, your statement says that at Guy's,  
 25 cryoprecipitate was not used, although it was

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1 **Q.** So that was effectively your decision and the decision  
 2 of the colleagues you've mentioned?

3 **A.** Yes.

4 **Q.** I'll come on later to the pros and cons of  
 5 cryoprecipitate, Dr Winter.

6 You also said in your statement that when you  
 7 started at Guy's there was no home treatment  
 8 programme, but you established one. Can you just  
 9 explain a little more how you went about it, what  
 10 discussions took place?

11 **A.** Well, it's only, as we've said, a pretty small number  
 12 of patients. But, you know, factor VIII concentrates  
 13 came in, what, '73/'74, and they instantly and  
 14 immediately revolutionised the quality of life for  
 15 people with haemophilia, and by the mid-1970s, most  
 16 centres had established this package of comprehensive  
 17 care which included the home treatment programme. So  
 18 this wasn't anything controversial. It was surprising  
 19 that Guy's, you know, for patients with severe  
 20 haemophilia, didn't have such a programme established.

21 So I spoke to Dr Barkhan, and he thought, you  
 22 know -- I mean, his attitude was he wasn't going to  
 23 get involved with the management of haemophilia care,  
 24 even though they were a designated haemophilia centre,  
 25 and he was very happy for us to take the matter

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1 available.

2 **A.** It was used on occasions. If we had, for instance,  
 3 a patient with mild haemophilia or von Willebrand's  
 4 disease -- already, you know, late 1970s -- we'll be  
 5 talking more about this, doubtless. But we're already  
 6 aware of the evolving data about abnormal liver  
 7 function, suggestive of hepatitis. We were trying to  
 8 limit the exposure of patients to Factor VIII  
 9 concentrates if they were not regularly treated  
 10 patients.

11 So I think, occasionally, if they were children,  
 12 if it was a rarely treated child, particularly if they  
 13 were adults, maybe on occasions if the products were  
 14 in short supply, we certainly did use occasional  
 15 cryoprecipitate. Cryoprecipitate is so laborious to  
 16 give up you don't forget giving it and, you know,  
 17 I can remember days when we sat there drawing it up  
 18 and giving it to patients, but there weren't very many  
 19 of those days.

20 **Q.** Maybe you don't know the answer to this, but do you  
 21 know whose decision it was at Guy's to make only  
 22 limited use of cryoprecipitate? Was that  
 23 Dr Barkhan's?

24 **A.** No. Everything -- all those clinical decisions were  
 25 left to the two registrars running the programme.

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1 forward. It didn't involve very much in the way of  
 2 financial input. It was really logistics. It was  
 3 training patients how to give their own injections,  
 4 training parents how to give injections, getting  
 5 transport arranged so we could get Factor VIII to the  
 6 home setting. There wasn't a great deal of expense  
 7 involved. It was really quite a straightforward  
 8 undertaking.

9 **Q.** Was any consideration given as to whether setting up  
 10 a home treatment programme would increase the demand  
 11 for concentrates and, therefore, potentially increase  
 12 the need for commercial concentrates to be used?

13 **A.** Well, I think there's data that the use of Factor VIII  
 14 was already increasing at that time, and, in  
 15 particular, people were beginning to start to use  
 16 prophylaxis; that's to say, Factor VIII given not to  
 17 treat a bleed but to prevent a bleed. People with  
 18 haemophilia, once they were established on home  
 19 therapy, which was such an enormous advantage, they  
 20 could take Factor VIII to their school or to their  
 21 work and inject it in the place where they were. You  
 22 know, their life didn't revolve around haemophilia  
 23 centres any longer. It just gave them, you know,  
 24 complete independence. They then began to look at  
 25 their lives and say, "Every Tuesday evening I play

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1 tennis and it seems to me sensible because it's a risk  
2 activity but one that I very much enjoy, I'm going to  
3 talk to the doctors about whether I might give myself  
4 an injection to target that period of activity".

5 So prophylaxis was, you know, pioneered by the  
6 Swedish, really, that were starting to be there as  
7 part of haemophilia management and something that most  
8 particularly for children, later for adults, was  
9 something that was really effective.

10 So Factor VIII was growing in usage from the  
11 mid-1970s onwards.

12 **Q.** What information or advice did you or your fellow  
13 registrar colleagues give to patients or parents of  
14 patients in relation to home treatment and the use of  
15 Factor VIII?

16 **A.** Well, I mean, there were criteria that you had to jump  
17 through to be able to get onto the programme. You'd  
18 be able to do your own injections if you were an  
19 adult. If it was a child, we needed to be satisfied  
20 that the parents had the ability to recognise a bleed  
21 and then to implement the Factor VIII therapy  
22 promptly. To keep records. So there were a number of  
23 hoops the patients had to jump through from our point  
24 of view, and then we obviously informed them as to,  
25 you know, the nature of concentrate, to look out for

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1 really difficult. So people with haemophilia need  
2 regular blood checks anyway as well as wellness  
3 checks, and part of that package of blood tests was to  
4 do hepatitis markers.

5 I was certainly aware of the evolving data  
6 around non-A, non-B. I can remember us talking about  
7 it. I can't recall at this distance of time whether  
8 we spoke to the patients about our concerns.

9 **Q.** I'll ask you a little more about that at a later stage  
10 but, again, just dealing with what, as a matter of  
11 fact, was established at Guy's, what you've said in  
12 your statement is, in terms of the treatments that  
13 were used for patients, with severe haemophilic  
14 adults you would use either the BPL, Elstree product  
15 or commercial depending upon supplies.

16 Do you have any sense or recollection as to how  
17 often it was that you had to use commercial products  
18 because there wasn't enough Elstree material  
19 available?

20 **A.** No, but it was such a recurrent thing for the next  
21 seven or eight years really, extending into my  
22 consultancy. Factor VIII was always in short supply  
23 nationally, as we all know, but it was in especially  
24 short supply in these two health authorities because  
25 it was being served by one transfusion centre, who

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1 any side effects, even though the side effects were  
2 much less than with cryoprecipitate, which really did  
3 quite commonly cause significant side effects.

4 I can't remember whether we gave them, at that  
5 stage, any written publications. It's more than  
6 40 years ago. I can't remember -- I can't remember  
7 whether we said anything to them about the evolving  
8 evidence about non-A, non-B.

9 We certainly would have spoken about hepatitis  
10 viruses because part of being on a comprehensive care  
11 programme, including home therapy, is to come in every  
12 two or three months and have a full clinical review,  
13 and that included blood tests which included hepatitis  
14 markers. So the patients certainly were aware that  
15 they were being screened every three months or so. We  
16 didn't have hepatitis B vaccine at that stage, but  
17 they were aware that part of the package of care they  
18 were getting was a range of blood tests which have to  
19 be carried out on people with haemophilia. Most  
20 especially for trying to see whether they had  
21 developed what we call an inhibitor. About  
22 10 per cent of people with haemophilia develop an  
23 antibody which recognises the Factor VIII and destroys  
24 it, and that's a very significant clinical development  
25 because it makes future treatment with Factor VIII

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1 were working flat out and who just couldn't cope with  
2 demand. So it was a very regular feature that you  
3 would have to top up with commercial.

4 **Q.** Do you know or recollect whether anything was said,  
5 for example, by you or your colleagues or Dr Barkhan  
6 or others about this shortage and this particular  
7 problem of having to depend on Tooting, which was  
8 covering these two large Thames Regional Health  
9 Authority areas? Was that problem raised with the  
10 Blood Transfusion Service; do you know?

11 **A.** Well, not to my knowledge. As I say, I wasn't  
12 a consultant. I was a doctor in training so I had no  
13 sort of managerial/administrative roles, and although  
14 it was a designated centre, you'll see, one of the  
15 papers you sent me of a UKHCDO meeting, I represented  
16 Dr Barkhan, and I can remember Dr Barkhan didn't ever  
17 go to haemophilia meetings. He used to ask me to  
18 represent him, which I was happy to do. But I had no  
19 sort of managerial responsibilities in doing that.

20 **Q.** Then in relation to moderate haemophiliacs, so again  
21 this is still at Guy's, your statement says that you  
22 would use DDAVP or, wherever possible, BPL  
23 concentrate?

24 **A.** Yes, moderate haemophiliacs, some do respond to DDAVP,  
25 some don't, so you would have to assess the situation.

16

1 If they did respond, fine, you would use that,  
2 depending on what was the need for Factor VIII. If  
3 they were about to have major surgery, the DDAVP  
4 wouldn't be enough.

5 **Q.** Where you say "wherever possible, BPL concentrate",  
6 does that mean that, in all probability, some moderate  
7 haemophiliacs would have received commercial  
8 concentrate because of the shortfall?

9 **A.** Yes. I mean, all these deliberations were based on an  
10 evolving understanding that you really did not want to  
11 use commercial concentrates if at all possible, as set  
12 out so unforgettably in the World in Action  
13 documentary which we had seen.

14 So this was something that we didn't really ever  
15 want to do. You know, if you had said to us, "What  
16 sort of Factor VIII would you want?", we would have  
17 said, "We want BPL Factor VIII for our patients and we  
18 don't want to use anything else". But the reality was  
19 there just weren't the supplies to do that, so it was  
20 with reluctance, great reluctance, that we used  
21 commercial product.

22 Then we obviously, as recommended by UKHCDO,  
23 started to say, "Well, who should we prioritise to  
24 give the BPL product to?" It was obviously children,  
25 mildly affected patients, patients that weren't having

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1 a different situation. Then it really depended on the  
2 answer to the question: why does this person need  
3 Factor VIII? If the answer was because they are  
4 having a hernia, which is a minor surgical procedure,  
5 you might say, "I really don't -- you know, this might  
6 be the only time in their life this patient gets  
7 Factor VIII, I might do a wait and see policy here.  
8 I might not give Factor VIII and see if we can get  
9 away with it, with local measures."

10 But if on the other hand they were having open  
11 heart surgery, I they would -- you would say, "Well,  
12 DDAVP doesn't work. This patient will have to have  
13 Factor VIII."

14 **Q.** You would give Elstree if it was available but if it  
15 was not available and you felt you had to use  
16 Factor VIII, for the reasons you have given, it could  
17 be commercial?

18 **A.** Correct.

19 **Q.** Then you have alluded to the position of children  
20 already but your statement says, as you've confirmed,  
21 children were prioritised to receive treatment with  
22 BPL supplies, if available effectively. So again,  
23 with children, is it possible/probable that, on some  
24 occasions at least, they may have had to be treated  
25 with Factor VIII concentrates that were commercial

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1 Factor VIII very often, because we were especially  
2 sensitive to the possibility of giving them viruses if  
3 they were only going to have a few life-time  
4 treatments.

5 **Q.** With mild haemophiliacs and those with von Willebrand  
6 disease, your statement suggests that the first  
7 treatment of choice would have been DDAVP.

8 **A.** Yes, we would have assessed them to see whether the  
9 DDAVP -- response to DDAVP is variable, you have to  
10 assess it, but we would have assessed them. I mean,  
11 von Willebrand's is a particular case because, in  
12 fact, Factor VIII is usually not an appropriate  
13 treatment. So all von Willebrand's we would have  
14 expected to treat with DDAVP, and mild haemophilia we  
15 would have expected to but it would have depended on  
16 how much rise in Factor VIII could the DDAVP treatment  
17 lead to.

18 **Q.** With mild haemophiliacs, if you couldn't use DDAVP, is  
19 it possible that at Guy's, because of the shortfall  
20 that you have explained, mild haemophiliacs might have  
21 been treated with commercial concentrates?

22 **A.** It is possible. It very much depended on the clinical  
23 context. If it was a mild haemophiliac and if DDAVP  
24 wasn't going to work -- which was unusual for mild but  
25 something that happened -- then you were in

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1 concentrates because you didn't have enough Elstree  
2 product?

3 **A.** Well, we had -- each month there was a supply, and the  
4 particular dynamic was, as I recall, the policy was  
5 Elstree sent out, in terms of Factor VIII -- there was  
6 a formula related to the amount of plasma that had  
7 gone in from the local Blood Transfusion Service. So  
8 how much Factor VIII came to your region was related  
9 to how much plasma Tooting had sent to Elstree. There  
10 was this formula.

11 But we did every month -- it was monthly, as  
12 I recall -- get a supply which came into pharmacy.  
13 Now, children would have been our priority, and of  
14 course they need less Factor VIII than adults. So my  
15 recollection is that I don't -- you know, this would  
16 have been the first choice, that a child always got  
17 BPL. I can't remember giving a child commercial but  
18 I couldn't be absolutely sure.

19 **Q.** The formula that you've mentioned, that the amount  
20 provided by way of BPL Factor VIII concentrate was  
21 related to the amount of plasma supplied, did that  
22 make it difficult to plan, because you would have no  
23 control and presumably no knowledge of how much plasma  
24 had been supplied by the transfusion centre to  
25 Elstree?

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1 A. It was a very long-running and thoroughly  
 2 unsatisfactory difficulty and, of course, there was  
 3 then this great variability of financial need. You  
 4 know, haemophilia doctors all round the region didn't  
 5 know whether they were going to need to top up or not.  
 6 The finance departments hated this sudden appearance  
 7 of a haemophilia doctor saying, "We didn't get as much  
 8 BPL Factor VIII this month as we expected, I'm going  
 9 to need to spend another £50,000 topping up." They  
 10 hated things like that. So it was a recurrent  
 11 difficulty. When we talk in a minute about the  
 12 future, I remember in particular that Dr Savidge at  
 13 St Thomas', and when I was at Canterbury, because we  
 14 had -- we had contracts set up with our pharmacies, we  
 15 had close contact with our pharmacy divisions,  
 16 I remember for some years we directed the BPL product  
 17 to the smaller centres because the doctors there  
 18 didn't have -- you know, they didn't have resource to  
 19 go and order commercial, they didn't have designated  
 20 budgets, they were essentially leukaemia doctors.  
 21 Of course if we had that policy, St Thomas' and  
 22 the Canterbury centre were buying in bulk, so it was  
 23 much better for the NHS because we could drive down  
 24 the price because we were buying such large amounts.  
 25 But I remember for several years the smaller centres

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1 causes joint damage causes bleeding. So a very common  
 2 finding was that patients would have one joint in  
 3 particular that was a bad one because they'd got into  
 4 this cycle.

5 So these were called target joints and there  
 6 would be occasions where they would, you know, get  
 7 a lot of bleeds. We'd see them for review and they  
 8 would say, "Well, I've had three bleeds into my right  
 9 knee in the last month", and we would say, "Well, we  
 10 want to calm this down by giving prophylaxis rather  
 11 than waiting for the knee to bleed again. So for the  
 12 next month we'd like you to inject yourself three  
 13 times a week at home" and that would calm the whole  
 14 thing down.

15 So those were the two very clear-cut indications  
 16 for prophylaxis in adults at that time. Years later  
 17 it changed very significantly.

18 Q. Would those adults falling within either of those two  
 19 categories, would those generally tend to be severe  
 20 haemophiliacs rather than mild or moderate?

21 A. Oh, yes. These features I'm discussing were only for  
 22 severe haemophiliacs. In mild and moderate  
 23 haemophilia you don't get that degree of bleeding.

24 Q. Then in relation to children, again we're still at  
 25 Guy's here, you say in your statement that children

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1 got the priority of BPL, which was never enough for  
 2 the two regions, and then we, the two major centres,  
 3 in with two -- South West Thames, South East Thames,  
 4 topped up with commercial.

5 Q. Now, can I just go back to the question of prophylaxis  
 6 at Guy's. What you've said in your witness statement  
 7 is that for adults there wasn't, at that stage,  
 8 a programme of prophylactic treatment unless it was  
 9 short-term for target joints or surgery.

10 A. Yes. Prophylactic treatment for adults didn't really  
 11 take off until later than that, although it was begun  
 12 to be talked about. But there was a couple of clear  
 13 indications which is really, as you say, if somebody  
 14 had had surgery they would need Factor VIII for  
 15 a couple of weeks to make sure that the wound didn't  
 16 break down and that they would re-bleed.

17 The other particular indication is that one of  
 18 the major clinical problems in haemophilia is that if  
 19 you, in those days, started to talk to, say, a ten  
 20 year old boy with haemophilia and say, "How are your  
 21 joints?" They would very often say, "I have one  
 22 particular problem." So the major clinical event in  
 23 haemophilia is a bleeding into a joint, the joint is  
 24 damaged, and because it's damaged it's then more  
 25 likely to bleed. So you get into a cycle of bleeding

22

1 were treated with prophylaxis if deemed appropriate.  
 2 Can you expand upon that, please.

3 A. Yes, I've covered some of that already. So it's quite  
 4 an undertaking and, you know, you are using very  
 5 expensive material. It needs to be given into a vein.  
 6 It needs to be given promptly by parents who recognise  
 7 a bleed. So there's a number of hoops that parents  
 8 needed to jump through to be able to do home  
 9 treatment.

10 Firstly, which wasn't always the case, the child  
 11 needed to have good veins. Realistically, you don't  
 12 get prophylaxis going until the child's about three  
 13 years old. When the children were about three we  
 14 would start teaching the parents how to administer  
 15 Factor VIII. But that was the hurdle number one.  
 16 Some, I would say about 10 per cent of children, their  
 17 veins were too poor, and on those circumstances, if  
 18 the child was severely infected, we would insert  
 19 central venous devices called portacaths. So they  
 20 would have to be put in under a surgical procedure,  
 21 and it would be like a little disk, like an old half  
 22 crown, which you could feel underneath the skin, and  
 23 then the parents were taught to inject straight  
 24 through the disk, and that would take into a --  
 25 straight into a blood vessel. But those could get

24

1 infected so we were reluctant to do that. You had to  
 2 be scrupulous with hygiene. But that was the first  
 3 hurdle.  
 4 Secondly, you know, it's a big commitment. So  
 5 we needed to be convinced that the parents were taking  
 6 this seriously. If it was from, you know, a family  
 7 with social difficulties, single-parent family, if we  
 8 weren't confident that the mother was going to be able  
 9 to do this, then we would discuss with her whether it  
 10 was actually -- whether she felt able to do this.  
 11 They had to be trained how to spot a bleed -- you  
 12 know, which was done by the nurses. The nurses would  
 13 go and visit the home. That was a key part of it.  
 14 They would go and see the facilities. Sometimes the  
 15 nurse would come back and say, "I really don't think  
 16 this is going to work, you know, the social  
 17 arrangements are so poor." So those were more  
 18 criteria. They had to be able to communicate. You  
 19 know, we absolutely needed to know if a child was  
 20 having problems. If a -- you know, we didn't want  
 21 a mother to come in and say, "Three weeks ago I gave a  
 22 treatment every day for a week because there was a bad  
 23 bleed", we'd say, "Why didn't you ring us?" We  
 24 absolutely wanted to know if there was a problem.  
 25 So these were the sort of things we addressed.

25

1 might notice on some months, when the supplies -- we  
 2 would have a van that would send out the supplies to  
 3 the parents' homes or, sometimes, if the patients were  
 4 coming in for review, they would pick up supplies and  
 5 goes home with supplies -- they were certainly aware  
 6 that concentrates came in two different generic types.  
 7 There was the British type and the American type and  
 8 the patients were understandably very keen and anxious  
 9 to have the British Factor VIII. You know, they used  
 10 to say to you, "You are going to give me British  
 11 Factor VIII this month, aren't you?"  
 12 If they had to have commercial Factor VIII,  
 13 there wouldn't have been any sort of conversation  
 14 about which particular product it was. I think it was  
 15 perceived, at that time in any case, there wasn't any  
 16 clinical difference in efficacy across the different  
 17 commercial concentrates, and we had no evidence there  
 18 was any difference in risk of infection across the  
 19 commercial concentrate. So as doctors we didn't have  
 20 any sort of impetus to start making noises with the  
 21 powers that be to say, "We don't really like giving  
 22 commercial concentrate but we understand why -- there  
 23 isn't enough BPL -- but we really want to have a say  
 24 as to what sort of commercial concentrate". That sort  
 25 of conversation didn't take place.

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1 Having said that, it was pretty unusual if we said,  
 2 "I don't think this is going to work", but it did  
 3 happen in a few families.  
 4 **Q.** So the children who went on to prophylactic treatment  
 5 would all have been severe haemophiliacs?  
 6 **A.** Severe.  
 7 **Q.** Was the product that was given to their families for  
 8 them to use at home on a prophylactic basis always NHS  
 9 product or was it --  
 10 **A.** By choice, yes, very much so.  
 11 **Q.** To what extent at Guy's were patients given a say or  
 12 a choice in the type of treatment that they had?  
 13 **A.** None, I would say, because in those days -- I mean,  
 14 I don't think the doctors were given a choice in terms  
 15 of what sort of commercial concentrate. I think  
 16 that -- you know, there was a manager in the centre.  
 17 I would go and say there was a BPL shortfall and the  
 18 manager would go and order some commercial concentrate  
 19 from the pharmacy, who didn't really know a great deal  
 20 about Factor VIII concentrates as it's not a drug,  
 21 it's a blood product, but they would come to some  
 22 arrangement with the commercial company for the supply  
 23 to come in. So we would certainly be talking to  
 24 patients about the types of concentrate and that we  
 25 had hoped to get them BPL concentrate, but that they

26

1 **Q.** You have said that patients would express a preference  
 2 for British concentrate. What was your understanding  
 3 of the reasons for that preference?  
 4 **A.** Well, haemophilia is a small and close-knit community.  
 5 All patients are encouraged to join The Haemophilia  
 6 Society. The Haemophilia Society used to produce lots  
 7 of written information for them and we used to have  
 8 these residential seminars. Once or twice a year,  
 9 there would be a national seminar and we very much  
 10 encouraged our patients to go. The weekends were free  
 11 and they were of great benefit to the patients. They  
 12 could be given lectures by doctors or nurses about  
 13 matters of interest. There would be little workshops  
 14 they could go and attend. There would be a dinner and  
 15 a few drinks on the Saturday night. They could meet  
 16 other parents. It was something that was terribly  
 17 valuable. And this sort of very strong feeling, which  
 18 we'll talk about later on, in terms of the critical  
 19 times coming five years later, there was this very,  
 20 very strong feeling amongst the British Haemophilia  
 21 Society population of -- I previously described it as  
 22 a sort of Tarzan-oid philosophy, you know: "British  
 23 good, American bad. I don't want to have American  
 24 Factor VIII."  
 25 A lot of that came from publications from The

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1 Haemophilia Society, or it came from these residential  
 2 weekends and meeting other patients. Of course no  
 3 internet in those days.

4 **Q.** Do you recall whether, during the years you were at  
 5 Guy's, you had conversations with patients about the  
 6 pros and cons of British concentrate versus commercial  
 7 concentrate?

8 **A.** Yes. I mean, we had conversations with them, and The  
 9 Haemophilia Society publications were saying that the  
 10 commercial concentrates theoretically carry more risk  
 11 and we're not happy about that and, as you know, by  
 12 this time UKHCDO were beginning to have dialogues with  
 13 Elstree and the transfusion services and there was  
 14 Dr David Owen's initiative, et cetera. So the  
 15 patients were well aware of the theoretical  
 16 differences. Which is where this philosophy came  
 17 from, which you have to completely understand. They  
 18 very much wanted to have British Factor VIII because  
 19 it was perceived as being less likely to transmit  
 20 viruses.

21 Of course at that time that phrase meant  
 22 "hepatitis" -- nothing known about AIDS.

23 **Q.** What about concentrates versus cryoprecipitate?  
 24 Again, I'm going to come in more detail to what you  
 25 say in your statement about disadvantages of

29

1 give. From every perspective, the concentrate was so  
 2 much better and it was a much more effective  
 3 treatment. You know, cryo was not a very effective  
 4 treatment at stopping bleeding. You couldn't use it  
 5 for prophylaxis.

6 So the patients were fully signed up to  
 7 concentrate. No patient ever said to us, "Can I go  
 8 back onto cryoprecipitate?" They would have had to  
 9 come off home therapy.

10 **Q.** Did you explain to patients the relative degree of  
 11 viral infection risks of cryoprecipitate versus  
 12 concentrate; in other words, that there was a greater  
 13 risk with concentrate because of pooling?

14 **A.** Well, I didn't know for certain that that was the  
 15 case. I mean, in theory, because cryo might come from  
 16 ten donors and the concentrates come from 20,000,  
 17 there were these theoretical risks. But, again,  
 18 I think the patients were well-informed as to how  
 19 concentrate was made, and I don't think they had any  
 20 reservations at all. No patient ever said to me, "I'm  
 21 really not happy about being on concentrate because of  
 22 this number of donors that the concentrates are  
 23 derived from. I want to go back to having  
 24 cryoprecipitate." It was known about. People maybe  
 25 didn't feel very comfortable about it. The doctors

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1 cryoprecipitate but, as a matter of fact, do you  
 2 recall whether you had conversations with your  
 3 patients at Guy's explaining to them that there was  
 4 this other treatment, cryoprecipitate? Many of them  
 5 would presumably have known that from earlier in the  
 6 '70s. Did you explain to them your views of the  
 7 relative merits of cryoprecipitate versus  
 8 concentrates?

9 **A.** Well, these are patients who, unless they were  
 10 a child, would previously have been treated with  
 11 cryoprecipitate, which was available in the late  
 12 1960s. So all of these patients, apart from children,  
 13 knew about cryoprecipitate because it was their  
 14 previous treatment before the concentrates came in and  
 15 then they didn't need any persuading at all. As  
 16 you've seen from the various documentaries that have  
 17 been on recently, it was such a sea change, to move  
 18 from cryoprecipitate -- which was the first treatment,  
 19 but it really was not, by any measure, a good  
 20 treatment, which we will talk about -- to suddenly  
 21 this treatment, which is what everybody, doctor,  
 22 nurse, patient had wanted, which was small volume,  
 23 kept in a domestic fridge, you knew the amount of  
 24 Factor VIII on the bottle, didn't have to be in a deep  
 25 freeze, reasonable supply, easy to draw up, quick to

30

1 didn't feel comfortable about it. It was recognised  
 2 as being an Achilles heel of a treatment that was  
 3 otherwise spectacularly successful.

4 **Q.** You left Guy's in late 1983. Did you ever find out  
 5 how many of the patients you cared for at Guy's were  
 6 infected with HIV?

7 **A.** No. There were one or two that moved down to Kent and  
 8 came under my care who obviously I did know what  
 9 happened to but the rest of them at Guy's I didn't.  
 10 I say, these weren't very large numbers. There were  
 11 probably, as far as I can recollect, ten to fifteen  
 12 patients on home therapy.

13 **Q.** I want to turn now, please, in more detail to some of  
 14 the matters you have alluded to about the developing  
 15 knowledge of risk from concentrates.

16 Can I start by asking you what you were taught  
 17 as part of both, first, your general medical training,  
 18 and then your specific haematology training, about the  
 19 risks of viral transmission from blood and blood  
 20 products.

21 **A.** Well ...

22 **Q.** I know I'm asking you to think back a long time,  
 23 Dr Winter --

24 **A.** A very long time.

25 **Q.** -- as best you can.

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1 A. I don't recall in my medical training anything about  
2 that, but then I qualified in 1973. I now know that  
3 there was data from the late 1960s about hepatitis  
4 transmission. Of course then, once I'd entered  
5 haematology training, I was working both at the  
6 Middlesex and Guy's for doctors who were not  
7 haemophilia specialists, so they didn't teach me  
8 anything about that either because they didn't know  
9 anything about it. So the answer is, no, I didn't get  
10 any teaching, but then I wasn't expecting it because  
11 there wasn't anybody, when I was in training, as it  
12 were, to be teaching me about haemophilia. I got my  
13 information from other sources, by reading and by  
14 going to meetings.

15 Q. Just in terms of reading material, written material,  
16 what journals or periodicals would you typically have  
17 read in the late 1970s/early 1980s?

18 A. I think there was a staple diet really. Everybody  
19 read the British Journal of Haematology, so you were a  
20 member of the British Society of Haematology. That  
21 was -- you know, it wasn't much haemophilia in that,  
22 but you read it. Everybody, as members of the BMA,  
23 had the British Medical Journal. There wasn't much  
24 haemophilia in that. There was The Lancet, probably  
25 the most important medical journal in Britain, and

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1 there was the New England Journal of Medicine. Those  
2 were your two main sources, because they would carry  
3 important articles about haemophilia. Both at the  
4 Middlesex and Guy's we had a weekly journal club,  
5 I remember. So the registrars were told by the  
6 professors to make a presentation each week on an  
7 article of interest from one of those journals.

8 Q. Then what other sources did you have of information?  
9 Leaving aside for a moment UKHCDO as a potential  
10 source, which I'll come on to in a moment, what other  
11 kind of conversations or meetings would you attend in  
12 the late '70s or early '80s where you would receive  
13 information about matters such as infection risks or  
14 other hazards?

15 A. Well, very little really. I mean, there's -- when  
16 you're training in haematology, you have already been  
17 through one postgraduate examination, which is the  
18 membership of the Royal College of physicians. So the  
19 later doctors, like of my generation, went into  
20 general medicine, did another exam to get what's  
21 called the MRCP. Then to be accredited, you had to  
22 pass yet another exam, the membership of the Royal  
23 College of Pathologists. So there were training  
24 programmes for that, as I reflect on your question.  
25 I remember going over London on one afternoon a week

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1 to a series of seminars that were put on by the  
2 Hammersmith Hospital by the Medical Research Council.  
3 So there were MRC path training programmes.  
4 They were mainly general haematology, but they were  
5 for registrars in training who were building up to  
6 this really quite substantial examination which took  
7 three days, including practicals, which you had to  
8 pass in order to be accredited and to become  
9 a consultant.

10 A very small fraction of those meetings, if you  
11 were lucky, might be about haemostasis and thrombosis.

12 Q. Do you recall whether any of those meetings would have  
13 covered viral risks from the use of blood or blood  
14 products?

15 A. No. I mean, as we're having this conversation, I'm  
16 getting these memories. The predecessor of Dr Savidge  
17 at St Thomas' was Professor Ilsley Ingram, who I came  
18 to know socially and he I remember going to listen to.  
19 He was one of the tutors on that course. So he was  
20 professor of haemophilia at St Thomas'. He must have  
21 spoken to us about haemophilia. I think in his  
22 department was Professor Mannucci as a trainee, and  
23 that's when DDAVP was discovered by Dr Mannucci when  
24 he was a registrar working for Professor Ingram. That  
25 would be 1970s. So I'm pretty sure that

35

1 Professor Ingram would have spoken to us about the  
2 work that Dr Mannucci was doing with DDAVP. I don't  
3 remember anything, even though I'm -- suddenly, you  
4 have taken me back to a sort of thing I haven't  
5 thought about. I don't remember anybody discussing  
6 with us, if you like, the word non-A, non-B. That was  
7 a concept that was only circulating in haemophilia  
8 centres that was beginning to evolve sort of mid-1970s  
9 onwards.

10 Q. Then Dr Barkhan was an infrequent but occasional  
11 attendee at UKHCDO meetings. There are a very small  
12 number we tracked down that he went to. Did he ever  
13 come back from UKHCDO meetings and share any of the  
14 information he'd gleaned with you?

15 A. No. I think he saw it as a managerial event.

16 Q. Again, in this period when you're either at the  
17 Middlesex or at Guy's, so before you take up your  
18 consultant post, did you ever see UKHCDO minutes,  
19 either of the Reference Centre Directors meetings,  
20 which was the meetings attended by ten or so, or the  
21 bigger meetings attended by all directors, or to which  
22 all directors were invited?

23 A. My recollection is we wouldn't have seen the AGM  
24 minutes which happened just once a year, but I think,  
25 as I've already said to you, we were aware of the

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1 recommendations about minimising concentrate exposure  
 2 in non-severe patients. So I think we would have seen  
 3 the advice given by the smaller working groups of  
 4 UKHCDO to be aware of that.

5 **Q.** You mention having become aware of publications or  
 6 information from the late 1960s about risks of  
 7 hepatitis. The Inquiry has seen evidence dating back  
 8 certainly to the 1940s to suggest that the risk of  
 9 hepatitis -- then referred to usually as serum  
 10 hepatitis, sometimes post-transfusion hepatitis -- was  
 11 known to be the major risk from blood transfusion and  
 12 had been known for decades.

13 First of all, do you accept that as correct?

14 **A.** Yes.

15 **Q.** Do you recall when you were first to become aware of  
 16 that?

17 **A.** Well, I can -- although we've just spoken about when  
 18 I was a student, I was aware that there were two types  
 19 of hepatitis, and that they were different, and that  
 20 hepatitis A was not usually transmitted by blood, but  
 21 hepatitis B was and we knew all about Australia  
 22 antigen, and it was, indeed, even called "serum  
 23 hepatitis". So, exactly as you say, by the end of the  
 24 1960s at the very latest, it was very well established  
 25 that, of the two known types of hepatitis, one of them

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1 reaction.

2 **Q.** Now, your witness statement says that you knew, or  
 3 clinicians knew by 1979 that commercial Factor VIII  
 4 was contaminated with non-A, non-B hepatitis and that  
 5 this caused cirrhosis in regularly treated patients.  
 6 I want to take that in two stages.

7 First of all, the existence of non-A, non-B  
 8 hepatitis. Can you recall, roughly at least, when you  
 9 became aware of the existence of this third type of  
 10 hepatitis?

11 **A.** So the easiest way to deal with this is to do  
 12 a timeline. Let's say 1973, concentrates are coming  
 13 in; you're setting up a comprehensive care programme  
 14 with home therapy; you're working out which blood  
 15 tests to do; and, as we've just been discussing,  
 16 you're going to monitor the patient for known  
 17 hepatitis viruses, for hepatitis A and hepatitis B.  
 18 So that's already established in 1973 and 1974.

19 There's this revolution. The patients are all  
 20 saying to you, my life is totally, utterly changed.  
 21 This is wonderful. We've always called this the  
 22 golden interval, a little two-year gap, about 1974 to  
 23 about 1976, where suddenly, after years of darkness,  
 24 disability, pain, inability to work properly, have to  
 25 go to a special boarding school, suddenly there's the

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1 could be transmitted by blood.

2 **Q.** You were I think aware, from what you've already said,  
 3 that commercial concentrates were made using large  
 4 pools of material from paid donors?

5 **A.** Yes.

6 **Q.** I think you may have already referred to this,  
 7 Dr Winter, but do you recall watching the 1975 World  
 8 in Action programme at the time in 1975?

9 **A.** Not at the time, but I've seen it, and I know it very  
 10 well because I've seen it so many times since.

11 **Q.** Do you recall whether, although you didn't watch it at  
 12 the time, you became aware of it? Was it a topic of  
 13 discussion after its broadcast in late 1975 in  
 14 haemophilia circles?

15 **A.** No. I have no recollection of that.

16 **Q.** I'm just going to ask to play a short extract from an  
 17 interview you gave in 1988, so you are going to see  
 18 your younger self on the screen in a moment, Dr  
 19 Winter. It's MDIA0000111. It is the first of the two  
 20 clips, please, Henry.

21 (video played).

22 I think you have seen that this morning, and you  
 23 accept that as an accurate account of your knowledge  
 24 at the time?

25 **A.** I don't think I regret any of that, is my immediate

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1 land of milk and honey, home therapy concentrates,  
 2 everything is wonderful, people are feeling really  
 3 good, their joints are good, started to do sports  
 4 again. Everything is really, really coming along  
 5 well. Then 1975, I recall -- again, we were just  
 6 talking about him. Professor Mannucci had gone on to  
 7 be head of the very large centre in Milan and he,  
 8 amongst several other people, produced data that  
 9 showed about 45 per cent, I think, in his paper of  
 10 regularly treated patients had abnormal liver function  
 11 tests of a hepatic pattern. They didn't have  
 12 hepatitis A, and hardly any of them had hepatitis B.  
 13 So this was the very start, as far as I'm concerned,  
 14 of this theoretical concept of, we think we're dealing  
 15 with a third virus.

16 This term non-A, non-B came from the haemophilia  
 17 doctors. You know, we started to realise something  
 18 else is going on in here. It looks like many of our  
 19 patients have been exposed to it.

20 However, they are not -- the pattern of the test  
 21 results is not changing very much. Obviously every  
 22 three months they came in and had the results checked.  
 23 The results weren't changing very much. There were no  
 24 signs of patients getting any clinical liver  
 25 disorders. The patients kept saying to us, "I've

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1 never felt as well as this, I never want to change,  
 2 this is the treatment I've always wanted". So I think  
 3 there was a feeling across the haemophilia doctors  
 4 that we've noted this. It looks like there's a third  
 5 virus, you've to speculate. If it is, it doesn't seem  
 6 to be doing any harm. You know, viruses are variable.  
 7 Maybe -- you see, cytomegalovirus can affect the  
 8 liver. It doesn't do a lot of symptomatology. Maybe  
 9 this is something like CMV. It's just causing  
 10 a little bit of mild inflammation. The massive  
 11 benefits of the new therapy are there for all to see.  
 12 We're just going to keep an eye on this. So this was  
 13 the first phase of what's going to change in a minute.  
 14 All of that changed radically around about  
 15 1978/79, again, of various studies. You are going to  
 16 be talking to Professor Preston. The Sheffield group,  
 17 in particular, did a study where they bravely did  
 18 liver biopsies on patients with haemophilia who had  
 19 abnormal liver function tests, and what their results  
 20 from that study blew out of the water instantly the  
 21 idea that this was nothing to worry about because  
 22 their study showed, as did other studies, that most of  
 23 these patients had very significant chronic liver  
 24 disease biopsy. They had chronic active -- there's  
 25 a range of different histological stages, ranging from

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1 chronic active hepatitis to cirrhosis. Most of these  
 2 patients were along that pathway.  
 3 So this was a dramatic finding and this changed  
 4 haemophilia doctors completely to believe this is not  
 5 something that we can just relax about and just keep  
 6 a look at and ignore -- not "ignore" but not get  
 7 excited about. This is a really serious evolving  
 8 clinical problem and we really have to look very hard  
 9 at, you know, how can we minimise exposure to this  
 10 third virus (non-A, non-B as we still called it), what  
 11 steps can we take to minimise further exposure to the  
 12 patients already seen to have it and what steps can we  
 13 take to minimise exposure to those patients who never  
 14 received the concentrate?

15 **Q.** Dr Winter, there's a handful of publications in the  
 16 1970s I want to look at with you but, sir, noting the  
 17 time I'd rather do that in one go and then ask you  
 18 about them, Dr Winter, than split it over the break.  
 19 Should we take the break now, sir?

20 **SIR BRIAN LANGSTAFF:** Yes. What we do, doctor, at breaks  
 21 is we take 45 minutes because it allows those who are  
 22 here to go and be served with their drinks and keep  
 23 socially distant. It takes a while. So 45 minutes.  
 24 We will come back at 11.45.

25 **(11.03 am)**

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**(A short break)**

1 **(11. 45 am)**

2 **MS RICHARDS:** Dr Winter, I want to ask you a little more  
 3 about your view that the sea change in the  
 4 understanding of non-A, non-B hepatitis and its  
 5 seriousness came with Professor Preston's publication  
 6 in 1978.

7 I want to show you a handful of materials from  
 8 1974 through to 1977 and then ask you about them. I'm  
 9 conscious they may not have been materials you would  
 10 have seen at the time, not least because for part of  
 11 that time you were still in general medicine, so that  
 12 is understood.

13 Before we look at the first document, can I ask  
 14 you this: would you agree that, at all the times we're  
 15 talking about in the 1970s, hepatitis B was known to  
 16 be a serious condition with potential long-term  
 17 consequences?

18 **THE WITNESS:** Yes, and there were indeed occasional  
 19 outbreaks of haemophilia B amongst treated  
 20 haemophiliacs. There was one in Bournemouth, I think.  
 21 So, yes, it was accepted that, whilst it didn't appear  
 22 to be the most predominant type of hepatitis, it was  
 23 a very significant virus and something that needed to  
 24 be monitored, and people need to be vaccinated if they  
 25

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1 hadn't been exposed.

2 **Q.** So, given that knowledge of hepatitis B, why would one  
 3 expect non-A, non-B hepatitis to take a significantly  
 4 different course?

5 **A.** Because, as I've said, different viruses have  
 6 different effects on the liver. You see, if you have  
 7 glandular fever, that usually -- if you measured  
 8 somebody's liver function tests, you would find that  
 9 part of a glandular fever episode that those tests  
 10 were not normal. So viruses cause a whole spectrum of  
 11 degrees of inflammation in the liver. Cytomegalovirus  
 12 is another one where the degree of liver inflammation  
 13 is relatively modest. I am sort of listening to  
 14 myself saying this to you. I'm not a liver expert,  
 15 but that's my understanding.

16 So viruses have different pathogenic effects on  
 17 the liver and the point I was trying to make before  
 18 the break was that we originally thought that non-A,  
 19 non-B might be just a mild virus and nothing to worry  
 20 about, and then things changed radically with these  
 21 studies that we're about to talk about.

22 **Q.** If we have up on screen, please, Henry, PRSE0001431.

23 This is an article published in The Lancet in  
 24 August of 1974 by Prince and others. We can see it's  
 25 entitled:

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1 "Long-Incubation Post-Transfusion Hepatitis  
 2 without Serological Evidence of Exposure to Hepatitis  
 3 B Virus."  
 4 There are just two passages I'm going to ask you  
 5 to look at, Dr Winter. The first is just the summary:  
 6 "An agent other than hepatitis B virus seemed to  
 7 be the cause of 36, 71 per cent, of 51 cases of  
 8 post-transfusion hepatitis identified during  
 9 prospective biweekly serological follow up of 204  
 10 cardiovascular surgery patients. The sera of the 36  
 11 cases showed no evidence of the antigen or antibody  
 12 response expected to accompany infection by HB virus  
 13 and to be detectable by the sensitive assays used.  
 14 Incubation periods and clinical and epidemiological  
 15 features were inconsistent with hepatitis A.  
 16 Cytomegalovirus-associated seroconversion was no more  
 17 common among the HB-negative cases than among the  
 18 HB-positive cases or among patients who did not  
 19 develop hepatitis. The data suggest that a large  
 20 proportion of long-incubation post-transfusion  
 21 hepatitis is unrelated to hepatitis B and that control  
 22 of the post-transfusion hepatitis will require  
 23 identification of a hepatitis virus(es) type C."  
 24 Then, Henry, could we go to the last page of  
 25 this, and we'll just pick up one more passage,

45

1 The second document -- Henry, could we have  
 2 PRSE0000381. This is a publication in the Yale  
 3 Journal of Biology and Medicine in 1976. "Non-A,  
 4 non-B hepatitis". Purcell, Alter and Dienstag.  
 5 If we could go, please, Henry, to the fourth  
 6 page, and if we could zoom in on the paragraph  
 7 beginning "Although type non-A, non-B". That's the  
 8 one there. Thank you. So this is now 1976, and this  
 9 particular paper says:  
 10 "Although type non-A, non-B hepatitis is  
 11 associated with less severe acute illness than type B  
 12 disease, as judged by frequency of jaundice and  
 13 magnitude of SGPT elevations, the long-term prognosis  
 14 for the two diseases may be similar. Thus, elevation  
 15 of transaminase values persisting for six or more  
 16 months has been observed more frequently following  
 17 non-A, non-B disease than following type B hepatitis.  
 18 Others have reported similar results. Transaminase  
 19 elevations have been documented for several years in  
 20 some patients. Three such patients at the NIH  
 21 underwent liver biopsy; two had histopathologic  
 22 changes in the liver compatible with chronic active  
 23 hepatitis, and the other was diagnosed as having  
 24 chronic persistent hepatitis. Thus, chronic non-A,  
 25 non-B hepatitis is not necessarily a benign infection

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1 Dr Winter. If you could zoom in on the top left-hand  
 2 column, please, Henry, picking up the third line down:  
 3 "The fact that non-B hepatitis cases are less  
 4 frequently associated with serious acute illness does  
 5 not imply that such cases are of lesser importance.  
 6 Long-term complications of acute hepatitis B  
 7 infection, such as chronic hepatitis, cirrhosis, and  
 8 hepatoma, have been reported to follow mild anicteric  
 9 infections more frequently than severe icteric cases;  
 10 consideration must thus also be given to the  
 11 possibility that non-B hepatitis may play a role in  
 12 the aetiology of some forms of chronic liver disease."

13 So that's the first one. I'm going to show you  
 14 four and then ask you some questions. As a matter of  
 15 fact, do you think you would have read that at the  
 16 time? It's The Lancet, but you were still in general  
 17 medicine.

- 18 A. I may well have done. I mean, it does bring -- we're  
 19 going to talk later about this, are we?
- 20 Q. I am going to show you four, I think, and then ask you  
 21 to discuss them. So that's the first.  
 22 So you might have seen it, but you can't say one  
 23 way or another?
- 24 A. I cannot remember papers I read 45 years ago.
- 25 Q. That's understandable.

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1 and may be the cause of a significant proportion of  
 2 chronic hepatitis not identifiable as type B disease."  
 3 Again, I'll come back to the content. As a  
 4 matter of fact, do you think it's likely that you  
 5 would have read in 1976 this, which is the Yale  
 6 Journal of Biology and Medicine?

- 7 A. No.
- 8 Q. Then the third one, Henry. Could we have  
 9 NHBT0000092\_002. This is the report in -- of an  
 10 international forum in Vox Sang, 1977. You will see  
 11 the title is:  
 12 "How Frequent is Post-Transfusion Hepatitis  
 13 After the Introduction of Third Generation Donor  
 14 Screening for Hepatitis B? What is Its Probable  
 15 Nature?"  
 16 It appears to be the text of a speech delivered  
 17 by Harvey Alter in the international forum, or a  
 18 publication for that purpose.  
 19 If we could just go to the second page, please,  
 20 Henry. The last paragraph of the article. If you  
 21 could zoom in on that:  
 22 "Although non-A, non-B hepatitis is, on the  
 23 average, less acutely severe than type B hepatitis, it  
 24 can cause severe acute disease and, more disturbing,  
 25 it appears to have considerable propensity to progress

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1 to chronic hepatitis. The major thrust of  
2 post-transfusion hepatitis research must now be  
3 directed at developing detection methods for the  
4 non-A, non-B agents, or developing some reliable  
5 method of viral inactivation or removal which would be  
6 independent of testing."

7 Again, before we consider the content, this is  
8 now 1977, so you're, I think, undergoing your  
9 specialist training by then, but is this the kind of  
10 publication you would have seen at the time?

11 **A.** Which journal was this?

12 **Q.** It's Vox Sang?

13 **A.** Vox Sang was really a sort of blood transfusion  
14 journal. I wouldn't have read that routinely.

15 **Q.** Then the fourth document, Henry, is RLIT0000228. This  
16 is another publication from 1977. It's by Hoofnagle  
17 and others. The publication, Dr Winter, is Annals of  
18 Internal Medicine. Could we go to the last page but  
19 one, Henry. It should be the sixth page. Could we  
20 zoom in on the right-hand column. It's quite a long  
21 passage, Dr Winter. I am going to read it, as much as  
22 anything, for the benefit of those listening:

23 "Several clinical and epidemiologic features of  
24 non-A, non-B hepatitis have become clear from studies  
25 such as the present one. First, non-A, non-B

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1 post-transfusion hepatitis may be due to non-A, non-B  
2 hepatitis.

3 That's 1977 Annals of Internal Medicine. Is  
4 that a journal that you would have read at the time?

5 **A.** That was on my reading list at that time.

6 **Q.** Now, we then get, obviously, to 1978 and  
7 Professor Preston's publication which you've referred  
8 to and which you recall and you have already  
9 described. Just looking at those materials, and  
10 Dr Winter, I accept that you were in training at this  
11 time or, indeed, in general medicine at the first  
12 time, but looking at that material now, would you  
13 accept that if clinicians in the mid-'70s had formed  
14 the view that non-A, non-B hepatitis was a mild or not  
15 clinically significant condition, they were wrong to  
16 do so at that time?

17 **A.** One of the major problems of all this is we did not  
18 know what we were dealing with. The term "non-A,  
19 non-B", there was talk very often this might be  
20 several viruses. This might be hepatitis C, D and E.  
21 It might not even be a hepatitis virus at all.  
22 Somebody getting non A non-B after a blood  
23 transfusion, 1 pint, how does that compare with  
24 someone getting non-A, non-B after being exposed to  
25 Factor VIII concentrate from 20,000 blood -- 20,000

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1 hepatitis closely resembles type B hepatitis. The  
2 incubation period, the clinical symptoms and signs,  
3 and the potential for chronicity appear to be similar  
4 to type B hepatitis. Undoubtedly, what was once  
5 referred to as serum hepatitis included both type B  
6 and non-A, non-B hepatitis. Second, non-A, non-B  
7 hepatitis appears to be spread predominantly by the  
8 parenteral route. Most cases have been described in  
9 association with transfusion, intravenous drug use or  
10 serum inoculation."

11 Then if we skip down to his third point:

12 "Third, non-A, non-B hepatitis appears to be  
13 associated with a chronic carrier state and chronic  
14 liver disease. In this study, sero taken from HB  
15 negative donors 149 to 385 days after an implicated  
16 transfusion were found to be infectious. These  
17 implicated blood donors were, for the most part,  
18 asymptomatic, although liver function tests and liver  
19 biopsy examinations frequently showed evidence of  
20 underlying chronic hepatitis. Finally, non-A, non-B  
21 hepatitis appears to be common. Three of the five  
22 infectious donor studied here transmitted this non-A,  
23 non-B hepatitis."

24 Can we scroll down a bit further, Henry. Then  
25 it goes on to suggest that more than 90 per cent of

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1 donors?

2 So I think those were all difficulties in  
3 interpretation really. I mean, as I recall, I don't  
4 think that haemophilia doctors dismissed the abnormal  
5 liver function tests. The major dynamic I can only  
6 stress to you because I remember it so clearly was, if  
7 you like, there was a sort of unwillingness to think  
8 it might be a problem because this new treatment had  
9 brought such spectacular benefits and because the  
10 patients were so enthusiastic about it that I think  
11 that people were reluctant, if you like, to say this  
12 is a serious problem.

13 There is a point here that we should have made  
14 a few minutes ago. When you get non-A, non-B, most  
15 but not all patients are asymptomatic. Some people do  
16 have symptoms. If you get Hep B, most people are  
17 symptomatic. When, 1991, whatever it was, I got Hep C  
18 testing, and I told all my positive patients, most of  
19 them said, I've never had any symptoms of jaundice.  
20 I don't recall an acute attack. Nobody ever said to  
21 me I was yellow. You know, this is a surprise to me  
22 because I've never felt unwell. Other patients very  
23 much did. So there are differences there.

24 I think it was just -- I do think the fact that  
25 it was linked into such an obviously tangible therapy

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1 was one aspect of this, but I don't think it's true to  
 2 say that haemophilia doctors dismissed it. We just  
 3 maybe -- you know, if we'd known then what we were to  
 4 know five years later, we might have done things  
 5 differently, maybe in terms even of doing liver  
 6 biopsies.

7 I mean, one of the major features that we learnt  
 8 subsequently, which is a very important observation,  
 9 is that when you take a blood test and look at  
 10 somebody's liver function tests, you know, the levels  
 11 might be twice the normal range or four times or six  
 12 times. It turned out there was very little link  
 13 between the degree of abnormality and what their liver  
 14 biopsy looked like. So that's very important. It was  
 15 totally invalid to say to somebody, oh, your liver's  
 16 less inflamed than three months ago because your AST  
 17 level was 140, and now it's only 80, so that's good,  
 18 isn't it? All that was completely not right.

19 This, again, of course, was another major  
 20 difficulty about monitoring the state of non-A, non-B.  
 21 We came to realise, just to do somebody's liver  
 22 function tests didn't actually tell you anything  
 23 informative, and the only real way to see what  
 24 clinical effect the hepatitis was having was to do  
 25 a liver biopsy, and nobody wanted to do a liver biopsy

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1 Are there any other reasons that you can think  
 2 of why clinicians don't appear to have fully grasped  
 3 that non-A, non-B hepatitis in its chronic stage could  
 4 be very serious, until Professor Preston's  
 5 publication?

6 **A.** Well, I think the initial symptomatology is another  
 7 part of it. I mean, if you've got somebody with  
 8 hepatitis B who's really sick at presentation, then  
 9 the patient will never forget that, and that's an  
 10 important part of the history that comes with the  
 11 patient.

12 I think part of it also were these patients were  
 13 not only well, they'd always been well. They hadn't  
 14 sort of come in with diagnoses of acute clinical  
 15 jaundice. So I think that's another feature.

16 I mean, subsequently, the UKHCDO always had  
 17 a liver disease working group, and it seems to me,  
 18 looking back now to this time, in view of all the  
 19 uncertainties that you're perfectly reasonably  
 20 raising, I wonder why, unless -- you know, why didn't  
 21 they constitute a liver working party at that time and  
 22 ask some liver specialists to get on board?

23 I mean, you're asking me all these questions  
 24 about the way in which haemophilia doctors thought.  
 25 Haemophilia doctors are not liver specialists, and,

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1 on someone with haemophilia. There was a patient who  
 2 died after having a liver biopsy. You know, these  
 3 people have the most profound bleeding tendency known  
 4 to medical science. You're probably spending £5,000  
 5 worth of Factor VIII beforehand and afterwards to make  
 6 sure they don't bleed. You really need a jolly good  
 7 reason to want to do that.

8 **Q.** I understand that there were uncertainties. Again,  
 9 just looking at this mid-70s period. I understand,  
 10 and the materials we've just looked at show this, that  
 11 there were differences observed in the acute stage of  
 12 the illness as between hepatitis B and what was  
 13 becoming known as non-A, non-B hepatitis.

14 What I'm really trying to do is try to  
 15 understand -- and in some respect, Dr Winter, you're  
 16 the vehicle for doing so -- try to understand why  
 17 clinicians worked or seemed to have worked, to some  
 18 extent at least, on the assumption that the long-term  
 19 consequences, beyond the acute stage into the chronic  
 20 stage, of non-A, non-B hepatitis was going to be less  
 21 severe than hepatitis B.

22 You have given us -- you've pointed to  
 23 uncertainty, you've pointed to what might have been an  
 24 unconscious unwillingness or even a conscious  
 25 unwillingness to look beneath this golden therapy.

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1 you know, we don't have specialist expertise in  
 2 matters of hepatitis.

3 So I don't know the answer to your questions but  
 4 it seems to me, in retrospect, I wonder whether  
 5 anybody had thought of forming a hepatitis working  
 6 party with some liver specialists on board. Because  
 7 that's certainly what happened in the 1980s. I don't  
 8 think I was ever on one but I remember such working  
 9 parties existing and there were liver specialists from  
 10 the Royal Free in particular, I remember, who gave  
 11 very valuable advice about the management of  
 12 hepatitis.

13 **Q.** There was, as a matter of fact, and there's no reason  
 14 why you would have personally known this at the time,  
 15 Dr Winter, there was a Hepatitis Working Party  
 16 established by UKHCDO in the 1970s -- I can't remember  
 17 off the top of my head the precise date -- with  
 18 Dr Joan Trowell, who was a liver specialist part of  
 19 it.

20 Before you joined Guy's and you were at  
 21 Middlesex, is it right that Professor Stewart was the  
 22 director there?

23 **A.** Professor Stewart.

24 **Q.** Did Professor Stewart ever report back to his  
 25 registrars information he'd gleaned from UKHCDO

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1 meetings about non-A, non-B hepatitis or liver  
 2 disease?  
 3 **A.** No, it was a very small centre and a major haematology  
 4 centre. So haemophilia was a very -- you know, it was  
 5 a very small part of the workload as far as  
 6 Professor Stewart was concerned.  
 7 **Q.** Lest you wonder me why I ask that, there was  
 8 a presentation by Dr Craske of the Hepatitis Working  
 9 Party in 1978 at the UKHCDO AGM which was attended by  
 10 both Professor Stewart and Dr Barkhan. But, in any  
 11 event, whatever they may have learnt from that was not  
 12 shared with you at that time?  
 13 **A.** No.  
 14 **Q.** You've already mentioned Professor Preston's research  
 15 which was published in The Lancet in 1978. That  
 16 appears on any view to you to have been a very  
 17 significant development, from the evidence that you  
 18 were giving before the break.  
 19 Would you accept that, at least from 1978  
 20 onwards, haemophilia clinicians should have worked on  
 21 the basis that non-A, non-B hepatitis was potentially  
 22 a very serious condition?  
 23 **A.** I mean, Professor Preston's was not the only study, as  
 24 I recall. This -- you know, doctors always -- not --  
 25 cynical's the wrong word, but you read a paper from

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1 I absolutely don't want to do that on somebody with  
 2 severe haemophilia."  
 3 So we've used the word "sea change". This is  
 4 one of the great sea change moments in the history,  
 5 and I would have expected every haemophilia doctor to  
 6 say all the rules have changed on this one and chronic  
 7 liver disease is a major clinical problem in  
 8 haemophilia.  
 9 Spilling out from that, more activity around the  
 10 question of self-sufficiency. You know, Dr Owen's  
 11 initiative has been and gone, things have gone into  
 12 not much in the way of progress '77/'78. We're still  
 13 importing significant amounts of imported blood.  
 14 Elstree's about to be closed down, I think, because of  
 15 the unsatisfactory state of the building.  
 16 You would think the other thing that would have  
 17 come out of this would have been increased political  
 18 pressure from the UKHCDO on the Department of Health  
 19 to say look at this data, you know, this is a really  
 20 different way of looking at this problem. It now  
 21 really does seem to be severe -- nothing known about  
 22 AIDS -- and it underscores what we've been saying for  
 23 the last few years about the importance of becoming  
 24 self-sufficient.  
 25 **Q.** Before I ask the question, let me show you a document.

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1 a particular group that puts as -- a new observation,  
 2 you want to see it confirmed by somebody else from  
 3 another centre and these observations were. So there  
 4 didn't seem any doubt at all for -- you know, any  
 5 reason why a doctor should look at this data and say,  
 6 "Well, I'm not sure I believe that". Sometimes  
 7 doctors do read papers and say, "I don't think  
 8 I believe that". The evidence seemed to be very  
 9 strong.  
 10 So, for me, this is one of the sort of key  
 11 moments -- in the whole of the viral epidemic amongst  
 12 haemophilia patients of contamination, this was an  
 13 absolutely key moment, where any haemophilia doctor  
 14 should have switched from a viewpoint which was "I've  
 15 noted the abnormal liver function tests of my patients  
 16 but they are very well and I'm just keeping an eye on  
 17 it and they have probably got a mild form of a virus"  
 18 to "I'm very concerned about what appears to be liver  
 19 biopsy demonstrable significant damage of a range of  
 20 abnormalities, from chronic active hepatitis to  
 21 cirrhosis, in these patients which doesn't seem to  
 22 bear any relationship to the state of their liver  
 23 function test, so I'm not going to be able to monitor  
 24 this accurately, I can't tell whether it's getting  
 25 worse or better except by doing a liver biopsy and

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1 This is March 1979, The Lancet, so it's one you may  
 2 have seen. It's PRSE0004067.  
 3 So this is The Lancet, March 1979, "Transmission  
 4 of non-A non-B hepatitis to chimpanzees by Factor IX  
 5 concentrates after fatal complications in patients  
 6 with chronic liver disease". It's a number of  
 7 authors, including, as you will see,  
 8 Professor Zuckerman.  
 9 Could we just go, Henry, please, to the last  
 10 page, last paragraph. No, that's not it. I'm sorry,  
 11 the last paragraph of this article. So it's the  
 12 left-hand column, Henry, my apologies. Beginning  
 13 "Until blood donors". No, not that bit, the paragraph  
 14 above.  
 15 So this was the view expressed by Professor  
 16 Zuckerman and others:  
 17 "Until blood-donors can be screened for the  
 18 non-A non-B hepatitis agent, it would seem wise to  
 19 restrict the use of both commercial and non-commercial  
 20 concentrates to life-threatening situations."  
 21 Then they go on to say that:  
 22 "In particular, their use in patients with  
 23 chronic liver disease should be avoided ..."  
 24 Do you think it likely that you would have seen  
 25 this article in The Lancet in '79?

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1 A. I probably would. I mean, there are two obvious  
 2 problems with this paper, talking about doctors  
 3 looking at papers and raising their eyebrow.  
 4 Firstly, we came to have no faith at all in  
 5 chimpanzees, anything to do with a chimpanzee. There  
 6 was a very famous study evaluating a new form of  
 7 Factor VIII which was given to chimpanzees and they  
 8 were absolutely fine and it was then introduced into  
 9 clinical practice, and several patients got hepatitis.  
 10 So it became clear that chimpanzees were a totally  
 11 unreliable model for looking at hepatitis. So, as  
 12 a doctor reading that, I wouldn't have been very  
 13 impressed about -- just because it's involving  
 14 chimpanzees.  
 15 The second thing, I mean, these people are not  
 16 blood specialists. They want to restrict the use of  
 17 concentrates to life-threatening situations.  
 18 Haemophilia is a life-threatening situation. There's  
 19 a very high incidence of very serious bleeding. So  
 20 I couldn't accept that bit. I could accept about  
 21 restricting the use of commercial concentrates  
 22 wherever possible. Doubtless we'll talk at some  
 23 stage, today or tomorrow, about haemophiliacs not  
 24 having treatment and maybe avoiding the risk of virus  
 25 infections. It's a very -- well, it is the most

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1 least in our centre and I'm sure in, you know, other  
 2 centres -- that, you know, one of the things that  
 3 happened at a comprehensive care review was review of  
 4 the previous visits' blood tests, and doctors like me  
 5 would sit down and say, "You know, you've done your  
 6 blood tests again and, as you know, you've got this  
 7 abnormal pattern of liver function, but it doesn't  
 8 seem to be changing". As I've said to you, we now  
 9 know it wasn't a valid statement as to in any way  
 10 predicting what their liver inflammation was going to  
 11 be in vivo, as it were, and patients were aware that  
 12 we were trying to, as a country, move over to  
 13 a situation of self-sufficiency, and they were  
 14 supportive of that. Very, very strongly. As I said  
 15 to you, they really did not want to have American  
 16 concentrate if at all possible.  
 17 Q. I understand your evidence that patients may have been  
 18 aware of non-A, non-B hepatitis as a concept -- at  
 19 least you say your patients would have been aware of  
 20 that -- but given that you have told us that  
 21 clinicians, until 1978, or some clinicians at least,  
 22 in the world of haemophilia didn't think it to be  
 23 necessarily a particularly serious condition  
 24 until 1978, when the risk of chronic liver disease  
 25 became apparent, unless the haemophilia clinicians

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1 severe bleeding tendency known to medical science. So  
 2 the idea of not treating it, to a clinician like me,  
 3 is not acceptable.  
 4 Q. I will come back to that, Dr Winter, but do you recall  
 5 whether there was any discussion about this  
 6 recommendation? Were you at Guy's by then?  
 7 A. No, it wouldn't. I can say for sure that it would not  
 8 have got off the ground if it had been presented at  
 9 a haemophilia meeting. The haemophilia clinicians  
 10 were completely signing up to the principle of  
 11 continuing to give treatment, as were the patients,  
 12 and, of course, including The Haemophilia Society, who  
 13 wrote a letter to the DOH imploring them not to stop  
 14 importing commercial concentrate. So this wasn't just  
 15 the doctors who wanted to carry on the treatment, it  
 16 was the patients' organisations as well.  
 17 Q. Do you accept that, given what you have said about the  
 18 change following Professor Preston's work, that  
 19 patients should have had that explained to them, spelt  
 20 out to them, that there was now a risk that they might  
 21 get non-A, non-B hepatitis which was now understood to  
 22 be potentially more serious than had previously been  
 23 thought?  
 24 A. I mean, patients already knew they had presumptive  
 25 non-A, non-B because, you know, they were told -- at

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1 tell the patients that it's now known that there's  
 2 a risk of chronic liver disease, patients aren't going  
 3 to know that, are they, because they are not going to  
 4 be reading Professor Preston's publication in The  
 5 Lancet?  
 6 So would you accept that patients should have  
 7 been told in or after 1978 of this new understanding  
 8 of the seriousness of non-A, non-B?  
 9 A. I mean, they were getting -- already getting advice  
 10 about healthy lifestyle. So they would have been told  
 11 how to minimise the chances of their liver problems  
 12 progressing. So, you know, eat a healthy diet, not  
 13 too much fats, particularly obviously about alcohol  
 14 usage.  
 15 So we get into quite an interesting area here.  
 16 Let's just walk through. I'm a doctor dealing with  
 17 a patient like that. I now believe that the liver  
 18 disease might be more significant than previously.  
 19 I'm already following the patient. I'm monitoring  
 20 him. Should I say to the patient, "There's a recent  
 21 paper that says that people like you actually might  
 22 get cirrhosis, and I'm just telling you this even  
 23 though I've got no way of monitoring you and no way of  
 24 treating you"? We get into quite philosophical  
 25 territories here about -- this is actually something

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1 we'll talk about with variant CJD as well, which is  
2 similar. I worked as a doctor by believing that the  
3 patient should have the truth, but does that go down  
4 to being every single paper that said the following  
5 things might happen to you even -- you know, how much  
6 can you and should you tell a patient? You obviously  
7 must tell them the core things about their illness.  
8 I can't remember, 40 years later, whether I discussed  
9 these papers with the patients. I wasn't even  
10 a consultant. I can't remember.

11 I think it's very important that the patients  
12 were aware that their liver function tests were  
13 abnormal because they needed to follow the  
14 instructions I've just outlined to you. I don't --  
15 I can't express a view as to whether they should have  
16 been told about what Professor Preston's papers had  
17 shown.

18 Q. I understand that you might not descend to the detail  
19 of specific papers with patients, Dr Winter, and  
20 I understand also the difficulty of being asked to  
21 recall what your advice would have been in the late  
22 1970s. But you've posed the philosophical question;  
23 I am going to pressure you to answer it.

24 Do you accept that in 1979 the patients should  
25 have been told that there was a possible risk of

1 is the potential risks and patients would need to know  
2 both, not least because, as you've said, they would  
3 need to take seriously the lifestyle and other advice  
4 that clinicians would be giving them.

5 A. Yes. I mean, I can't stress to you enough the  
6 difference that the concentrate made. In the  
7 documentary, you know, one of the mothers said, "You  
8 know, my son went to hospital 79 times last year and  
9 missed 35 days off school on cryoprecipitate."

10 It was not at all a good treatment. It was  
11 a treatment.

12 I think there was an element, too, you've quite  
13 rightly got these two sort of scales: benefit and  
14 risk. We were so full of benefit. This was the first  
15 time -- haemophilia was around in biblical times. In  
16 2,000 years of early death from bleeding at the age of  
17 about 20 on average, for the first time there's  
18 a decent treatment. The boarding school is closed,  
19 people can work, people can play sport, people got  
20 their lives back and, if you like, they didn't want to  
21 see the risk. And I think that applies to not only  
22 the patients, it very much applied to the doctors.

23 And I -- you know, there are ways in which  
24 doctors and patients look at illnesses, and I think  
25 I accept the point maybe it was understated at the

1 chronic liver disease from the treatment they were  
2 receiving?

3 A. I really do accept that, yes. And I think because it  
4 would help to reinforce the point (which for some  
5 patients, you'll understand, they were reluctant to  
6 follow) that they really needed to take this issue  
7 seriously and, for some of them in particular, that  
8 really did mean moderating their alcohol intake.

9 So I think as a sort of lever for patient  
10 compliance as well as a process of giving the patient  
11 information, I do accept that patients should have  
12 been aware that not only did they have a form of  
13 abnormal liver function, which I'm sure they all knew,  
14 but that there was evidence that it could have been --  
15 you know, this matter might be more serious than had  
16 been thought previously.

17 Q. You said in your statement that the information that  
18 would have been given to patients -- this isn't  
19 specifically as at 1979, but would have been strongly  
20 in favour of the expectation of a positive improvement  
21 in lifestyle.

22 I think what I'm suggesting, and I think you  
23 probably agreed with this, is that that's one side of  
24 the coin, that's the great advantage of the  
25 concentrate treatment, and the other side of the coin

1 time. It's so difficult 40 years later. I don't  
2 think the patients wanted to hear about risk and  
3 I think the doctors, you know, didn't want to hear  
4 about risk. That's the way the brain works. They --  
5 everybody was so full of "this is incredible, the  
6 change".

7 You know, to see a patient with haemophilia  
8 brought up before concentrate, or who'd never had  
9 Factor VIII concentrate in their life, if you went to  
10 a World Federation of Haemophilia you'd see these poor  
11 people with, like, the worst arthritis you have ever  
12 seen in their life. They'd be just shuffling along.  
13 None of their joints moved. If you watch television  
14 footage, there is some, of the tsarevich in Russia,  
15 he's 13 years old, before his murder. He's being  
16 carried. He is being carried by a sailor. He can't  
17 walk.

18 So this is what life was like for people with  
19 haemophilia. Even on cryo. Cryo was a treatment, but  
20 it wasn't a good treatment.

21 So suddenly, for the first time ever for this  
22 dreadful disorder, there is a decent treatment.  
23 People don't want to hear, oh, there might be  
24 a problem. I'm just making a point about the way the  
25 illness was looked at.

1 I accept the points you make but that's the way  
2 it was perceived. I fully accept -- because it was  
3 difficult to get patients to comply, some patients,  
4 because some human beings like to drink and some  
5 people obviously felt, "You don't want me to have  
6 alcohol" -- that's the ideal -- "I've got this  
7 hepatitis", and to be able to say -- or you've got to  
8 say to them, you know, "There's recent evidence that  
9 this thing might be more serious than we had  
10 originally thought", that should have been made clear  
11 to them. Of course I accept that.

12 Q. I know it's hard to remember what you did, as a matter  
13 of fact, say, over four decades ago or four decades  
14 ago. Do you think, however, it's more likely than not  
15 that in your personal case -- not talking about other  
16 clinicians -- that you advised your patients about  
17 this change in understanding, albeit potentially in an  
18 understated way?

19 A. I just can't remember. They would certainly have been  
20 told their liver function tests. They would have been  
21 given information from me and written information  
22 about diet and alcohol avoidance. I just can't  
23 remember as to whether I spoke about  
24 Professor Preston's paper.

25 Q. Before we turn to consider HIV, just a more general

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1 trying to get Factor VIII for your patients, there  
2 were two aspects to that safety. There's the viruses  
3 you know about, but there's also the purity of the  
4 concentrate. I had great difficulty trying to  
5 persuade or to get enough finance to enable me to get  
6 a treatment that was not only very safe, away from the  
7 viruses we knew about, but was very pure.

8 Concentrates contain proteins. Even recombinant  
9 contain proteins. So I felt that the more pure the  
10 product was, it was more likely, too, to be getting  
11 rid of any viruses you hadn't yet encountered.

12 So your points, actually, are really important.  
13 At all times, we were wary of the possibility of new  
14 viruses coming through, and, you know, that hadn't yet  
15 been discovered. There was this work going on for  
16 self-sufficiency. It wasn't just to combat the  
17 viruses we knew about and the theoretical ones --  
18 non-A, non-B -- that we were -- you know, when we  
19 spoke about non-A, non-B in the mid-1970s, we were  
20 right. There was a non-A, non-B, and 15 years later,  
21 we were proved to be correct. So there were a lot of  
22 conversations about, you know, what if? What if there  
23 are other viruses? So that was a very central part of  
24 the thinking.

25 Q. That leads us on to HIV.

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1 question, again, thinking about the 1970s in general,  
2 rather than any specific year within that.

3 Would you have consciously understood and  
4 thought about the risk that pooled products, whether  
5 they were imported or domestic, might contain viruses  
6 not yet known to medical science? Is that something  
7 that clinicians would have had in mind, that  
8 possibility that there could be something there just  
9 not yet known about?

10 A. Very much so. A central mantra for all the time that  
11 I was working was, it wasn't the virus you knew about;  
12 it was the virus that you didn't know about. If you  
13 looked at the history of blood products, every few  
14 years you would come -- there would be a new virus  
15 apparent and, most importantly, it would then become  
16 apparent (as we'll discuss with HIV and obviously with  
17 hepatitis C) that it had been there for some time. So  
18 we used to have a system in the hospital where we were  
19 told to bag up high risk. Somebody had hepatitis;  
20 they had to go in a special blood sample. And  
21 I vehemently opposed that because I said to the  
22 microbiologist, but all blood is -- all blood and  
23 blood products are risky because, you know, how do you  
24 know what we're about to discover in three years?  
25 What's built up from that is, when you are

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1 SIR BRIAN LANGSTAFF: Just before we go there, if I may,  
2 may I just ask you this, doctor: you have described  
3 the unwillingness of colleagues, others in jobs such  
4 as yours, to accept that the factor concentrate that  
5 they were having might have this dangerous virus we  
6 now know as hepatitis C, then non-A, non-B.

7 Why do you think -- what do you think was the  
8 consequence of accepting that it did that they feared?

9 A. Well, I hope we haven't been at a misunderstanding.  
10 I've not tried to say that haemophilia clinicians  
11 thought that their patients, the majority of regularly  
12 treated patients. Had some form of chronic hepatitis.  
13 I think everybody accepted that. The issue was: how  
14 serious was it? The point I tried to make was, for  
15 several years, particularly in tandem with the  
16 tangible benefits, it was accepted as being there, but  
17 the patients were well, so we'll just keep an eye on  
18 it. And then suddenly to this very profound change  
19 when these reports of abnormal liver biopsies started  
20 coming through. I think that's the major point I've  
21 been trying to get across, you know, throughout this  
22 conversation.

23 I don't think for a minute any haemophilia  
24 doctor denied that there were issues around the  
25 abnormal liver function in these patients who were

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1 regularly treated.

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

3 **MS RICHARDS:** Dr Winter, so turning to HIV, we'll look at,

4 please, Henry, PRSE0000523. This is really just to

5 give us a date to work with, Dr Winter. This is the

6 MMWR for 16 July 1982 and the Centers for Disease

7 Control reports of three cases of PCP pneumonia among

8 patients with haemophilia A. That, obviously, is in

9 the context, and I'm confident from your testimony to

10 Lord Archer and to Lord Penrose that you know the

11 pre-history of earlier reports from, in particular,

12 through 1981 and the first part of 1982 of the

13 increasing number of cases of what later became

14 referred to as AIDS.

15 So this is a report of cases amongst patients

16 with haemophilia. Would you have at the time seen

17 MMWRs?

18 **A.** Yes. Very much so. So, if we may, let's just walk

19 through that one year because it's so central to what

20 happens next.

21 So all doctors would have been aware of, you

22 know, 1981, these reports of the gay patients with

23 a new disease. What's it due to? Well, the

24 suggestion initially, for at least a year, was that

25 these were clearly disorders that were only seen in

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1 he had three hospitals on the phone, these three

2 patients saying, "I've got a patient with haemophilia,

3 with pneumocystis. Could you please send me some

4 pentamidine?" Bruce Evatt obviously said, "Well, why?

5 Why are these patients with haemophilia getting the

6 same immunosuppressed-type illness that the gay

7 patients from last year" -- so this is an absolutely

8 critical moment. Here is surely a sign that we are

9 dealing with a transmissible agent of some

10 description, followed shortly by this case in

11 San Francisco of a baby who had a platelet transfusion

12 from a donor who subsequently developed AIDS.

13 So in this period of six months, say, from

14 July '82 to December '82, by the end of that period,

15 as a haemophilia doctor, you would have to look at

16 that data and say, I'm really concerned that this new

17 disease is actually nothing to do with poppers or

18 anything like that. This is something which is in

19 blood. This must be a virus or something like that,

20 and we urgently need more information to tell us who

21 else might have this virus, if that's what it is, so

22 we know how to respond to this apparent potentially

23 very serious problem.

24 **Q.** I'm just going to ask you to look at the way you put

25 it in your evidence to Lord Penrose. Henry, it's

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1 people whose immune systems were not working properly,

2 either because they had an underlying medical

3 disorder, or because they'd been on chemotherapy or

4 something like that. So it was clear these people --

5 these were gay patients -- something had happened to

6 their immune systems as if they had just had

7 chemotherapy. So what could have been doing that?

8 There was evidence that poppers, amyl nitrite that

9 they were taking on social occasions, was suppressing

10 the immune system.

11 That was the initial theory. There was no

12 suggestion at all it was anything to do with blood or

13 anything transmissible. And here's another major sea

14 change moment in the whole of the epidemic is this

15 report. I'm going to tell you, if you don't know

16 this, the background as to how this happened.

17 When you have this pneumocystis, this unusual

18 pneumonia that only happens in immunosuppressed

19 patients, the treatment of choice is a drug called

20 pentamidine (which is a very, very rarely used

21 antibiotic) and it transpired that the only way you

22 could get pentamidine in the US was to ring up the

23 Center for Disease Control in Atlanta and speak to

24 a doctor called Bruce Evatt, who became a very major

25 figure in haemophilia. And in the space of one month,

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1 PRSE0006016. This was your evidence in April 2011.

2 Could we go to page 8, please, Henry.

3 We can see the way in which you put it, picking

4 it up at line 10. This is part of your answer:

5 "So shall we say September 1982 there is

6 uncertainty. There is this very small number of

7 cases. We don't have an agent. What does it mean?

8 There are other theories. Most of the patients are

9 gay."

10 And then you say this, and I'm just going to

11 read it aloud for the benefit of others as well:

12 "By December 1982 that theory is no longer

13 tenable because you have now ten patients with

14 haemophilia, but most particularly you have this

15 case."

16 That was the San Francisco baby case I think you

17 were referring to there, Dr Winter:

18 "Any clinician looking at this data would have

19 to believe that AIDS was a transmissible disorder and

20 that it could be transmitted by blood and by blood

21 products. It was the only clinical interpretation of

22 the data that was available. There was no other way

23 that this child could have acquired this very unusual

24 condition; very unusual for a baby to have these

25 series of opportunistic infections. So it was very

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1 highly likely that it must be AIDS and must have been  
 2 caused by the blood transfusion from the donor who  
 3 subsequently developed AIDS. So here is a really  
 4 critical moment. Doctors everywhere now have to  
 5 believe that AIDS is a transmissible disorder."

6 That is effectively the same answer that you  
 7 have already given a few minutes ago, but would you --  
 8 does that remain your view?

9 **A.** Yes. So at this moment in time, we're now really  
 10 believing that there are two major problems with  
 11 concentrate therapy. Firstly is, the liver disease is  
 12 much more significant than we thought. Secondly,  
 13 we're at the start of something which we are really  
 14 very concerned about. This sounds -- this new disease  
 15 sounds like a transmissible disorder, and we very  
 16 rapidly need identification of what the agent is,  
 17 a test for it, and some understanding of how to  
 18 respond to it. But it is underscoring -- set against  
 19 the extraordinary benefits of concentrate therapy,  
 20 it's really stressing the dangers of concentrate  
 21 therapy.

22 **Q.** In addition, too, by December 1982, understanding as  
 23 you explained there and have explained again that the  
 24 likelihood that this is a -- something transmissible  
 25 by blood, would you accept that it is also clear at

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1 will minimise this risk, the current home infusion  
 2 programme needs to be revised. The studies reported  
 3 in this issue demonstrate in vitro abnormalities of  
 4 immuno-regulation, but the numbers are too small for  
 5 definitive comparison of the risks of different modes  
 6 of treatment. Unfortunately, the data are consistent  
 7 with a greater potential for AIDS in the population  
 8 treated with concentrate. Physicians involved in the  
 9 care of haemophiliacs must now be alert to this risk.  
 10 Preventing the complications of the present treatment  
 11 may have to take precedence over preventing the  
 12 complications of haemophilia itself."

13 Now, I'm going to come back to or come on to in  
 14 a while the question of the use of cryoprecipitate.  
 15 But you recall, as I understand it, reading that  
 16 article at the time?

17 **A.** I do.

18 **Q.** We're just going to play a second extract from that  
 19 1988 documentary, so be prepared for your younger self  
 20 on the screen again, Dr Winter. MDIA0000111, and it's  
 21 the second excerpt, please, Henry.

22 (Video played)

23 You would, I think, agree, given your evidence  
 24 thus far, that this was a warning that haemophilia  
 25 clinicians could not and should not ignore?

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1 that stage, December 1982, that this is a condition  
 2 with a very high mortality rate?

3 **A.** Well, that seemed to be the case. Obviously, you are  
 4 dealing with very, very small numbers of cases.

5 **Q.** It was also evidence, by that stage, that there was  
 6 potentially a significant lapse of time between the  
 7 initial infection or transmission of the agent and  
 8 symptoms presenting themselves.

9 **A.** Well, we didn't know that because we didn't know -- we  
 10 didn't know when the gay patients had been infected if  
 11 it was an infectious agent and we didn't know,  
 12 similarly, with the haemophilia patients because they  
 13 would have been multi-treated, and we didn't know  
 14 which batch might have had the agent in it.

15 **Q.** You have already referred to the New England Journal  
 16 of Medicine, and we'll just look at that. I know you  
 17 are familiar with it, Dr Winter. It is PRSE0002410,  
 18 please.

19 This is January 13, 1983. You see on the  
 20 right-hand side, "AIDS and the preventative treatment  
 21 in haemophilia". We will just look at the last  
 22 paragraph of this article which is on the next page,  
 23 Henry, bottom of the left-hand column. It says this:

24 "The fact that haemophiliacs are at risk for  
 25 AIDS is becoming clear. If the use of cryoprecipitate

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1 **A.** Well, however many alarm bells a human being has, they  
 2 should all have been ringing at this stage.

3 **Q.** Now, you were still working at Guy's at this time, end  
 4 of 1982, and indeed for most of 1983. Can you recall  
 5 what discussions took place between you and your  
 6 colleagues, your fellow registrars who are managing  
 7 the haemophilia patients, or with either of the two  
 8 consultants about this issue?

9 **A.** Well, what I recall is that UKHCDO had responded to  
 10 the evolving situation, in terms of issuing  
 11 recommendations to minimise risk. So we certainly  
 12 implemented trying to avoid the use of concentrate  
 13 where at all possible. So DDAVP, obviously, for  
 14 mildly affected patients with haemophilia where at all  
 15 possible; could surgery be postponed if it was a cold  
 16 surgery and the patient didn't need to have the  
 17 surgery too quickly; the use of cryoprecipitate maybe  
 18 in children very reluctantly. These were the sort of  
 19 factors that UKHCDO were recommending as a sort of  
 20 holding measure that haemophilia centres introduce.

21 There was no recommendation that concentrate  
 22 should be withheld or withdrawn. As I've said to you,  
 23 the patients wanted to go on with treatment. The  
 24 Haemophilia Society wanted to go on with treatment.  
 25 That was really the sort of only interventions we

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1 could do, or modifications if you like, of the current  
 2 programme to minimise risk.  
 3 Parallel with this, one would like to know, if  
 4 it hasn't, you know, come out in the Inquiry already,  
 5 why were all the alarm bells not ringing at the  
 6 Department of Health, you know, in terms of  
 7 accelerating a process of redeveloping our blood  
 8 fractionation plants so that this country could be  
 9 self-sufficient in blood products, as other countries  
 10 had achieved. So this alarm bells question, of  
 11 course, isn't just for clinicians; it's for  
 12 politicians and people who plan the supplies of the  
 13 concentrates that we were using.  
 14 **Q.** We will certainly be looking at that.  
 15 The UKHCDO advice -- it was June 1983, but  
 16 I just want to -- and, again, I know I'm asking you  
 17 about events a long time ago, but I just want to go  
 18 back to the beginning of 1983. So for the first half  
 19 of 1983, there's no published advice from UKHCDO. Do  
 20 you recall whether you began to make the adjustments  
 21 you have described at the beginning of 1983, or was  
 22 that only after the UKHCDO recommendations from June  
 23 of 1983?  
 24 **A.** I can't remember. I mean, I certainly read the  
 25 Deforge paper, and we were aware of it, and we had

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1 **A.** Well, a patient with a significant bleed, which is  
 2 normally meaning joints and muscles. Obviously, any  
 3 period of internal bleeding, most especially cerebral  
 4 or gastrointestinal. Patients who had had trauma,  
 5 significant trauma, that wasn't settling down with  
 6 conservative measures, and patients who needed major  
 7 surgery which could not be postponed because they had  
 8 cancer or something like that. Those would be the  
 9 sort of major indications.  
 10 **Q.** So the aim would have been to use concentrates only in  
 11 those kind of occasions, and would that only have been  
 12 for severe haemophiliacs by then?  
 13 **A.** Mainly, but if you had a mild haemophiliac who had  
 14 bowel cancer and needed major bowel surgery, you would  
 15 have to give them Factor VIII.  
 16 **Q.** Do you recall whether given this, as you say, this  
 17 second new risk, were any attempts made to get more  
 18 BPL product to reduce the size of the shortfall  
 19 through discussions with Tooting or elsewhere?  
 20 **A.** Certainly not by the consultants who I worked for who  
 21 had really devolved haemophilia care to us and, in any  
 22 case, it was a long-running issue (the shortfall of  
 23 BPL, as I've described to you) in these two Thames  
 24 regions. It was a very long-running and  
 25 unsatisfactory saga and there was nothing, as

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1 taken what steps we could. So I'd like to be able to  
 2 say we introduced those changes that UKHCDO  
 3 recommended a few months later at that time, but in  
 4 all honesty, I can't remember whether we did or  
 5 didn't.  
 6 **Q.** You have said in your statement that, in relation to  
 7 children, BPL product was prioritised. You already  
 8 were prioritising it, so is it right to say it became  
 9 a greater priority?  
 10 **A.** Well, we already were. We would have been  
 11 extremely -- it already was the first priority, and we  
 12 had enough BPL supplies coming in to treat children  
 13 because, obviously, the amount you needed for the  
 14 children was less than adults, and there weren't in  
 15 any case many children. So I'm sure that we went on  
 16 treating these children with BPL product. But we very  
 17 much sort of concentrated things around when the  
 18 concentrate was actually needed. I mean, it's  
 19 possible that we might have suspended prophylaxis  
 20 programmes. I just can't remember. But we  
 21 certainly -- to senior registrars, we would have said  
 22 to each other -- the key message was, do not give  
 23 concentrate unless the patient absolutely needs it.  
 24 **Q.** What would the criteria have been for absolutely  
 25 needing it, then?

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1 registrars, that we could do to increase the supply.  
 2 Everybody wanted more supplies from BPL and the reply  
 3 was always the same: you're only getting so much  
 4 because Tooting are only sending so much to Elstree.  
 5 **Q.** Then the next question, Dr Winter, is, given what you  
 6 say should have dawned on haemophilia clinicians by  
 7 the end of 1982, do you accept that this is  
 8 information that should have been shared with  
 9 patients?  
 10 **A.** About what in particular?  
 11 **Q.** About the view, as described by you to Lord Penrose  
 12 and in your evidence here today, that the AIDS was in  
 13 all likelihood caused by blood or blood products and  
 14 haemophiliacs might be at risk?  
 15 **A.** Oh, yes. Because, you know, it really was  
 16 a significant concern. There was a clear policy of  
 17 moderating concentrate usage. So we would have said  
 18 to patients, "You know, we want you to go on using  
 19 concentrate for occasions when it really is needed" --  
 20 and we would have outlined that -- "but, you know, we  
 21 want you to be absolutely sure in the home setting  
 22 that you give it for a good reason."  
 23 I mean, the reality of haemophilia life is that  
 24 patients didn't always give Factor VIII for a good  
 25 reason in the home setting, and we wanted to make sure

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1 that they were only using it under the sort of  
 2 clinical indications that I've just given to you.  
 3 **Q.** To ensure that, do you accept, first of all, that  
 4 patients should have been told of the possible risk of  
 5 AIDS?  
 6 **A.** I do.  
 7 **Q.** Do you recall that that was information that you  
 8 yourself gave to the patients at Guy's at the time?  
 9 **A.** I do. In any case, around this time there are  
 10 communications from The Haemophilia Society to  
 11 patients, are there not, about this new disease  
 12 I think?  
 13 **Q.** There are.  
 14 **A.** You are going to know the answer to this better than  
 15 me.  
 16 **Q.** There are. Whether those are communications which  
 17 correctly conveyed the risk is another matter which  
 18 the chair will be considering in due course.  
 19 **A.** Yes. But suffice it to say that the new disease, if  
 20 we call it that, was being widely discussed throughout  
 21 the wider haemophilia community, in terms of  
 22 Haemophilia Society meetings, seminars, the bulletins  
 23 that went out to each of the patients, in addition to  
 24 the information that patients were getting from their  
 25 own centres.

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1 out that cryoprecipitate which was much less effective  
 2 clinically than Factor VIII concentrate.  
 3 First of all, can I ask you to explain what you  
 4 meant by that.  
 5 **A.** So let's just walk through this. I'm picking this up  
 6 as a demonstration as this is actually the size of  
 7 a bag of cryoprecipitate roughly. *(Indicated)*  
 8 So these had to be deep frozen and to give  
 9 somebody cryoprecipitate, you would go to the deep  
 10 freeze -- hospital treatment only, people didn't have  
 11 domestic deep freezers, there was no home therapy --  
 12 and two doctors or transfusion technicians would take  
 13 out 20 of these bags and throw them into a water bath,  
 14 where they had to be left for about half-an-hour to  
 15 thaw, and you would then be left with a sort of yellow  
 16 sludge that looked rather like Lucozade, if anybody is  
 17 old enough to remember Lucozade.  
 18 You then, the two of you, rolled them up into  
 19 a big master bag, almost the size of this console,  
 20 which you agitated until you were confident that all  
 21 of the cryo had gone into it. You then had to inject  
 22 something, as I recall, to wash out the last few bits,  
 23 which then went into the master bag. So by the time  
 24 that you had done all that, the two of you, it had  
 25 taken probably at least an hour to do that while the

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1 **Q.** Now I want to move to ask you some questions about  
 2 cryoprecipitate. In your witness statement -- and it  
 3 may assist if you have your witness statement before  
 4 you, I think you've got a hard copy of that?  
 5 **A.** I haven't got one. It's in the other room.  
 6 **Q.** In that case we can always rectify that after lunch  
 7 because it will probably take longer than seven or  
 8 eight minutes. But in your witness statement at  
 9 paragraph 35.3 --  
 10 *(Handed)*  
 11 **A.** Thank you.  
 12 **Q.** So if you turn, Dr Winter, to paragraph 35.3.  
 13 **A.** 35?  
 14 **Q.** Yes, 35.3. So it's on page 6 of 25. Under the  
 15 heading "Cryoprecipitate", you have identified there,  
 16 and over the page, seven disadvantages of  
 17 cryoprecipitate, and I want to ask you about those.  
 18 The second disadvantage you have identified is  
 19 it wasn't effective in Factor IX deficiency. I am  
 20 going to ask you to leave that to one side because  
 21 that might be relevant, obviously, to treatment  
 22 decisions in relation to treatments with haemophilia B  
 23 but wouldn't be relevant to treatment of patients with  
 24 haemophilia A.  
 25 So could we start then with the view there set

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1 patient was waiting for their treatment, with a bleed,  
 2 which was probably a painful one.  
 3 Once you had done that with the 20 bags, you  
 4 still didn't end up with much in the way of  
 5 Factor VIII. So in terms of efficacy, which was your  
 6 question, it was nothing like as efficacious as  
 7 concentrate. It didn't have as much Factor VIII in  
 8 it. So point number 1: it was not as clinically  
 9 effective.  
 10 Then I go on to describe here the other problems  
 11 with it. It was, as I've described to you, difficult  
 12 and laborious and it had to be deep frozen. It caused  
 13 side effects. So a very common thing was that during  
 14 the infusion, which was slow, you had to put up  
 15 a drip -- whereas concentrate took five minutes,  
 16 cryoprecipitate might take an hour to get it all in --  
 17 very often the patient, in a hospital bed, if you  
 18 could find one, or a corner of the casualty  
 19 department, often got the chills and the shakes and  
 20 the shivers, which weren't very pleasant, and then  
 21 they had to be monitored afterwards, "You can't go  
 22 home yet, I'm just going to make sure you're okay."  
 23 So for all these reasons, you know, it wasn't  
 24 good as concentrate. It wasn't as good for the people  
 25 who had to draw it up. It caused side effects.

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1 Now, another final particular issue is if you  
2 had a young child you ended up with a bag where you  
3 had 500mls, maybe, of cryo to give them, there are  
4 real issues, obviously, about giving young children  
5 high volumes of an infusion. So there were also  
6 particular issues about using cryoprecipitate in the  
7 treatment of young children with haemophilia.

8 So, for all those reasons, whilst it was the  
9 first treatment ever, in 2,000 years, for people with  
10 haemophilia, it undoubtedly saved lives, but it was  
11 a very primitive, I think is a good word to use,  
12 treatment. It was so unsophisticated in every regard  
13 compared with the concentrate, which was everything  
14 that the cryo wasn't: it was easily made up; took five  
15 minutes; suitable for home freezers; didn't cause  
16 side effects; it said on the bottle how much  
17 Factor VIII there was in each bottle, how many  
18 electrolytes -- here's another factor. You didn't  
19 know how much sodium or potassium and things was in  
20 the cryo.

21 So the concentrate had everything that the cryo  
22 didn't. So the idea of going from concentrate, with  
23 all its massive advantages, particularly, frankly,  
24 giving people their lives back -- you know, as we've  
25 been stressing, to move from a hospital-based

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1 **Q.** I am going to try and unpick a number of those, which  
2 I'll largely do after lunch looking at the time.  
3 There's just one factual question I wanted to ask you  
4 first about supply.

5 Let's leave aside for the moment the question of  
6 supply on a national scale and what the Committee on  
7 Safety of Medicines may have been advised or  
8 understood.

9 Your witness statement says that  
10 cryoprecipitate -- this was talking about it when you  
11 were at Guy's -- wasn't used but was available. Was  
12 there a particular supply problem with cryoprecipitate  
13 local to your area, to Tooting? Because we know, not  
14 least, for example, from what Dr Chisholm raised at  
15 a UKHCDO meeting in the autumn of 1983, she had no  
16 difficulty in her area getting cryoprecipitate  
17 supplies, and the minutes record agreement by other  
18 directors that they are in the same position. So it  
19 may be a variable picture geographically.

20 What about your area, Dr Winter?

21 **A.** There was a problem with all supplies from Tooting.  
22 Blood, whole blood, fresh frozen plasma. This was  
23 a centre under enormous pressure because it was the  
24 only centre serving two regions. Not only that, the  
25 regions were London regions, with enormous -- some of

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1 existence with haemophilia -- many of my patients  
2 never went on holiday. They said, "I can't go on  
3 holiday, I need to be near my haemophilia centre".  
4 You know, certainly there was liberty. They could go  
5 and have a more or less -- it wasn't a completely  
6 normal existence, we didn't let people do high contact  
7 sports like rugby or karate or boxing, but virtually  
8 everything else about their lives became normal for  
9 the first time ever.

10 So there was this extreme reluctance of patients  
11 to change and for doctors to change. So the idea of  
12 moving, it was very difficult, in a time when we've  
13 now got two major problems we're really, really  
14 worried about, firstly, nobody wanted to go back to  
15 cryo for all the reasons I've said.

16 Now, finally, a very important point, this was  
17 raised at various bodies. The Committee on Safety of  
18 Medicine said, well, you can't in any case, because  
19 there's no supply. Because, you know, the production  
20 of cryo had been diminishing greatly, because it was  
21 being sent to -- plasma was being sent to Elstree to  
22 turn into Factor VIII concentrate.

23 So even if we'd wanted to switch to cryo, which  
24 we certainly didn't, there wasn't the supply anyway.  
25 So it was a non-starter.

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1 the biggest hospitals in Britain. So nobody got what  
2 they wanted from Tooting.

3 **Q.** Did anyone from Guy's or, to your knowledge, any of  
4 the other haemophilia centres served by Tooting  
5 approach Tooting at this point in time and say, "Well,  
6 what we actually need now is some more cryoprecipitate  
7 because of the risks of Factor VIII concentrates"?

8 **A.** No, because nobody -- I don't think anybody  
9 considered -- apart from the subgroups I've mentioned  
10 to you, which were few and far between, nobody was  
11 considering, for all the reasons I've said, switching  
12 the therapy of a patient with severe haemophilia back  
13 to cryoprecipitate.

14 **MS RICHARDS:** Sir, I note the time. There's quite a lot  
15 I need to discuss and ask Dr Winter on this issue.  
16 Shall we do that after lunch?

17 **SIR BRIAN LANGSTAFF:** Yes.

18 Well, as before, Doctor, don't talk about your  
19 evidence to anyone, whatever else you may wish to talk  
20 about, and we'll meet back at 2.00, shall we.  
21 2 o'clock.

22 **(1.02 pm)**

**(Luncheon Adjournment)**

23 **(2.00 pm)**

24 **SIR BRIAN LANGSTAFF:** There's no need to stand when I come  
25

1 in if you are more comfortable sitting. It's entirely  
 2 a matter for you.  
 3 **A.** Okay.  
 4 **MS RICHARDS:** Can you hear okay?  
 5 **A.** No. I've changed my battery.  
 6 **SIR BRIAN LANGSTAFF:** Can you hear me now?  
 7 **A.** Not as well as I could this morning.  
 8 **MS RICHARDS:** We won't start until we have sorted this  
 9 out.  
 10 **A.** Something seems to have happened after he changed my  
 11 battery. I can hear myself, but I'm not getting the  
 12 loop.  
 13 **MS RICHARDS:** Don't worry, we will get our technical  
 14 person in.  
 15 *(Pause)*  
 16 **SIR BRIAN LANGSTAFF:** All I was saying to you, so that  
 17 there's no mystery about it, was there's no need,  
 18 unless you want to do so, to stand up when I come in.  
 19 Counsel will because she performs the role she has  
 20 standing, but if you are more comfortable sitting,  
 21 that's fine.  
 22 **MS RICHARDS:** Dr Winter, we were talking about  
 23 cryoprecipitate. One of the observations you made was  
 24 that it was not suitable for home treatment. Now,  
 25 I should say the Inquiry has had evidence that

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1 so it was clinically efficacious, even if it took  
 2 longer or was a more laborious process than  
 3 concentrate?  
 4 **A.** Yes. I've already stated that. It was just not as  
 5 effective.  
 6 **Q.** Then, in terms of side effects, as I understand your  
 7 evidence from before lunch, the side effects from  
 8 cryoprecipitate that you were describing, the chills  
 9 and shakes and need to be monitored, so, as you say,  
 10 certainly not pleasant, but not long-term and serious  
 11 side effects?  
 12 **A.** No. They were just transient, maybe lasting a few  
 13 minutes, but they needed to be monitored.  
 14 **Q.** You also suggested that cryoprecipitate couldn't be  
 15 used in children, although I think your answer was  
 16 young children. As we'll come on to see, you have  
 17 already made reference to, the UKHCDO recommendation  
 18 that emerged in the middle of 1983 did actually  
 19 include a recommendation to use cryoprecipitate for  
 20 children. So it was, as a matter of fact, something  
 21 that could be used for children, I think?  
 22 **A.** Yes. It just had practical problems if the child was  
 23 young, as you say.  
 24 **Q.** So we come, essentially, to a number of practical  
 25 issues in relation to cryoprecipitate -- it took

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1 cryoprecipitate was used for home treatment at Great  
 2 Ormond Street, at Birmingham Children's Hospital, and  
 3 we know it was used by Katherine Dormandy at the Royal  
 4 Free.  
 5 I can entirely see that it may have been -- or  
 6 the concentrate home treatment might be more  
 7 straightforward, less laborious and so on, but I think  
 8 it is not right to say that it was impracticable or  
 9 impossible to have cryoprecipitate as home treatment?  
 10 Would you accept that?  
 11 **A.** But you have to have a deep freeze, and that was  
 12 a problem.  
 13 **Q.** Certainly, Dr Dormandy at the Royal Free made those  
 14 arrangements for her patients.  
 15 **A.** Right.  
 16 **Q.** Do you accept that cryoprecipitate posed a lower risk  
 17 of infection for HIV and non-A, non-B hepatitis?  
 18 **A.** Yes, because it only came from -- you know, gave  
 19 somebody 20 bags; that was exposure to 20 donors  
 20 rather than to the 20,000 with an infusion of  
 21 concentrate.  
 22 **Q.** You have explained why you thought cryoprecipitate was  
 23 less clinically effective than concentrate, but would  
 24 you agree that cryoprecipitate could be used, and  
 25 indeed had been used, to raise Factor VIII levels, and

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1 longer, you might need a deep freeze, but if in  
 2 hospital you would have that facility, but it would  
 3 take longer; it would need medical staff. So those  
 4 are practical disadvantages, but would you accept that  
 5 one has to set against that the fact that it was  
 6 safer? Why would the practical disadvantages outweigh  
 7 the safety of the product?  
 8 **A.** If you're moving towards why didn't we use cryo on  
 9 everybody, I've already told you, there was just no  
 10 supply. Secondly, there was massive -- there would  
 11 have been massive antipathy from the patients, and  
 12 there would have been great reluctance from the  
 13 doctors. It was -- I don't ever recall any  
 14 haemophilia doctor ever suggesting, in response at  
 15 this critical moment, that we should switch all  
 16 patients to cryoprecipitate. I have no recollection  
 17 of any haemophilia doctor thinking that that was  
 18 a possible way forward.  
 19 I think there was Dr Ratnoff in Cleveland  
 20 I think he was. I think he was always remembered as  
 21 the one doctor who kept his patients on  
 22 cryoprecipitate, but it was just not considered as  
 23 a realistic option in this country.  
 24 **Q.** Yes, and we may hear some evidence at least to the  
 25 contrary, but I understand that to be your

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1 understanding.  
 2 In terms of supply, if there wasn't enough  
 3 available for an immediate switch of everybody from  
 4 concentrate to cryoprecipitate, would there have been  
 5 enough to ration it so that cryoprecipitate was used  
 6 for children and previously untreated patients or mild  
 7 haemophiliacs?  
 8 **A.** Well, that's what UKHCDO was recommending, wasn't it,  
 9 and that's what happened at Guy's, to my recollection.  
 10 **Q.** Would you agree that if there was a switch from  
 11 reverting to cryoprecipitate instead of concentrate,  
 12 there may have been an ability to catch up, in terms  
 13 of supply issues, because you could utilise the plasma  
 14 that would previously have been required for  
 15 concentrate to make cryoprecipitate?  
 16 **A.** That would only be the British plasma, obviously.  
 17 **Q.** Yes.  
 18 **A.** Of which there wasn't very much.  
 19 **Q.** What about the option of switching to cryoprecipitate  
 20 for more patients on a temporary basis until more was  
 21 known about the risk of AIDS, or more known about the  
 22 possibility of viral inactivation? Was that an  
 23 option?  
 24 **A.** Isn't that the same thing as we've just been  
 25 discussing?

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1 could go back on cryoprecipitate?  
 2 **A.** No.  
 3 **Q.** If they had -- this is a hypothetical question, but if  
 4 they had, what would your response have been?  
 5 **A.** Well, I would have talked it through with them.  
 6 I mean, if they were very, very concerned about going  
 7 on with concentrate, if I could have got guaranteed  
 8 supplies of cryoprecipitate, if they understood the  
 9 implications of what that decision meant, in terms of  
 10 having to come into hospital each time they had  
 11 a bleed, which is quite a significant thing, then  
 12 I would certainly have had an open discussion with  
 13 them.  
 14 But our recommendation was, you know, as we've  
 15 been discussing, to introduce these restrictions to  
 16 these particular sort of subgroups of patients who we  
 17 could get away from concentrate to, you know, express  
 18 our anxiety about the situation and the lack of  
 19 apparent progress towards self-sufficiency. I mean,  
 20 of course, I am still a trainee at this time, so  
 21 I don't have any managerial authority or anything, and  
 22 that was really as far as we could go.  
 23 **Q.** You may or may not know the answer to this, Dr Winter,  
 24 but in terms of cost, and leave aside for one moment  
 25 the practical question that there may have been supply

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1 **Q.** I think we've discussed using cryoprecipitate for  
 2 children and the other categories identified in the  
 3 UKHCDO --  
 4 **A.** So we're 1983, aren't we?  
 5 **Q.** So we're 1983.  
 6 **A.** Yes.  
 7 **Q.** What about using cryoprecipitate for a wider range of  
 8 patients, including adults who are severely affected,  
 9 as a temporary option? Was supply the only reason?  
 10 **A.** Same answers, I think, you know. No supply. I mean,  
 11 you know, there was very little cryo around, as far as  
 12 I can recollect. At least the part of the world where  
 13 I was working, it would have meant cessation of home  
 14 therapy, patient reluctance, less efficacious,  
 15 et cetera. I mean, safer. I'm not denying the  
 16 importance of that, but it just didn't seem an option  
 17 to it for all those reasons.  
 18 **Q.** Do you recall whether you had or your colleagues at  
 19 Guy's at this time had any discussions with patients  
 20 to offer them cryoprecipitate?  
 21 **A.** No.  
 22 **Q.** As in, no, you can't recall, or you didn't have --  
 23 **A.** No, I can't recall.  
 24 **Q.** I think you have already told us that no patient  
 25 positively asked you to go back on -- asked if they

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1 issues in relation to the Tooting centre -- in terms  
 2 of cost, do you know whether cryoprecipitate was, to  
 3 the health authority, more expensive or cheaper than  
 4 factor concentrates?  
 5 **A.** Oh, much cheaper.  
 6 **Q.** Then can I ask you just a little about commercial  
 7 versus British concentrates?  
 8 **SIR BRIAN LANGSTAFF:** May I just ask this: did any patient  
 9 later on, when you were a consultant -- did any of the  
 10 patients whom you treated who were young -- that is  
 11 children who were having cryoprecipitate in accordance  
 12 with the guidelines, or mild, early affected, and  
 13 having it in accordance with the guidelines, or first  
 14 just newly diagnosed -- did any of them say to you,  
 15 well, look, these other people we've come across, they  
 16 get this factor concentrate to keep in their fridge at  
 17 home. Can I have some of that?  
 18 **A.** No. No, they didn't. I mean, as I stressed, this was  
 19 a very small centre with very small numbers of  
 20 children only, but none of the patients approached me  
 21 with that sort of conversation, and I can't recall at  
 22 this distance of time -- I mean, I can remember using  
 23 cryoprecipitate in a child, but I can't remember -- my  
 24 recollection is that most of them we were able to  
 25 secure BPL concentrate, and that's the way we treated

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1 them, and we advised them to only use it for times  
 2 when it was absolutely necessary. We didn't have  
 3 prophylaxis programmes going in children, so we  
 4 suspended prophylaxis, so it was only given for  
 5 episodes of significant bleeding.

6 **MS RICHARDS:** Then the question of commercial versus  
 7 British concentrates. Your statement says, and your  
 8 evidence has been clear, that in terms of  
 9 concentrates, BPL concentrate was your treatment of  
 10 choice. Was the reason for that your understanding  
 11 that it was, relatively speaking, safer than  
 12 commercial concentrates?

13 **A.** Yes, because I'd been signed up for a long time --  
 14 well, really during all my time as a trainee -- to  
 15 a firm belief that if you had Factor VIII that was  
 16 derived from a pool of voluntary donors, it was --  
 17 wherever those donors lived, it was going to be much  
 18 safer than if the concentrate was derived from a pool  
 19 of paid donors, for obvious reasons. Because the  
 20 voluntary donors were giving it through altruism, and  
 21 the paid donors were doing it because they needed the  
 22 money and were, therefore, much likely to have alcohol  
 23 and drug problems and, therefore, much more likely to  
 24 be carriers of viruses.

25 **Q.** Other than safety, were there any other advantages or

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1 commercial concentrates were of equal clinical  
 2 efficacy and safety my main responsibility was then to  
 3 purchase coagulation factor concentrate at the most  
 4 advantageous price."

5 As I understand that, you are not saying that  
 6 commercial concentrates were of equal safety to  
 7 British concentrate, you are saying that, as between  
 8 the various different commercial concentrates, you  
 9 weren't aware of anything to pick and choose between  
 10 them. Is that right?

11 **A.** That's correct in terms of both efficacy and safety.

12 **Q.** Thank you.

13 Before we get to you being a consultant, which  
 14 I promise we will get to, I just wanted to ask you  
 15 a handful of questions about UKHCDO and its decisions  
 16 and actions during this period.

17 So if we go first, please, Henry, to  
 18 CBLA0001619.

19 We can see these are the minutes of a UKHCDO  
 20 meeting on 13 September 1982. If we go to the bottom  
 21 of the second page, please, Henry, we can see, towards  
 22 the very bottom, that you're there in place of  
 23 Dr Barkhan, and Dr Barkhan was represented by you and  
 24 apologies had been received by him.

25 This was, I think, the first UKHCDO directors'

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1 disadvantages of British product over commercial  
 2 product?

3 **A.** No. I mean, we had obviously wished, as the situation  
 4 was in Scotland, to be entirely self-sufficient in  
 5 what would have been English Factor VIII. That's what  
 6 we wanted. But that was the only consideration -- and  
 7 we wanted that because it was safer.

8 **Q.** Were you aware at this time that in the United Kingdom  
 9 there was still collection of blood from prisoners?

10 **A.** In the US?

11 **Q.** No, in the United Kingdom.

12 **A.** No.

13 **Q.** Can I ask you just to clarify one point in your  
 14 witness statement, Dr Winter, before I move to a next  
 15 topic. It's paragraph 23(c) of your witness statement  
 16 if you just have the hard copy.

17 **A.** Could I ask you to get the audio person back. I'm  
 18 still not picking you up.

19 **MS RICHARDS:** Certainly. We will just pause there.  
 20 *(Pause)*  
 21 I just wanted to check one point in your witness  
 22 statement to see that I've correctly understood it.  
 23 It's paragraph 23 of your witness statement, and at  
 24 paragraph 23(c) you say:  
 25 "As I believed that all of the available

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1 meeting that you attended, and you attended at this  
 2 stage not as a director but still as a registrar?

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

4 **Q.** Then if we go, please, to page 10, Henry.

5 We can see that AIDS was discussed. It's the  
 6 bottom of page 10. It's said that:  
 7 "The Reference Centre Directors had asked  
 8 Dr Craske to look into the report from the  
 9 United States of this syndrome mainly in homosexuals  
 10 but including three haemophiliacs. It appeared that  
 11 there was a remote possibility that commercial blood  
 12 products had been involved. Dr Craske asked the  
 13 Directors to let him know if they had any cases of the  
 14 syndrome. The Working Party was considering the  
 15 implications of the reports of the USA."  
 16 So that's the sum total of the discussion on  
 17 AIDS as recorded in those minutes.  
 18 First of all, what, if anything, do you recall  
 19 of that meeting?

20 **A.** Nothing. But I -- obviously, interestingly, you  
 21 reading the words there, look at it. I mean, the  
 22 phrase "remote possibility" doesn't seem the best of  
 23 phrasing, does it? I certainly would not have used  
 24 that phrase at all, because it seemed to me that, by  
 25 this stage, you would have had to use a phrase like it

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1 was considered a "significant possibility" that these  
 2 patients had been infected by an agent in blood  
 3 products.  
 4 **Q.** So that's September '82 when you're there. Now I'm  
 5 going to go now to a meeting which I know you weren't  
 6 at, Dr Winter. It's HCDO000003\_008 please, Henry.  
 7 I will just get an alternative reference.  
 8 Forgive me. We'll see if we can find a difference  
 9 reference for that, Dr Winter. Let me tell you what  
 10 it was. It was a meeting of Reference Centre  
 11 Directors at St Thomas' on 13 May 1983 to discuss  
 12 AIDS.  
 13 Could I ask you whether you have any reflection  
 14 on the lapse of time between September 1982, the  
 15 meeting we have just looked at, and there not being a  
 16 special meeting to discuss this until May of 1983.  
 17 Do you think that can -- showed sufficient urgency on  
 18 the part of Reference Centre Directors?  
 19 **A.** Well, of course this was an organisation that I didn't  
 20 belong to at that time. It seems to me that -- if my  
 21 memory's correct, it was the end of 1982 that we had  
 22 the San Francisco baby --  
 23 **Q.** Yes.  
 24 **A.** -- which was important sort of additional information,  
 25 in addition to the three original American cases. We

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1 it's dated 24 June 1983. You can see, if we just  
 2 scroll down a little, "general recommendations":  
 3 "1. For mildly affected patients with  
 4 haemophilia A or von Willebrand's disease and minor  
 5 lesions, treatment with DDAVP should be considered.  
 6 Because of the increased risk of transmitting  
 7 hepatitis by means of large pool concentrates in such  
 8 patients, this is in any case the usual practice of  
 9 many Directors."  
 10 That reflected the practice at Guy's?  
 11 **A.** It did.  
 12 **Q.** Then:  
 13 "For treatment of children and mildly affected  
 14 patients or patients unexposed to imported  
 15 concentrates many Directors already reserve supplies  
 16 of NHS concentrates (cryoprecipitate or freeze-dried)  
 17 and it would be circumspect to continue this policy."  
 18 So the recommendation is cryoprecipitate or NHS  
 19 factor concentrate for those categories?  
 20 **A.** Which is what were already implemented.  
 21 **Q.** At Guy's at this stage?  
 22 **A.** Yes.  
 23 **Q.** You may or may not have view on this, Dr Winter, but  
 24 this is voiced as "general recommendations", and what  
 25 we see in paragraphs 1 and 2 is, well, this is the

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1 would have had a small number of further American  
 2 cases. We didn't get the first British case until  
 3 May '83 I think, in Cardiff.  
 4 **Q.** It was publicly reported in May of '83. We've seen  
 5 evidence to suggest that the patient presented to  
 6 Professor Bloom in Cardiff in March of '83.  
 7 **A.** Yes. I mean, you know, looking back I just don't know  
 8 what drove them to schedule the meetings in that way.  
 9 I mean, the Haemophilia Directors, now known as  
 10 Comprehensive Care, is a pretty small community, and  
 11 we -- you know, outside of the meetings, we are all in  
 12 touch with each other pretty closely, or most of each  
 13 other. So for all I know there may have been quite  
 14 a lot of telephone dialogue going on about the  
 15 evolving situation, but I obviously don't know why  
 16 they didn't meet again until May, which -- here's the  
 17 document now in front of me.  
 18 **Q.** Yes. That's fair enough, Dr Winter.  
 19 Can we then look at the document that you did  
 20 become aware of, which was the recommendation sent out  
 21 after this meeting in June of 1983.  
 22 I'm hoping this is the right reference, Henry,  
 23 HCDO0000270\_004.  
 24 So after that meeting in May, this letter was  
 25 sent by Professor Bloom and Dr Rizza. You will see

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1 practice generally, "circumspect to continue" is the  
 2 language of paragraph 2.  
 3 It falls short of being an instruction or firm  
 4 advice. It's to some extent leaving it to clinical  
 5 judgment; would you agree?  
 6 **A.** Yes, it's interesting to reflect on this. Medicine  
 7 now is different to medicine then and there was  
 8 a great stall then, the famous phrase "clinical  
 9 freedom", the ability of a doctor to look at some  
 10 guidelines and say, "I'm going to do something totally  
 11 opposite to that because I have clinical freedom" --  
 12 a very dangerous concept.  
 13 I think, therefore, for some doctors at that  
 14 time, these documents were seen as advisory but not  
 15 binding. I think now the word "protocol", which is  
 16 not mentioned here, we don't -- well, when I was  
 17 working we didn't have advisory documents, we had  
 18 protocols, and it was generally agreed that once the  
 19 haemophilia directors had issued a protocol to the  
 20 haemophilia -- to the UKHCDO members, they were on  
 21 dangerous ground if they deviated from that and  
 22 something went wrong with the patient. So this was,  
 23 you know, this moved from being a guidance, which is  
 24 advisory, over the course of the next 30 years to  
 25 being essentially a strongly recommended protocol

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1 which was produced by experts and you were expected to  
2 follow it. If you didn't follow it, then that might  
3 be a problem.

4 **Q.** Then we'll move from June 1983 to October 1983.

5 Henry, could we have PRSE0004440, please.

6 So we can see this is a meeting of the directors  
7 on 17 October 1983. If we go down we can see --  
8 actually, if you leave it there, Henry, that's great.

9 I don't know whether you see, if you go down, in  
10 alphabetical order, the list of attendees. We have,  
11 I believe, Dr Chisholm, Dr KGA Clark, Guy's Hospital,  
12 London. That's the other consultant?

13 **A.** That is the case. He is not a haemophilia specialist.

14 **Q.** Then if we could go to page 10, please, Henry.

15 We can see under the heading "Any other  
16 business", bottom half of the page:

17 "Dr Chisholm raising the problem of patients  
18 refusing to take up commercial Factor VIII concentrate  
19 because of the AIDS scare. She wondered, in view of  
20 the worry of the patients whether the directors could  
21 revert to using cryoprecipitate for home therapy."

22 Then this is Professor Bloom's response:

23 "He felt that there was no need for patients to  
24 stop using the commercial concentrates because, at  
25 present, there was no proof that the commercial

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1 **SIR BRIAN LANGSTAFF:** You are right. I think this is  
2 a question, ultimately, for me to evaluate. What  
3 counsel is doing, I think, is finding out what the  
4 views were of different clinicians as to what the  
5 answer should be, although ultimately it's one which  
6 I will have to decide. So it's helpful. You have --  
7 I think the background to this is you have just  
8 described the word "remote" possibility. The word  
9 "remote" used several months before this as being  
10 misplaced and significant would be better. You have  
11 indicated that you understood there is a real risk --  
12 leave aside the question of certainty -- the question  
13 might be put this way: is a significant or real risk  
14 a proper ground for action? You've said it was, for  
15 yourself, a year later or a few months later when you  
16 had to consider what action to take in advance of  
17 there being definite proof of cause and effect.

18 **A.** I mean, of course, if I may say so, I stress, you  
19 know, this has been a very long conversation. You're  
20 talking now about what interactions I had with other  
21 haemophilia doctors. I didn't have any. I wasn't  
22 a consultant. I didn't -- I was not part of UKHCDO.  
23 I was not having regular dialogues with other  
24 haemophilia treaters around the country because I  
25 didn't know them because I was a trainee. So all this

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1 concentrates were the cause of AIDS."

2 Would you agree with this, that to await proof  
3 before taking action in circumstances where the link,  
4 although not proven, is pretty clear, is the wrong  
5 course to take?

6 **A.** Well, we're only a few months away from the events of  
7 April and May 1984, which we'll talk about in a few  
8 minutes, where exactly that situation arose. And,  
9 together with some other doctors, I did have to make  
10 very radical changes to therapy on theoretical  
11 considerations alone.

12 **Q.** You have told us you were pretty satisfied, and as far  
13 as you are concerned, most haemophilia clinicians were  
14 pretty satisfied at the beginning of 1983 that blood,  
15 blood products, were the cause of -- or were the  
16 relevant transmissible agent. And yet here's  
17 Professor Bloom saying, well, there's no need to stop  
18 using concentrates, and the reason he gives is not  
19 supply or anything else. The reason he gives is no  
20 proof. Would you agree that's the wrong question for  
21 him to have been posing, or the wrong answer for him  
22 to be giving at that time?

23 **A.** When I've done these inquiries, one of the  
24 difficulties is being asked to explain why other  
25 doctors said and did something.

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1 will change in a minute when I eventually do get to be  
2 appointed as a consultant. But if I've been rather  
3 vague with my answers for this last couple of hours,  
4 it's because, you know, I was in a little bubble at  
5 Guy's Hospital working as a senior registrar, and  
6 I was not part of the UKHCDO network, and I can't tell  
7 what interactions they were having at their level,  
8 which was presumably by telephone and informal  
9 meetings.

10 **MS RICHARDS:** I understand that. Now, we know that the  
11 next document or set of recommendations issued by  
12 UKHCDO was in December of 1984, and I know you have  
13 got some observations you want to make about that  
14 document. What I'll do is come back to that when  
15 you've explained the decisions and actions you took in  
16 the course of 1984, so we can look at it in that  
17 context.

18 Can I just ask this, though: you talked about  
19 the status of UKHCDO recommendations. If -- and this  
20 is hypothetical -- but if the Chief Medical Officer  
21 had issued guidance (for example, guidance saying  
22 clinicians should no longer use imported concentrates,  
23 or clinicians should revert to using cryoprecipitate),  
24 would you have expected to follow guidance from the  
25 Chief Medical Officer?

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1 A. I think that that's -- it became a very significant  
 2 issue as we, over the next few years, dealing with all  
 3 these very spectacular problems, the lack of very what  
 4 you might call powerful, influential, centralised  
 5 advice. I think we're going to talk about this when  
 6 we talk about how to tell patients they've got HIV,  
 7 how to test them, and so on, and so on. There were  
 8 many of these issues. It was made a lot more  
 9 difficult to cope with at local level as a consultant  
 10 trying to respond to these spectacularly difficult  
 11 problems that there was no central body that had  
 12 published very clear, firm guidance or protocol, or  
 13 call it what you will, to haemophilia doctors saying,  
 14 this is what we think you should do in this situation.  
 15 You know, this is why one of the key things for me in  
 16 the whole academic is the variability word, and all  
 17 these things we've already been speaking about of each  
 18 doctor having the freedom to do what he wanted.  
 19 That was just one of the very, very major  
 20 difficulties that emanated out of a very clear  
 21 diktat -- let's use a proper word -- from somewhere  
 22 powerful and central saying this is what you should  
 23 do, and we really lacked that. Particularly when HIV  
 24 broke, we were blood specialists, haemophilia doctors,  
 25 not virologists dealing [on a] day-to-day basis with

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1 in his evidence to the Archer Inquiry was very  
 2 critical of UKHCDO. He said it was run pretty much as  
 3 a club by the ten or so main players, and there was  
 4 something of an information vacuum for directors in  
 5 particular of smaller centres.  
 6 Would you agree with that, based upon your own  
 7 experience once you became a director?  
 8 A. I don't agree with that. I think we should state  
 9 UKHCDO was generally regarded by the other haemophilia  
 10 societies and doctors and other countries as actually  
 11 being a model of its kind. There isn't really any  
 12 other country where haemophilia doctors came together  
 13 and collaborated to such an extent that every patient  
 14 with an inherited blood disease in the country was  
 15 registered, we knew the number of patients with the  
 16 condition, we knew the severity of the condition, we  
 17 knew whether they had an inhibitor, we knew whether  
 18 they were on home treatment, we knew whether they were  
 19 alive or dead. No other country had information like  
 20 this and every time you went to a World Federation  
 21 meeting, people would say, you know, your system you  
 22 have in the UK is light years of what we have in our  
 23 country. We have nothing like it.  
 24 Then, in addition to that, as we've seen  
 25 already, it was a very active organisation, in

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1 the problems caused by a virus of which we were not  
 2 specialists.

3 So I think that point you are raising is  
 4 a really core one. We very much lacked firm, central  
 5 guidance from whatever body; you know, a body set up  
 6 for national virological advice, or the Chief Medical  
 7 Officer or whatever.

8 Q. And you -- I infer from your answers -- would have  
 9 welcomed such guidance, whether it was from the CMO or  
 10 others?

11 A. Yes.

12 Q. Because what you have described is a situation in  
 13 which you as a registrar with your fellow registrars  
 14 in a centre in which the two consultants are not  
 15 specialists in this field are having to take your own  
 16 decisions?

17 A. Well, yes. We had the UKHCDO guideline, which we'd  
 18 followed, about how to minimise concentrate usage.  
 19 But apart from that, yes.

20 Q. Can I ask you one further question about UKHCDO, not  
 21 at any one point in time, but in the knowledge that  
 22 you are about to become a member, in the end of 1983,  
 23 when you become a director in Kent.

24 Professor Savidge, who you obviously dealt with  
 25 quite extensively over the following months and years,

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1 addition to all the day-to-day work we were doing. At  
 2 any one time, there would be six, seven, eight working  
 3 parties in specialist areas. So I thought the UKHCDO  
 4 was a very good thing. Of course, there were  
 5 personalities involved, of which Professor Savidge was  
 6 a large one.

7 Q. So we've finally, Dr Winter, reached December 1983  
 8 when you took up your appointment in Kent as the  
 9 centre director and consultant haematologist.

10 Could you just describe what the services were  
 11 when you arrived in Margate at the haemophilia centre.

12 A. Well, very unsatisfactory really. There were very --  
 13 although it was a centre and covering a very wide  
 14 geographical area and with quite a good number of  
 15 patients, there was no proper centre as such. It was  
 16 just a haematology department.

17 There was a particularly unsatisfactory state of  
 18 affairs in that the patients got Factor VIII on  
 19 prescription from the general practitioner, and it  
 20 wasn't clear to me how this completely inappropriate  
 21 system had come about. But what that meant was when  
 22 the patient needed Factor VIII, they went off to a GP  
 23 who wrote a prescription -- please issue ten bottles  
 24 of Factor VIII, and they went to a local pharmacy who  
 25 had never heard of Factor VIII but looked it up and

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1 found somebody who would sell it at an inflated price,  
2 doubtless. And the particular and very, very  
3 unsatisfactory aspect to all this was that, of course,  
4 no batch numbers were taken.

5 So when I took over, I had no information  
6 whatsoever as to what people had been receiving over  
7 the years and that became critical when, over the  
8 months to come as HIV broke, UKHCDO would start  
9 circulating to all haemophilia treaters details of  
10 contaminated batches. You would get a letter saying,  
11 "We now know that the following batches, a patient's  
12 got HIV. Please let us know if your patients have  
13 received that batch" and I couldn't tell them because  
14 I had absolutely no records at all.

15 So that was one of my top priorities, was to get  
16 rid of that completely inappropriate system.

17 **Q.** We'll just look at a couple of documents in relation  
18 to that, if we may, Dr Winter, just to illuminate  
19 that. HCDO0000174\_009, please. We can see this is  
20 7 February 1984, and it's a letter that you wrote to  
21 Miss Spooner at the Oxford Haemophilia Centre. You  
22 say that you recently replaced Dr Harold Sterndale as  
23 director. You enclose the annual returns and then you  
24 say this. You note:

25 "I have not been able to give you any

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1 out-patient, and that it's NHS Factor IX concentrate.  
2 No commercial Factor IX concentrate has been used at  
3 the hospital, but you are not able to give any figures  
4 for home treatment. It's nil because you don't have  
5 the data.

6 **A.** It's useful to see this because it gives everybody an  
7 idea of the way in which the Oxford returns -- every  
8 January or February, all haemophilia doctors would sit  
9 down and submit information about the previous year's  
10 treatment. These are patients with haemophilia B, not  
11 A.

12 **Q.** Yes, we will look at --

13 **A.** The haemophilia A would look very similar to that.

14 **Q.** Yes, and we've got that. Henry it is the same, but  
15 004 at the end.

16 **A.** Then, in addition to this, each patient is registered  
17 with Oxford, has a unique identification code, so  
18 there would be a separate piece of paperwork to do  
19 where for every registered patient you would provide  
20 agreed information along the lines of had they had  
21 treatment, are they still alive, have they developed  
22 an inhibitor, et cetera.

23 **Q.** Yes. Then we can see again -- if we look at the  
24 column, we've got -- at the top, we've got total  
25 number of haemophilia A patients treated during the

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1 information about material used in the home treatment  
2 of our haemophilic patients. I understand that there  
3 was a serious lack of local funding a few years ago,  
4 and for these reasons an arrangement was made whereby  
5 all haemophiliacs on home treatment received  
6 Factor VIII concentrate from their general  
7 practitioners on prescription."

8 Then you explain that you are extremely unhappy  
9 about that and taking every step you can to abolish it  
10 and issue Factor VIII directly. Then you are afraid  
11 you have no data on the type or amount of Factor VIII  
12 that was used by our haemophiliacs on home treatment.

13 If we just look at the returns.

14 **A.** Can we just point out that she is the secretary of  
15 UKHCDO which, at that time, was based in Oxford and  
16 subsequently moved to Manchester.

17 **Q.** Yes. We've seen that from other documents. Thank  
18 you.

19 Then if we could have, please, Henry,  
20 HCDO0000174\_003. So we can see this is the annual  
21 return for 1983 for Margate. Your name is there.

22 This is in relation to haemophilia B. Total number of  
23 patients treated during the year, three. Then we can  
24 see that you have been able to give a figure for the  
25 total used at hospital, whether in-patient or

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1 year, 25, and then we can see for the haemophilia A  
2 patients, for in-patient or out-patient treatment, so  
3 treatment at the hospital, there's 48,750 units there  
4 of NHS Factor VIII. Then we can see the figure for  
5 commercial Factor VIII at 16,320 of Kryobulin. But in  
6 terms of home treatment you've put nil, and then  
7 you've put amount unknown, for the reason you've given  
8 because the home treatment system was being done  
9 through the GP and local pharmacies.

10 **A.** These are tiny amounts; less than 5 per cent of the  
11 usage, I would think. So nearly everything has gone  
12 through a general practitioner.

13 **Q.** So that system -- and I appreciate entirely it's not  
14 a system for which you were responsible, and it's  
15 a system which you were horrified by, but that meant  
16 that either a GP -- not a specialist -- or  
17 a pharmacist -- not a clinician -- was determining  
18 what actual product the haemophilic patient had for  
19 their home treatment?

20 **A.** It was not the GP at all who had also not heard of  
21 Factor VIII. He wouldn't have known anything about  
22 Factor VIII or even if it came in different types. It  
23 was all down to the pharmacist who also had not heard  
24 of Factor VIII who went and looked it up in a book and  
25 found there were suppliers and, for whatever reason,

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1 chose one of the suppliers and rang them up and said,  
 2 how much is a bottle of Factor VIII? Whereas most  
 3 haemophilia centres would have been ordering several  
 4 hundred bottles at a go, they must have been highly  
 5 amused at a commercial company to have a local  
 6 pharmacist ring up and ask to buy ten bottles of  
 7 Factor VIII. But that's what happened.

8 **Q.** Is this a correct inference to draw, that the patients  
 9 who would have been receiving their Factor VIII in  
 10 this way would have been receiving exclusively  
 11 commercial concentrates because the pharmacist  
 12 wouldn't have access to the regional transfusion  
 13 centre supply?

14 **A.** That's correct. This is a reflection of what we've  
 15 been talking about earlier; the great shortage of  
 16 Elstree BPL in the south-west Thames and south-east  
 17 Thames regions, and therefore the need to buy  
 18 commercial.

19 **Q.** It's probably clear from the letter you wrote to  
 20 Miss Spooner, but would you agree that this was  
 21 a completely inappropriate way to manage the care of  
 22 the patients at the centre?

23 **A.** Well, it wasn't any form of management at all. It was  
 24 anti-management.

25 **Q.** You then arrived in December of 1983, and at that

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1 a responsibility that you perhaps hadn't had at Guy's.  
 2 Did you raise the question of the shortfall or  
 3 inadequate supply of NHS concentrate with anyone at  
 4 the Tooting regional transfusion centre or in the  
 5 Blood Transfusion Service?

6 **A.** I think something very influential happened.  
 7 Dr Savidge, as he was then, rang me up very, very  
 8 early in my consultancy and he said, "I think we need  
 9 to meet and to talk", which was extremely helpful.  
 10 I remember going to meet him at St Thomas' very,  
 11 shortly after I started, and we actually, rather than  
 12 talking about shortage of BPL, what we spoke about at  
 13 that meeting were the double problems, what we were  
 14 going to do about the new disease, which seemed to be  
 15 in the blood supply, what were we going to do about  
 16 chronic liver disease and we actually immediately --  
 17 most our conversation was could we get heat treatment.  
 18 I know we're just about to come on to talk about  
 19 that but he was extremely helpful and influential in  
 20 persuading me as to the right way forward over the  
 21 next few months and -- because, if you like, we were  
 22 very hopeful of -- we'd accepted that Tooting was  
 23 never going to be able to come up with any  
 24 improvement. This had been a very long-running saga  
 25 and, as I say, at really all aspects of their

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1 point, as consultant, the decision as to which form of  
 2 treatment to use or which particular product to use  
 3 was yours. Your witness statement says that it's the  
 4 ultimate responsibility of the local trust. Can  
 5 I just ask what you mean by that; do you mean you are  
 6 an employee of the health authority and, in that  
 7 sense, it's the trust's responsibility?

8 **A.** Yes, I mean, the ultimate responsibility laid with me,  
 9 really, as the clinician. It was solely my decision  
 10 as to which type of concentrate a patient received.  
 11 And that, for the first three or four months of my  
 12 consultancy, until we move on in a minute to talk  
 13 about heat treatment, was basically a situation where  
 14 there was very little Elstree available. So I was  
 15 also, of course, continuing to follow the same  
 16 recommendations that we had been implementing at Guy's  
 17 about moderating concentrate usage for this first  
 18 three or four months in early 1984. Then for the  
 19 other regular severely affected patients I was having  
 20 to purchase commercial Factor VIII.

21 **Q.** The source of NHS concentrate for you in Margate,  
 22 would it still have been Tooting?

23 **A.** Mmm.

24 **Q.** It was. You were now a consultant and therefore had  
 25 a status you hadn't had at Guy's, and indeed

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1 operation.  
 2 You know, we'd have situations in the hospital  
 3 where we would ring up Tooting at night for emergency  
 4 supplies and be told, "Oh, we're very short". There  
 5 was a chronic shortage of all blood and blood products  
 6 from Tooting because of this situation where they were  
 7 covering the two health authorities. So we didn't  
 8 think there was any mileage in trying to get more  
 9 supplies of Elstree. By January there was so much of  
 10 concern that we were already at that stage talking,  
 11 the two of us, asking ourselves: can we get  
 12 inactivated Factor VIII? Because that's going to be  
 13 the way forward.

14 **Q.** Now, in the period from December 1983 until May 1984,  
 15 when you started to use the heat-treated product, are  
 16 you able to give us any idea, on a very rough basis,  
 17 what the percentage was of NHS versus commercial that  
 18 you were using for your patients?

19 **A.** Well, as you've seen from the previous year, there was  
 20 hardly any Elstree reaching Margate. The supplies  
 21 were so limited. There was a feeling, of course, in  
 22 the provinces, that it all went into central London  
 23 and that we were an afterthought, but this -- I can  
 24 only reflect that we had very, very little BPL, as the  
 25 previous year's returns show.

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1 Q. So is it fair to say that probably the majority of the  
 2 treatment was commercial concentrates?  
 3 A. Yes -- nearly all of it.  
 4 Q. Where you were using factor concentrates --  
 5 A. For that three or four months when I was in post.  
 6 Q. You told the Penrose Inquiry that -- I can take you to  
 7 it if need be but I will just summarise and if you  
 8 don't remember and want to look at it, we will.  
 9 You told the Penrose Inquiry the patients didn't  
 10 want to have American concentrate or some patients  
 11 didn't want to, and you say it took quite a bit of  
 12 work to persuade patients in some cases to continue to  
 13 receive commercial concentrate. Do you want to look  
 14 at the passage?  
 15 A. No. So this is really, now, one of the next of  
 16 a number of absolute key points in the epidemic.  
 17 Q. I wanted to ask, that process you talk of, persuading  
 18 patients to continue to receive commercial  
 19 concentrate, are you talking there about the  
 20 heat-treated concentrate?  
 21 A. Well, that's -- I wasn't sure whether you were talking  
 22 about -- are you talking about -- before we switched  
 23 to heat treatment, about carrying on with commercial?  
 24 Q. Yes, I really just wanted to know that that  
 25 description of persuading patients in some cases to

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1 A. Well, before the switch, because it was the only  
 2 Factor VIII I had, because I didn't have any Elstree,  
 3 and as we've discussed I didn't want to go back to  
 4 cryoprecipitate.  
 5 Q. Then for this first few months of your consultancy,  
 6 was it the case that you were still trying to treat in  
 7 accordance with the UKHCDO recommendation from the  
 8 June of the previous year?  
 9 A. Yes.  
 10 Q. So for children, for newly diagnosed, for mildly  
 11 affected patients, would you be trying to use NHS  
 12 concentrate?  
 13 A. Try to use NHS, use DDAVP where appropriate, try and  
 14 postpone surgery if it wasn't necessary, use BPL for  
 15 children, maybe cryo for an older child if it was  
 16 possible. Do all you can to restrict concentrate  
 17 usage for children and mildly affected patients.  
 18 Q. Was there any prophylactic programme during these  
 19 first few months --  
 20 A. No, not at that time.  
 21 Q. So just given that there had been this previous rather  
 22 unsatisfactory situation of the GP and the pharmacist,  
 23 could you just talk us briefly through what you then  
 24 did. This is, again, before heat treatment. Did you  
 25 call every patient in or invite every patient for an

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1 continue to receive commercial concentrate, what time  
 2 period does that relate to?  
 3 A. Well, in my experience, the whole history was,  
 4 haemophilia patients, from the moment of their  
 5 diagnosis and growing up and going to meetings, learnt  
 6 that one of the sort of key things to follow was that  
 7 you -- you know, people used to say to them in the  
 8 Sunday morning meeting in a Haemophilia Society  
 9 seminar in wherever, "You know, when you get back to  
 10 your centre, you want to make sure that you get  
 11 British Factor VIII. Don't ever get American  
 12 Factor VIII". Very early on in the haemophilia  
 13 experience the patient would have that message from  
 14 somebody. It's a family illness; other people,  
 15 a cousin or somebody, an auntie, might have said, "You  
 16 make sure". All the patients knew.  
 17 You know, in my experience, whether it's this  
 18 period, January '84 or at a time a few months later,  
 19 when we're trying to persuade people to switch, people  
 20 were very, very reluctant -- completely  
 21 understandably, they were right -- to have Factor VIII  
 22 from commercial donors.  
 23 Q. The reason -- I'm really just interested in your use  
 24 of the verb "persuade". What was the reason you were  
 25 trying to persuade patients to do so?

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1 appointment and explain that the situation was going  
 2 to now be different?  
 3 A. Yes. I mean, when patients come in to a haemophilia  
 4 centre and they get supplies, they get enough for  
 5 a couple of months, say. On this very inappropriate  
 6 system, the ten bottles they were given might only  
 7 last them a week or something, so the patients were  
 8 having to get prescriptions very regularly, so they  
 9 ran out very quickly. So it was actually pretty easy  
 10 to send for them to say, "I need to talk to you about  
 11 what's going to happen in the future, I've got  
 12 a better system, we're going to give you the  
 13 Factor VIII from the hospital and you don't need to go  
 14 to the GP anymore."  
 15 Q. Given that the time-frame we're talking about is end  
 16 of 1983/early 1984, in the course of that conversation  
 17 that you're having with your patients because you're  
 18 changing the way in which they receive their  
 19 treatment, did you tell your patients anything about  
 20 the risks from commercial concentrates in terms of  
 21 either AIDS or non-A, non-B hepatitis?  
 22 A. Well, I certainly, in a very major way, did, as we're  
 23 coming on to talk about, in April and May. These  
 24 patients had not been particularly well informed about  
 25 haemophilia, really, let alone its treatment. I think

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1 because I was already in a discussion with Dr Savidge,  
 2 my priority -- I had a highly inappropriate, dangerous  
 3 system. My priority was to get a proper haemophilia  
 4 treatment programme going with dispensation -- that's  
 5 the wrong word -- dispensing being done from the  
 6 hospital rather than GP and a pharmacy.  
 7 So my priority was to get the patients onto, you  
 8 know, a system where they collected from us, and  
 9 I thought: let me do that first of all and then I can  
 10 talk to the patient about a range of things.  
 11 There was hardly any home therapy I wanted to  
 12 do, there was no prophylaxis I wanted to do. The  
 13 major thing bubbling under was: are we about to switch  
 14 to heat treatment?  
 15 **Q.** So in those first few months is it right to understand  
 16 from your answer that you wouldn't have necessarily  
 17 have been telling your patients as a matter of routine  
 18 about the risks of AIDS and non-A, non-B hepatitis?  
 19 **A.** I didn't start until 12 December, so by the time --  
 20 you know, Christmas, and then most of these patients  
 21 I'd never met and they were coming in for reviews once  
 22 every couple of months or so, by which time I was well  
 23 on the way to trying to switch.  
 24 **Q.** Then you've told us I think of some of the initiatives  
 25 of trying to implement the UKHCDO recommendations, and  
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1 talking about, I think we saw a number on the return,  
 2 your statement had estimated about 20 or so severe  
 3 haemophiliacs, with haemophilia A?  
 4 **A.** I think that's right. We had a sort of hub and  
 5 spokes. So I did also look after patients in adjacent  
 6 centres. They would go for day-to-day treatment to  
 7 Medway or Maidstone or places like that, and then they  
 8 would come to me for reviews, as a haemophilia  
 9 specialist. So, in all, I'm thinking about  
 10 35 patients with significant haemophilia and I say  
 11 that because those were the patients who were coming  
 12 on later in the year to get HIV tested.  
 13 **Q.** Then, if we just look at your witness statement again  
 14 please, Dr Winter, at paragraph 35.4 you say this:  
 15 "At this highly critical time there were  
 16 therefore only three options for haemophilia  
 17 clinicians:  
 18 "... suspend treatment ..."  
 19 I'm sorry, I'll wait -- do you have that?  
 20 **A.** Yes.  
 21 **Q.** My apologies.  
 22 So your option 1 was "suspend treatment"  
 23 completely?  
 24 **A.** Yes.  
 25 **Q.** Your option 2 was to "continue with BPL concentrate  
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1 you mentioned possibly delaying surgery, not having  
 2 prophylactic treatment until you can sort the  
 3 situation out. Was the giving of advice about how to  
 4 manage the condition, through lifestyle changes,  
 5 through rest, was that ever part of the conversation  
 6 at that point in time?  
 7 **A.** To be honest, it was -- I was starting from scratch  
 8 there. I did not have a haemophilia nurse, I didn't  
 9 have a physio, I didn't have a centre, I didn't have  
 10 a finance manager, I didn't have a secretary, I didn't  
 11 have a centre. All my patients were getting  
 12 Factor VIII from a GP. I mean, you couldn't have  
 13 started from a lower position.  
 14 So I started -- you know -- and also, as if that  
 15 wasn't enough, I was immediately into a situation  
 16 where I knew there were two really serious issues  
 17 which was really also at the core of my thinking. So  
 18 I had a whole range of really important priorities  
 19 about, firstly, establishing, in effect, for quite  
 20 a lot of patients, coming in from all over Kent, for  
 21 the first time a proper centre. So -- and there were  
 22 just me. So there were a whole range of priorities  
 23 I had to do first. By then it's spring time, by then  
 24 we're into heat treatment.  
 25 **Q.** Just in terms of the numbers of patients that we're  
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1 only". Your option 3 was to "switch to heat-treated  
 2 Factor VIII and IX".  
 3 Now, we know you opted for option 3, and we'll  
 4 talk about that in a moment. I just wanted to ask  
 5 whether the position was truly as stark as you there  
 6 set out. Because presumably you wouldn't have to  
 7 suspend all treatment; you could reduce the amount of  
 8 treatment, suggest "try and use a little bit more  
 9 cryoprecipitate", give advice about management and bed  
 10 rest, on a temporary basis at least. Was it  
 11 a more nuanced set of options than this perhaps  
 12 suggests?  
 13 **A.** No. Nobody ever gave bed rest to a person with  
 14 haemophilia. They're bleeding and they need to have  
 15 the bleeding stopped.  
 16 With hepatitis C we know you almost certainly  
 17 got hepatitis C the first time you had a treatment, so  
 18 the viral risk from one treatment might have been the  
 19 same as from 30 treatments. So where was the logic in  
 20 trying to reduce treatment? You know, you were still  
 21 going to give the treatment that had the virus, so  
 22 there was no logic there.  
 23 So it really did seem, as a matter of sort of  
 24 strategic principle, those were the three core choices  
 25 that lay in front of us.  
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1 Q. So could you then talk us through your reasoning for  
 2 taking what was -- I think, could fairly be  
 3 characterised as a bold decision, in the spring of  
 4 1984, to use heat-treated products?  
 5 A. Yes. This is one of the absolute key moments in the  
 6 history of the epidemic. We'll have heard on the  
 7 documentary and other things there was a certain view  
 8 retrospectively from some people with haemophilia: why  
 9 did I have to continue to have Factor VIII, couldn't  
 10 I have stopped? Haemophilia clinicians like me were  
 11 very unhappy about that suggestion. Cerebral bleeding  
 12 has always been the most common cause of death in  
 13 haemophilia. I think in that year there had already  
 14 been ten deaths from cerebral bleeding in haemophilia.  
 15 These are things, of course, the patients don't see  
 16 unless it happens to their family relative. It's the  
 17 sort of thing that the doctors see.  
 18 If you look at the Birch report of the early  
 19 1930s, an American doctor I think, she looked at life  
 20 expectancy of patients with severe haemophilia. Of  
 21 course there was no treatment. Nearly all the  
 22 patients were dead by the age of 21/22. The World  
 23 Federation of Haemophilia have a twinning system and  
 24 every two years at the World Federation a centre like  
 25 ours, from the developed world, would get twinned with

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1 what the issues were.  
 2 Firstly, we have the patients', "British, good,  
 3 American, bad". So the choice is: you can stay on  
 4 British Factor VIII. It's from voluntary donated  
 5 plasma: good. It's got a full product licence: good.  
 6 It's cheap: good. The patients like it: good. But  
 7 there's no inactivation step. Surely you have to  
 8 believe that this new virus, which hadn't -- well, it  
 9 had been identified by then, and we had better make  
 10 the point. In mid-1983, the French and then the  
 11 American groups had identified the virus that we now  
 12 know as HIV. So we knew that we were dealing with  
 13 a virus, we just didn't have a test for it.  
 14 So that was the big "but": did you believe, with  
 15 increasing numbers of cases -- still not very many --  
 16 did you believe that the new virus would only be  
 17 present in American Factor VIII or could it be  
 18 possibly there also in British Factor VIII?  
 19 So that was the British choice.  
 20 Or did you say to yourself, "People with  
 21 haemophilia are so vulnerable, the batches are from  
 22 20,000 donors, if one of those donors has a virus, the  
 23 patient's likely to get it, they are incredibly  
 24 vulnerable to any virus, therefore if I go for  
 25 American, not liked by the patients, 50 per cent more

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1 a developing centre, and we became twinned with  
 2 Islamabad, in Pakistan, who we went to see. They are  
 3 a nuclear power but they had no Factor VIII at all,  
 4 nothing. On the first day we did a clinic for about  
 5 50 children, all of whom got carried in by their  
 6 fathers, unable to walk, and at the end of the day  
 7 I said to the centre director from Islamabad, "Well,  
 8 tomorrow presumably we can go and do a clinic at the  
 9 adult centre", and he just looked at me and said,  
 10 "There isn't one. We don't need one. All of these  
 11 children will die of bleeding."  
 12 So the natural history of haemophilia,  
 13 untreated, is to die of bleeding. So you'd never get  
 14 a clinical doctor like me to sign up to a situation  
 15 where I said to a patient, "Why don't you stop having  
 16 Factor VIII for a bit?" Bleeding is a very, very  
 17 serious issue. As I keep on saying, it's the most  
 18 potent bleeding disorder known to man.  
 19 So that was the easiest of the three options.  
 20 It was absolutely not an option not to treat. So that  
 21 was the easy bit.  
 22 Now we come to the really hard bit. For years,  
 23 I reflected on this very difficult time and thought it  
 24 was the hardest decision I ever had to make as  
 25 a doctor. So let me just try and walk you through

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1 expensive, no licence, but it's heated"?  
 2 Now there was experimental evidence. The  
 3 companies had started to bring in heat-treated  
 4 Factor VIII to try and see if it inactivated  
 5 hepatitis, before anything was known about AIDS. So  
 6 the companies in the US had started to work on heat  
 7 inactivation. In 1983 the Germans had a heat-treated  
 8 product, Bering, but we were not able to get that.  
 9 But -- so that was the choice.  
 10 You know, and I sat down with the patients and  
 11 said, "I'm not happy about no treatment. This is  
 12 a really, really difficult call, but ..."  
 13 Again, I stress, I owe a debt of gratitude to  
 14 Dr Savidge, who was very, very clear and strong that  
 15 he thought we ought to switch -- everybody -- to both  
 16 Factor VIII and Factor IX.  
 17 By February 1984, one of the companies, Alpha,  
 18 who had a plant in Norfolk, they are an American  
 19 company, they had a licence in the US for the  
 20 heat-treated product. That was a major step forward.  
 21 Dr Savidge and I approached them together with the two  
 22 other doctors in Britain and said: we're aware of this  
 23 licence in the US, do you think you would be able to  
 24 get supplies for us? Which we would have to give on  
 25 a named patient basis. So, you understand, if a drug

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1 doesn't have a licence, doctors in this country still  
2 have the ability to use a drug on a named patient  
3 basis. The answer was, "Yes, we can. It's going to  
4 be 50 per cent more expensive".

5 So we decided that was the route we really ought  
6 to go down, because we were so very concerned, for all  
7 the reasons we've discussed this morning, that HIV --  
8 we now had a virus. We couldn't convince ourselves  
9 that it wasn't going to be in British Factor VIII as  
10 well as American because of the intrinsic  
11 vulnerability of the system.

12 There was very widespread disagreement with  
13 those views, and I'm never critical -- you can ask the  
14 other doctors who are coming who didn't go down that  
15 pathway. The arguments against were: some people  
16 believed, including Professor Bloom the Chairman, that  
17 this was a problem to do with commercial Factor VIII.  
18 The whole virus story, non-A, non-B, HIV, it was  
19 commercial. Terrible donor practices. It was not  
20 going to happen to Britain with altruistic voluntary  
21 donors. This was an American problem. That was view  
22 number one.

23 Secondly, the Germans always used huge amounts  
24 of Factor VIII, much higher than Britain, from German  
25 donors. They had -- apparently, they had had little

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1 un-heat-treated supplies in, getting heat-treated  
2 supplies out. So it was -- just in terms of  
3 logistics, once you'd done that, it was complicated,  
4 and you had other doctors saying to us at meetings,  
5 I don't know why you're doing this.

6 Anyway, finally, very poignantly, although for a  
7 long time I thought this was just the most  
8 unimaginably difficult decision, I now realise -- and  
9 this is quite a powerful thing to say -- actually, it  
10 was all probably irrelevant because I now realise that  
11 nearly all of the patients had already been infected.  
12 And at some stage, I'd like to talk to you about that  
13 data.

14 **Q.** Absolutely. We will come to that.

15 **A.** Anyway, that was the heat treatment dialogue.

16 **Q.** Can I just ask -- sorry. You mentioned two other  
17 doctors along with you and Professor Savidge. I think  
18 you've named Middlesex and Sheffield as the areas.  
19 Could you just let us know who the doctors were?

20 **A.** Yes. There was a Professor Eric Preston, who you are  
21 due to be seeing, and Professor Sam Machin from the  
22 Middlesex. They were -- his is quite a smaller  
23 centre.

24 **Q.** Did you consider heat-treated products other than  
25 Alpha? Were there other options available to you that

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1 or no HIV. That was quoted.

2 Then, thirdly, there was a very understandable  
3 concern -- we've spoken about inhibitors. About  
4 10 per cent of patients develop inhibitors which makes  
5 the future treatment with Factor VIII effectively  
6 impossible. Some doctors very reasonably said, I'm  
7 really worried about this because the heat treatment  
8 might alter the antigenic nature of Factor VIII in the  
9 bottle so that when it's injected into the patient,  
10 the antibodies, the patient's immune system might  
11 recognise the injection as being foreign for the first  
12 time and make an inhibitor. This was a very  
13 serious -- you know, it would have been a very serious  
14 development, and it was a perfectly -- it was  
15 perfectly reasonable to put up that as an argument.

16 Having said all that and had this incredibly --  
17 I can't stress to you enough -- the difficulties and  
18 the -- plus all the implementation of it, I had to  
19 persuade the patients who were anti-American. I had  
20 to, in the middle of a financial year, increase the  
21 budget by 50 per cent. At some stage in the next day  
22 and a half, I would like to talk to you about the way  
23 finances were arranged in haemophilia and priorities  
24 and things because that's a particularly important  
25 thing. We had all the logistics of getting

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1 un-heat-treated supplies in, getting heat-treated  
2 supplies out. So it was -- just in terms of  
3 logistics, once you'd done that, it was complicated,  
4 and you had other doctors saying to us at meetings,  
5 I don't know why you're doing this.

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7 long time I thought this was just the most  
8 unimaginably difficult decision, I now realise -- and  
9 this is quite a powerful thing to say -- actually, it  
10 was all probably irrelevant because I now realise that  
11 nearly all of the patients had already been infected.  
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21 due to be seeing, and Professor Sam Machin from the  
22 Middlesex. They were -- his is quite a smaller  
23 centre.

24 **Q.** Did you consider heat-treated products other than  
25 Alpha? Were there other options available to you that

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1 time?

2 **A.** No, that was the only one available, and we were very,  
3 very keen to get on with it as soon as possible. We  
4 were -- we made the decision. It seemed absolutely  
5 right but difficult, and we absolutely wanted to get  
6 it done, so we started May 1984. There were then some  
7 supply problems, but from June '84, all of those four  
8 centres were using only heat-treated Factor VIII and  
9 Factor IX, and they did not get any more viral  
10 infections in those centres after those dates, whilst  
11 other centres, as we will discuss, were going on using  
12 un-heat-treated material all the way through till  
13 September the following year, a period of about  
14 15 months or so.

15 **Q.** Can I just ask before we break again, Dr Winter, in  
16 terms of the categories of patient who switched to  
17 heat-treated product in May of 1984, was that all of  
18 your patients, so those who had been on some form of  
19 NHS or cryoprecipitate? Presumably it wasn't those  
20 for whom DDAVP was the most appropriate treatment?

21 **A.** No, DDAVP is fine. For everybody else, we were making  
22 a core statement. Any concentrate is unsafe because  
23 of the nature of concentrate manufacture. You know,  
24 the vulnerability of a haemophiliac patient to get  
25 a virus is so strong with 20,000 whatever it is

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1 donors, be it donor from voluntary donor or commercial  
 2 donor. We'd convinced ourselves all -- at that moment  
 3 in time, you were very, very unwise to continue to  
 4 treat any patient with a concentrate that had not had  
 5 a step to inactivate a virus.

6 **Q.** If we leave aside von Willebrand's and mild  
 7 haemophiliacs, for whom DDAVP was appropriate, all the  
 8 rest of the patients, haemophilia A and haemophilia  
 9 B --

10 **A.** And haemophilia B as well. Even though there were no  
 11 patients with AIDS, we felt, as a principle, if it was  
 12 in Factor VIII concentrate, why shouldn't it be in  
 13 Factor IX as well? We wanted everybody to switch.

14 **Q.** I'll ask you a little about the process, but I note  
 15 the time, sir. Is this a convenient moment for the  
 16 afternoon break?

17 **SIR BRIAN LANGSTAFF:** Well, it will be after I have asked  
 18 one further question, if I may.

19 You have described how difficult a decision it  
 20 was. You've given credit to the arguments against  
 21 that decision. Was there one factor in particular  
 22 which made you decide the way you did or not? And if  
 23 so, what was it?

24 **A.** Well, I think the combination of these particular  
 25 factors -- I was totally sold up, and had been since

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1 **MS RICHARDS:** Dr Winter, are you able to hear me okay?  
 2 **A.** I can.

3 **Q.** So you had been describing the switch of your patients  
 4 to heat-treated product in May of 1984. You'd said  
 5 that that was essentially for all your patients, other  
 6 than those who could be treated as mild patients or  
 7 von Willebrand's patients with DDAVP.

8 Was there any space left, as it were, for the  
 9 treatment of cryoprecipitate? Did that continue at  
 10 all for any category of patient, or was it, other than  
 11 DDAVP, all now heat-treated concentrates?

12 **A.** No. As you'll gather from my remarks, cryo was really  
 13 regarded as obsolete, and we didn't want to use it  
 14 unless we absolutely had to. After an initial hiccup,  
 15 we were able to get all the supplies of the  
 16 heat-treated material that we needed from Alpha so we  
 17 could get all the patients across, as I say, by the  
 18 end of June '84.

19 **Q.** So the switch took place, I think, between May and  
 20 June, or in the course of May and June 1984.

21 Can you just describe for us, please, the  
 22 process in terms of your meetings with patients and  
 23 the information that was provided to patients.

24 **A.** So I sat down -- we're probably talking about a switch  
 25 of about -- you know, this is initially with the

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1 1982, to the idea that AIDS was due to a transmissible  
 2 agent. I then knew, by the middle of '83, that that  
 3 was the case because the virus had been identified.  
 4 I knew then that that virus had been causing illness  
 5 in a small number of American haemophiliacs and, by  
 6 that stage, a British haemophiliac and I knew that the  
 7 patients were incredibly vulnerable because they were  
 8 receiving concentrate from thousands of donors. So if  
 9 you added in all those little things, you had a pretty  
 10 clear view. You had just lost confidence, if you ever  
 11 had confidence, that concentrates were safe.

12 When historians in 50 years will write histories  
 13 of haemophilia, they'll say concentrates brought  
 14 unimaginable benefits to people with haemophilia for  
 15 the first time: home therapy, schools, work, exercise,  
 16 et cetera, a normal life with a huge but -- a huge  
 17 but. The Achilles heel: it came from thousands of  
 18 blood donors. If there was a virus in town in blood,  
 19 the haemophiliacs would get it.

20 **SIR BRIAN LANGSTAFF:** Thank you very much. We will take  
 21 a break until quarter to four. Half an hour, I hope,  
 22 is okay for you. Quarter to four, doctor.

23 (3.15 pm)

(A short break)

24 (3.45 pm)

1 regularly treated patients who were going to be  
 2 switched as a priority, and there were probably about  
 3 30 of those, I suppose. So some of those had upcoming  
 4 appointments. If they didn't, I sent for them.

5 I don't know about other centres, but my  
 6 patients were well-read and knew of the issues and had  
 7 obviously been talking about the possibility of  
 8 getting treatment that had been virally inactivated.  
 9 So I sat down with them, usually with their wife or  
 10 partner, and said, "I really need to have a very  
 11 significant discussion with you because we've got  
 12 a big decision to make because I can now" --  
 13 I explained all about heat treatment. I explained all  
 14 about why I was very worried about carrying on with  
 15 any form of concentrate that hadn't been virally  
 16 inactivated. And I said, you know, we've now got  
 17 a choice, but I can get supplies of heat-treated  
 18 Factor VIII, or Factor IX if they were a haemophilia B  
 19 patient.

20 I mean, I wouldn't say I pushed them, but  
 21 I said, you know, this is my recommendation.  
 22 I really -- we thought about this very hard. I said  
 23 St Thomas' are going to do the same thing, and  
 24 I really think we should -- it's the best way forward  
 25 for you. You know, as I'm the centre director looking

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1 after you, this is going to be your choice, but my  
2 recommendation would be that we did change you over on  
3 to this different treatment.

- 4 **Q.** Did all the patients that you spoke to accept that  
5 recommendation?  
6 **A.** Yes. I mean, the issue was the word "American", and  
7 we spoke through all that, about -- I said even if  
8 I could get them British unheated Factor VIII -- which  
9 I couldn't -- but if I could, you know, I still had  
10 significant concerns that although the virus load  
11 might be less than in American un-heat-treated, it was  
12 still significant. So for that reason -- this was the  
13 total reversal of everything they always wanted to  
14 hear, but I was saying, controversially, American  
15 heat-treated was safer than British unheated, even  
16 though the latter came from voluntary donors.

17 So it was a very dramatic switch, and for some  
18 of them, you know, they sort of needed an intake of a  
19 few moments to really think about what I was saying,  
20 and -- but, you know, this wasn't a surprise to them.  
21 It had been in the air. I may have been speaking  
22 about them in February, you know, earlier when -- for  
23 the first time I was thinking about trying to switch.

24 That's what happened, and they -- I mean, some  
25 were more enthusiastic than others, but nobody

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1 budgets are not easy at the best of times. But to  
2 go -- you know, when the budgets have all been set  
3 early in the year and to go and see the finance people  
4 and say, I really want to change to using a different  
5 type of Factor VIII. It's 50 per cent more expensive.  
6 The reason I want to do this is theoretical. And  
7 they've got people coming in, the neurologists coming  
8 in saying there's a new drug for multiple sclerosis.  
9 The oncologists are coming in and saying there's a new  
10 drug for breast cancer. Haemophilia is low priority  
11 in the Health Service because it's a chronic  
12 disability. You've heard this. Priorities in the  
13 Health Service are: accident and emergency, cancer  
14 waiting times, surgery waiting times. Chronic  
15 disability is low, and haemophilia is especially  
16 unpopular. What finance people like are low cost,  
17 high volume, totally predictable. They want to go to  
18 a Trust and say, we're going to commission 20,000 hip  
19 replacements from you. Haemophilia was a complete  
20 nightmare because it was everything they hated: low  
21 volume, high cost, and totally unpredictable.

22 Every March, I used to sit down with them, and  
23 they used to say to me, "Dr Winter, how much are you  
24 going to spend on Factor VIII this year"? And I said,  
25 "You're asking me how often my patients are going to

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1 disagreed, which made it easier because that would  
2 have been very messy logistically to have some  
3 patients on heat-treated and some on un-heat-treated.  
4 But we managed to get everybody to agree to switch,  
5 and that's what happened.

- 6 **Q.** What was the mechanism for the named patient basis?  
7 Was there any particular procedure that you had to go  
8 through?  
9 **A.** Yes. That was another area. I can't remember the  
10 exact way it's done now, but it's all very formal, and  
11 you have forms to fill in for each patient that you  
12 might treat, not only the regular ones. So I had to  
13 do it for every patient in the centre who was likely  
14 to need clotting factor concentrate. So there was  
15 a lot of administration to be done. This would have  
16 been a national form for doctors to treat patients on  
17 a named patient basis. That must have been sent off  
18 to some national committee somewhere to be registered.  
19 So all that had to be done and approved. Doubtless,  
20 there was work with my Trust to get them to agree that  
21 I should start treating patients on a named patient  
22 basis. I would have had to go to the ethical  
23 committee, and then there was the finance. You know,  
24 this is what may -- I'm buying it -- well, the new  
25 financial year's just started in April, and NHS

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1 bleed, and I don't know the answer to that". So  
2 haemophilia was a nightmare for finance.  
3 Sorry, you've rather started me off on  
4 a long-winded theme, but I'm not quite sure how we  
5 manage to get the finance, given all those things, but  
6 I think there must have been a bit of press activity.  
7 In fact, I'm sure there was. I think there was  
8 a Sunday Times campaign or something. My local MP was  
9 Jonathan Aitken, and I got him to ask a question in  
10 the House of Commons. He was the first MP to ask  
11 a question about AIDS. So I think there was a bit of  
12 political activity going on which must have helped.  
13 Anyway, we somehow did manage to get the money.

- 14 **Q.** You may not know the answer to this, given what you've  
15 said a few moments ago, but the named patient forms,  
16 I've been going to ask you who you sent them to. You  
17 thought it was potentially some national committee or  
18 organisation?  
19 **A.** Yes.  
20 **Q.** But you don't at this stage recall that?  
21 **A.** I cannot remember who it was, but there was definitely  
22 a mandatory process for each patient. You know, what  
23 was the name of the patient, the name of the drug, why  
24 you were doing it.  
25 **Q.** Then how did you manage asking your patients to return

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1 to you any stocks they had of unheated product?  
 2 **A.** So I think -- because we knew it was going to be  
 3 a rolling period over a few weeks, most of the  
 4 patients had upcoming appointments, so by that stage  
 5 I had one or two haemophilia nurses appointed. They  
 6 were responsible for home therapy administration. So  
 7 they would have rung up the patients and said, you  
 8 know, Dr Winter was talking to you about this switch.  
 9 We're now in a position to do the switch, so the next  
 10 time you come to the centre, we're going to give you  
 11 the new supplies of the new treatment and show you how  
 12 to draw it up and how it works. Please will you bring  
 13 with your any unused bottles of the old concentrate.  
 14 That was pretty straightforward.  
 15 **Q.** Now, that was May/June. The exclusive product, in  
 16 terms of concentrate used from then onwards in the  
 17 centre, was the heat-treated Alpha concentrate.  
 18 Did you -- and presumably that was used both in  
 19 the hospital and for home therapy?  
 20 **A.** For all treatment.  
 21 **Q.** Did you initiate a prophylactic programme at that  
 22 stage?  
 23 **A.** I did.  
 24 **Q.** For children or adults?  
 25 **A.** Just for children.

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1 off a test was a patient who you had told why you were  
 2 asking them for a blood sample?  
 3 **A.** Because they had to come to the hospital to have a  
 4 blood test. But there was a whole diversity of  
 5 practice, as you will gather, and it appears that in  
 6 some centres blood tests were done on these patients  
 7 without them being informed. I think that's clear.  
 8 It seems that in some centres they had blood stored  
 9 down which they sent off to Dr Tedder and it seems  
 10 that in some centres they maybe, at that stage, didn't  
 11 test at all but tested a bit later. So there was  
 12 a whole range of things that happened in response to  
 13 this announcement that the test was available. But  
 14 anyway, that's what happened in our centre.  
 15 **Q.** All the patients who you invited to come to give  
 16 a sample to be tested, did all of them agree?  
 17 **A.** They did, and they were very pleased about it because  
 18 it had been such a major worry. They wanted to know  
 19 what was going on.  
 20 **Q.** You have explained the process of conversation you had  
 21 with your patient. One of the questions you were  
 22 asked to consider in your statement was the question  
 23 of pre-test counselling, and you said that wasn't  
 24 a concept that was in practice at the time. What  
 25 would you understand now about pre-test counselling

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1 **Q.** You then -- in the summer of '84, testing for HIV  
 2 started to become available.  
 3 Can you talk us through the process whereby you  
 4 sent off or collected blood samples and sent them off  
 5 for testing.  
 6 **A.** Yes. It was actually a bit later. It was  
 7 October 1984. A viral test then known as HTLV-III --  
 8 it was an antibody test. Not for the virus but for  
 9 antibody -- was available through the laboratory of  
 10 Dr Richard Tedder who was a virologist at the  
 11 Middlesex Hospital and it was not being advertised to  
 12 any of the hospitals because everybody suddenly wanted  
 13 this test. But the UKHCDO came to an arrangement with  
 14 Dr Tedder that haemophilia centres could send him  
 15 blood samples on their patients for that test to be  
 16 done.  
 17 A range of things then happened, apparently,  
 18 from centre to centre. In my centre -- I hadn't been  
 19 there all that long -- there were no stored blood  
 20 samples. So I had to speak to each patient by writing  
 21 and say, you know about this new virus. I can now get  
 22 you the blood test. Please will you come and see me  
 23 on such and such a date so we can have this test done.  
 24 That was the process that happened in my centre.  
 25 **Q.** So every patient who -- in respect of whom you sent

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1 and how would that differ from the conversations that  
 2 you did have?  
 3 **A.** So -- I think we did discuss this earlier -- the  
 4 performance of blood testing was just seen as part of  
 5 a comprehensive care package. You know, you came in  
 6 every three months, you saw a doctor, a nurse for home  
 7 therapy, a physio for review, a social worker or  
 8 a counsellor, and you had your blood test and you  
 9 picked up supplies and that was the deal. That was  
 10 the package of what became known as comprehensive  
 11 care. It was understood that the blood test had to be  
 12 done because you needed to be screened for an  
 13 inhibitor. These blood tests were very often -- the  
 14 patient would say, "I'm due" -- you know, "I'm due  
 15 Factor VIII today", so it wasn't even an extra venous  
 16 injection because they were going to have Factor VIII  
 17 anyway.  
 18 They knew that they were having their hepatitis  
 19 status checked for the hepatitis A and B, they knew  
 20 that they were having their liver function tests  
 21 looked at because of the non-A, non-B situation, they  
 22 knew that they were having, sort of, wellness blood  
 23 tests and that was accepted as part of the things that  
 24 haemophilia doctors did for patients.  
 25 So when the HIV test came along, it was assumed

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1 that doctors would add this to their list. It was  
 2 just yet another blood test to add to quite a long  
 3 list.  
 4 Now, what happened then was particularly  
 5 important. Not haemophiliacs, but outside of  
 6 haemophilia, the test became more widely available.  
 7 Members of the general public were having the test  
 8 done maybe at the end of a relationship, "I just want  
 9 to see if I'm okay", or starting a new relationship,  
 10 they would have the test done, they would test  
 11 negative, they would then get together with their new  
 12 partner and apply for life insurance or a mortgage,  
 13 the building society would say, "have you ever had an  
 14 HIV test?" They would say, "Yes, but it was negative"  
 15 and the building society or insurance company would  
 16 load the premium on the basis that they felt you must  
 17 have been in some sort of risk group to have had that  
 18 test carried out.

19 So here for the first time in medical practice  
 20 was a test which if you had it done, even if the  
 21 result was negative, it could have significant  
 22 implications for your life. So this is where the  
 23 whole concept of pre-test counselling came from. It  
 24 came from the AIDS test. It did not exist in medical  
 25 practice beforehand.

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1 concern after the San Francisco baby, the American  
 2 cases, it looks like there must be a virus. We're  
 3 very concerned, we need to know what the cause is.  
 4 Okay, it's -- now it's the middle of '83, it's  
 5 a virus, now we need the test, we must have a test.  
 6 And now we've got the test.

7 We've got some people in Britain,  
 8 Professor Bloom, saying that this isn't going to be  
 9 a problem. You know, there might be a small number of  
 10 cases, I really don't think it's going to be a big  
 11 problem. We've got some major American haemophilia  
 12 treaters, huge numbers of patients, saying formally --  
 13 director of the New York centre, New England -- "This  
 14 is not a big deal to the patients, just -- you don't  
 15 need to get excited about this, there might be a few  
 16 cases, this is not going to be anything to worry  
 17 about."

18 So we're really relieved to have the test, and  
 19 we've done these tests thinking, well, this is good,  
 20 you know, maybe we're going to get 5 per cent,  
 21 10 per cent positivity and I can't tell you the sort  
 22 of reaction of all of us when we saw the results.

23 I rang up Dr Savidge and said, "How do your  
 24 tests look?" He said, "I've got the majority  
 25 positive". He said, "I've just spoken to

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1 We'll see I'm sure in a moment a document from  
 2 UKHCDO telling haemophilia doctors to test the  
 3 patients. It says nothing at all about counselling,  
 4 pre-test advice. It says: test the patients.

5 **Q.** We will come to that. So you obtained your patients'  
 6 consent to give blood samples for the HIV test, the  
 7 HTLV-III test?

8 **A.** Yes.

9 **Q.** You sent those samples off to Dr Tedder?

10 **A.** Yes.

11 **Q.** 31 you say in your statement?

12 **A.** About that number, yes.

13 **Q.** You then had the results back, you've said again in  
 14 your statement, by 26 October --

15 **A.** Around then.

16 **Q.** -- of that year. What was the outcome?

17 **A.** The outcome was all but one of them were positive for  
 18 HTLV-III.

19 **Q.** And of that, about half were children?

20 **A.** About that. So maybe -- I think this is such another  
 21 watershed moment. Maybe I could just make a couple of  
 22 comments around that because it's such a turning point  
 23 in the epidemic.

24 So if you think about the build-up to this test  
 25 being available, we've got this nearly two years of

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1 Peter Kernoff at the Royal Free, he's got 100 positive  
 2 results."

3 So this was a complete turning point. You knew  
 4 from that moment, whatever part of the haemophilia  
 5 community you were in, a doctor, a nurse, a patient,  
 6 or a relative, life would never, ever be the same  
 7 again. This was the start of something dreadful and  
 8 you knew that immediately; you just saw and feared  
 9 everything that was about to happen. And it was just  
 10 all so unexpected, really.

11 **Q.** Some of those who tested positive would presumably  
 12 have been moderate or mild haemophiliacs because  
 13 you -- I think you've given a rough figure, you had  
 14 about 20 severe haemophiliacs?

15 **A.** Yes. That's correct. The rest would have been  
 16 moderate. I mean, we've tried very hard. One of the  
 17 worst aspects of the whole epidemic was the people who  
 18 got HIV and died who only had very, very, very  
 19 occasional Factor VIII, either because they had mild  
 20 haemophilia or they were a haemophilia carrier. Some  
 21 girls got treated with Factor VIII and got HIV and  
 22 died.

23 Even worse were the people with  
 24 von Willebrand's, because nearly everybody with  
 25 von Willebrand's, a related condition -- Factor VIII

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1 is not actually the treatment of choice. They should  
 2 have DDAVP. And through Macfarlane Trust, I became  
 3 aware there were a number of patients with  
 4 von Willebrand's who had been given Factor VIII. So  
 5 firstly they had been given the wrong treatment and  
 6 then been infected HIV and died. So this was some of  
 7 the very worst aspects of the whole epidemic.

8 **Q.** Can you describe what you then did once you had  
 9 received these test results of all but one positive.  
 10 What did you do in relation to that information and  
 11 telling patients?

12 **A.** Well, I think I had already given the patients'  
 13 appointments for about six or eight weeks, knowing --  
 14 or hoping the results should be back. So they had  
 15 scheduled appointments to come back and -- this would  
 16 be the adults. I'm just talking adults firstly. So  
 17 I knew they were coming to see me.

18 So I've sat down with them and told them the  
 19 result was positive. Now, it was very difficult for  
 20 doctors to know what a positive result meant. This  
 21 was an antibody test so it meant they had been  
 22 exposed. Some virus infections that you get,  
 23 chicken pox, mumps, measles, if you have antibody it  
 24 means you are immune. So one possible interpretation  
 25 was these patients had been exposed, there was

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1 to you" -- this is something haemophilia doctors have  
 2 never had to do before, talk to them about sexual  
 3 activity and possible transmission. There were no  
 4 cases of sexual transmission at that stage. But  
 5 I said, you know, we need to consider the possibility  
 6 you might be able to transmit the virus by sexual  
 7 activity.

8 There was a curious system, you could actually  
 9 prescribe condoms on the NHS, I discovered. So we  
 10 used to issue the patients with prescriptions for  
 11 condoms and off they went and got supplies -- because  
 12 we were, you know, concerned about that. A lot of  
 13 people were in denial and it took a lot of  
 14 reinforcing.

15 So I tried to keep the interview quite short and  
 16 then followed it up a few weeks later with  
 17 a follow-up. I'm sure I'd asked them to come with  
 18 their partners, so it wasn't just them, there would be  
 19 the patient and their wife as well, and then we'd  
 20 follow it up a few weeks later. I didn't have any  
 21 written information at that time.

22 **Q.** So that I understand the setting, as it were -- we've  
 23 heard evidence of people being given their diagnosis  
 24 in corridors, of being given their diagnosis in group  
 25 meetings, in being given their diagnosis in the

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1 a theory the virus might be dead because it had been  
 2 fractionated in a laboratory. How could it have  
 3 survived? So people said: oh, they've got antibody  
 4 positive, that's just because they have been exposed  
 5 to dead virus. They are not really infected. So that  
 6 was one explanation.

7 The other explanation was they had antibody  
 8 because they had been exposed to it and they were  
 9 carriers of the virus, which sadly turned out to be  
 10 the case. So the first thing I had to say to them,  
 11 once I told them the test was positive, was to say  
 12 I wasn't completely sure as a doctor what it meant,  
 13 but it either meant one of those two things.

14 I then said I didn't know what the future would  
 15 hold but we'd be following them really closely because  
 16 we knew that the virus might or might not damage the  
 17 immune system and we had these markers for immune  
 18 system function which we could follow. So we would be  
 19 following them more closely than we normally did and  
 20 we'd want to know from them very urgently if they had  
 21 any particular problems with infection. I think we  
 22 issued antibiotics and gave them instructions to have  
 23 that at home if they had a bug over the weekend and  
 24 were having problems getting access.

25 In particular I said, "You know, I need to talk

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1 presence of others. Were your communications your  
 2 consultations with patients private consultations,  
 3 with just the patient and their family member?

4 **A.** They were. But obviously one of the things I wanted  
 5 to say to you when I came to talk to this  
 6 Inquest(sic), reflecting on everything, but  
 7 particularly with the Macfarlane Trust's -- maybe we  
 8 are going to talk more about that tomorrow, but for  
 9 12 years I interacted with every centre in the country  
 10 and I became painfully aware of the way in which many  
 11 people had been told of their diagnosis, and I wanted  
 12 to state in this forum how I feel that many patients  
 13 were badly let down by some centres.

14 Medicine was different then. We've heard all  
 15 about this paternalism. When I was doing my general  
 16 medicine, a patient would come in very sick and after  
 17 a couple of days we'd established that they had cancer  
 18 of the pancreas and I would say to the consultant,  
 19 "This is the diagnosis". The consultant would say,  
 20 "I'd like to see this patient's wife", and we would  
 21 sit down with the wife and the consultant would say,  
 22 "I'm very sorry to say your husband's got pancreatic  
 23 cancer, he's probably going to die within a couple of  
 24 weeks". He would then say, "Do you think he would  
 25 want to know?"

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1 So the whole process -- this was standard. You  
 2 did not tell the patient first; you went to the  
 3 relatives and asked the relatives what they wanted.  
 4 And some of the relatives said, "Oh, yes, we must  
 5 tell", and some of the relatives said, "No, do you  
 6 know, I think it would be kinder if we just let him  
 7 go". So that's the background to everything.

8 Then we've got the situation, and I'm fully  
 9 aware -- exactly as you say -- of people being told in  
 10 corridors. There was one group of patients I know who  
 11 got their results by letter from the centre, and it  
 12 said, I've seen the letter: It turns out that you're  
 13 testing positive for HTLV-III. If you have any  
 14 concerns about this, you should go and discuss this  
 15 with your general practitioner.

16 So I think I wanted to say -- I very much wanted  
 17 to say -- that I think a lot of patients have a right  
 18 to feel very badly let down by the way they were told  
 19 by their centres, and this is nothing to do with  
 20 medicine being different in those days. I can only  
 21 say it was down to a lack of humanity, for want of  
 22 a better expression.

23 **Q.** Your consultations, therefore, were private  
 24 consultations with the patient, and it was the  
 25 patient's choice as to whether they brought their

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1 **A.** Yes.

2 **Q.** -- which you said you started with. Then you had 15  
 3 or so children in respect of whom the results were  
 4 positive. How did you go about the process of  
 5 informing their parents or them of the diagnosis?

6 **A.** So, again, this had been discussed at national level.  
 7 No formal recommendations. There was a conference  
 8 which took place, and I remember vividly half the day  
 9 was taken up on children -- should you tell and should  
 10 you not tell? And the first presentation was by  
 11 a Scottish group who thought it was better not to  
 12 tell. By the way, we should record that at UKHCDO --  
 13 Dr Craske had said initially, advising haemophilia  
 14 doctors, that in the first instance it was probably  
 15 all right not to tell patients, which I didn't think  
 16 was the right advice.

17 Anyway, at this conference, I was the sort of  
 18 follow-up after the talk that said, we don't think you  
 19 should tell. My talk was why you should tell. You  
 20 know, we'd discussed it a lot with other people. The  
 21 argument seemed quite clear really. If adults have  
 22 rights to know, so do children. I felt it was a very  
 23 dangerous situation not to tell. I felt that many of  
 24 the children probably suspected anyway, or would  
 25 suspect. I felt it was better to be honest and tell

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1 partners --

2 **A.** They were encouraged to because I felt it was better  
 3 that they had somebody with them.

4 **Q.** It was arrangements, if any, were made for testing or  
 5 offering testing to partners?

6 **A.** That came a bit later. I think I had learnt or -- my  
 7 feelings were you shouldn't overload them with lots of  
 8 things at the start. I said, "Let's get the important  
 9 things sorted out". Obviously, I spoke to them about  
 10 the importance of the dangers of viral transmission  
 11 through sexual activity, and then at the next  
 12 interview or the one after, I started to say to them,  
 13 "You know, you have had a chance to think about this  
 14 very difficult news I've given you, and how does your  
 15 wife feel? Would you like to have a test? I think  
 16 that would probably be a good idea."

17 A number of people said, "No, thanks. I don't  
 18 want to". A number of people said, "Yes, please."

19 In one case, quite an elderly couple, they said  
 20 no, and they came back to us about several months  
 21 later and said, "We realise now we've just been in  
 22 complete denial. We were so, so shocked at what you  
 23 told us". And they said, "we think she ought to have  
 24 a test" which she did, and she was positive.

25 **Q.** That was the process of telling adults --

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1 them. If I did tell them, a few weeks later if I said  
 2 to them, your blood tests are looking better, they  
 3 would believe me. They would say, if a doctor tells  
 4 me news like that, I can always believe what they are  
 5 telling me.

6 So I decided to tell, and I had a counsellor by  
 7 this stage who was extraordinarily helpful. And we  
 8 just sat down one day and said, "How are we going to  
 9 do it?" And we thought we would just -- again, no  
 10 guidelines; nobody advising us. We just said, "Well,  
 11 let's do basic principles. Let's just do it briefly.  
 12 Let's do it when they're well. Let's do it in the  
 13 school holidays. Let's follow it up with a quick  
 14 appointment. We don't want too many people there" --  
 15 the parents, me and the child probably, unless the  
 16 parents wanted anybody else.

17 **Q.** Just pausing there. The parents had already been  
 18 told, or --

19 **A.** No. This was before. This was a principle of what we  
 20 felt we ought to do. So once we got an agreed thing  
 21 of what was our view, the next step was I approached  
 22 all the parents, and -- just on their own, both of  
 23 them, and told them the results of the test, which was  
 24 obviously very distressing. And I said to them, "It's  
 25 our view we need to tell the child". There were some

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1 exceptions. There was a boy who was four, so we  
2 didn't tell him.

3 **Q.** The --

4 **A.** Can I -- I just want to go on.

5 **Q.** Yes, of course.

6 **A.** I'm just having a moment.

7 So we then sat down with the parents and said  
8 we'd really like to tell and I got varying responses  
9 really. One or two of the parents were very, very  
10 reluctant. It was too distressing to think about.  
11 But eventually they had all agreed. And so we then  
12 went on, and that's what we did. We told them in the  
13 way in which I just outlined to you, and then they all  
14 knew, apart from the very young child.

15 **Q.** I think -- I won't put it on the screen, but we've got  
16 the text of a talk you gave which was all about why  
17 you thought a child should be told and how to tell the  
18 child.

19 One of the observations you make in your  
20 statement about the information you were giving to  
21 your patients at this time is, you told them not to  
22 inform too many people, or you advised them not to  
23 inform too many people, not to share the news too  
24 widely. Is that correct?

25 **A.** Yes. That works for all patients. You know,

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1 recently come under my care who extraordinarily had  
2 never been to a normal school because of his  
3 haemophilia, a practice that had been abandoned ten  
4 years previously when Lord Mayor Treloar was closing  
5 down really. This school was adamant they would not  
6 have this child, and there was a very, very  
7 spectacular series of meeting with the school and the  
8 Education Authority.

9 Eventually, the Education Authority agreed to  
10 employ a nurse who sat alongside the child, holding  
11 a burn bin and a bottle of disinfectant, wearing  
12 gloves, so that if the child had a nosebleed she could  
13 clean it up. And I obviously very vehemently  
14 protested against this because, you know, the whole  
15 thing was completely inappropriate, and the child was  
16 being stigmatised in a very dramatic way.

17 So things did settle down after a bit but, yes,  
18 it was a very difficult initial exercise trying to get  
19 the schools to accept the children.

20 **Q.** Do you recall over the months that followed -- so this  
21 is towards the end of 1984, perhaps beginning of  
22 1985 --

23 **A.** Yes.

24 **Q.** Over the course of 1985, how often would you typically  
25 see the patients who had had a positive test result in

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1 everybody. You know, this was a time of great  
2 stigmatisation. As if there was not enough for the  
3 patients to bear, this was a disease where -- I mean,  
4 we had people who had windows smashed. We had  
5 somebody went into a laundrette and they wouldn't  
6 clean their trousers because they knew they had HIV.  
7 We had kids on the school bus chanting, you've got  
8 AIDS. You know, there was widespread stigma.

9 So we said to the patients, you know, we really  
10 advise you to be careful who you tell.

11 **Q.** In terms of the stigma specifically in relation to  
12 children, your statement refers to schools reacting  
13 particularly badly. Can you just explain a little bit  
14 about what happened in relation to that.

15 **A.** Well, there was -- all of the schools said, we can't  
16 have this child anymore; it's not possible. For  
17 a variety of reasons that were given. One of the  
18 schools produced a long document saying, he couldn't  
19 go on the school bus because he might bump into  
20 somebody and bleed. He couldn't have lunch because he  
21 might stab himself with a fork and bleed. He couldn't  
22 do pottery classes because he might scratch himself  
23 and bleed, and so on, and so on.

24 There was an especially difficult encounter with  
25 a school where I was trying to get a child in who had

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1 order to monitor them, talk to them, counsel them?

2 **A.** It would depend on how their tests were looking. If  
3 I had someone whose tests showed quite advanced  
4 immunosuppression who was particularly vulnerable for  
5 opportunistic infections, I would have wanted to see  
6 them every month. If they were very stable and  
7 healthy, it might have been, you know, every couple of  
8 months, something like that.

9 **Q.** I'm just going to ask you about two particular  
10 cases -- not identifying anybody by name -- that you  
11 refer to in your Archer and Penrose, and that will  
12 probably be it then, sir, for today.

13 In your Penrose evidence, you referred to two  
14 cases of patients in the area for which the centre was  
15 ultimately responsible who became infected with HIV.

16 I just wanted to ask you a little about both of  
17 them. The first is a child with mild haemophilia who  
18 was, in April of 1984, given Factor VIII -- not by you  
19 but at the William Harvey Hospital in Ashford -- and  
20 infected with HIV as a result, and the patient  
21 subsequently died.

22 Do you know how it came about that a child was  
23 being given Factor VIII as at April 1984, not under  
24 the care of a specialist centre or clinician, but in  
25 a local hospital?

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1 A. Well, I'm actually reluctant to talk about individual  
 2 cases, but in this particular case, the boy's  
 3 haemophilia was not known. He had a routine  
 4 tonsillectomy. This is the four-year-old boy. He had  
 5 a perfectly routine tonsillectomy. He bled  
 6 excessively. He was in a hospital ten miles from my  
 7 hospital, the haemophilia centre. So he bled  
 8 excessively after his tonsillectomy, and his mild  
 9 haemophilia was diagnosed correct. At that point, as  
 10 they were not a haemophilia centre, they should have  
 11 been on the phone to me ten miles away, you know,  
 12 24-hour response service. Somebody should have rung  
 13 me to say, we've got this situation with this boy.  
 14 What do we do? How do we treat? But that didn't  
 15 happen. They treated him with commercial Factor VIII  
 16 which they'd got hold of, and he was infected with HIV  
 17 on that first treatment and eventually died.

18 Q. And the second case you referred to is a patient who  
 19 was one of your patients treated with heat-treated  
 20 Factor VIII in May of 1984 in the way in which you  
 21 have described but was then -- again, I think at the  
 22 William Harvey Hospital in Ashford -- given non-heat  
 23 treated Factor VIII -- not by you, obviously, but by a  
 24 different hospital -- and infected with HIV as a  
 25 result.

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1 Do you know anything -- again, nothing to do  
 2 with individuals. It's about looking at systemic  
 3 issues. Do you know anything about how that came to  
 4 occur?

5 A. Well, yes, I do because this was a man with mild  
 6 haemophilia who was under my care. He'd never had  
 7 Factor VIII in his lifetime because of his mild  
 8 haemophilia, and he had to have some sort of surgery,  
 9 and it was May 1984. So he timed that well I thought  
 10 because the surgery was significant enough for me to  
 11 want to cover him, but I had heat-treated. So I gave  
 12 him heat-treated Factor VIII in May/June 1984, and  
 13 then a couple of months later, he cut his arm on  
 14 a greenhouse, had an accident and was taken into this  
 15 other hospital bleeding, and they gave him commercial  
 16 Factor VIII un-heat-treated, and he got HIV, and then  
 17 eventually died.

18 Q. I know you want to talk about the December 1984  
 19 document issued by UKHCDO. That will take a little  
 20 while, but it's the right moment in the chronology,  
 21 but rather than do it today, given the time, sir, I am  
 22 going to suggest it's an appropriate moment to stop,  
 23 and then we can pick that up tomorrow morning.

24 SIR BRIAN LANGSTAFF: Yes, indeed. So we will do that  
 25 now. We will break for the day. Thank you very much,

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1 indeed, Dr Winter, so far.

2 Tomorrow we start at ten o'clock, as we did  
 3 today, so we look forward to seeing you back then  
 4 tomorrow. For those of you who are coming back  
 5 tomorrow, I look forward to seeing you too. In the  
 6 meantime, stay safe.

7 MS RICHARDS: Sir, before we end, can I just update on the  
 8 timetable for next week in relation to the  
 9 presentations?

10 So we'll continue and conclude Dr Winter's  
 11 evidence tomorrow. We have the evidence of  
 12 Dr Brian Colvin on Tuesday and Wednesday of next week,  
 13 and then the proposal is that on Thursday I will  
 14 complete the Cardiff presentation, there's probably  
 15 about an hour or so left of that; then the  
 16 presentation on St Thomas' Hospital and  
 17 Professor Savidge on Thursday; then we are going to  
 18 sit on Friday as an extra day for the Oxford  
 19 presentation. So I wanted to make that clear now so  
 20 that both those here and anyone watching remotely will  
 21 know what the position is for next week. We will be  
 22 updating the timetable on the Inquiry website to  
 23 reflect that.

24 SIR BRIAN LANGSTAFF: Thank you very much. So a full  
 25 four-day week next week. Thank you.

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1 (4.28 pm)  
 2 (Adjourned until 10.00 am the following day)  
 3 I N D E X  
 4 DR MARK WINTER (affirmed) ..... 1  
 5 Questioned by MS RICHARDS ..... 1

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<p><b>MS RICHARDS: [12]</b> 43/3 73/3 92/14 93/4 93/8 93/13 93/22 101/6 102/19 112/10 143/1 171/7</p> <p><b>SIR BRIAN LANGSTAFF: [17]</b> 1/3 1/7 1/10 1/19 42/20 72/1 73/2 92/17 92/25 93/6 93/16 100/8 111/1 141/17 142/20 170/24 171/24</p> <p><b>THE WITNESS: [1]</b> 43/19</p> <hr/> <p>'70s [3] 30/6 34/12 51/13 '73 [1] 11/13 '73/'74 [1] 11/13 '74 [1] 11/13 '77 [1] 59/12 '77/'78 [1] 59/12 '78 [1] 59/12 '79 [1] 60/25 '80s [1] 34/12 '82 [3] 75/14 75/14 105/4 '83 [5] 106/3 106/4 106/6 142/2 155/4 '84 [4] 126/18 140/7 143/18 150/1</p> <hr/> <p><b>0</b></p> <p>002 [1] 48/9 003 [1] 118/20 004 [2] 106/23 119/15 008 [1] 105/6 009 [1] 117/19</p> <hr/> <p><b>1</b></p> <p>1 December [1] 3/15 1 October [1] 1/1 1.02 pm [1] 92/22 10 [4] 76/4 104/4 104/6 109/14 10 per cent [4] 14/22 24/16 138/4 155/21 10.00 [2] 1/2 172/2 100 positive [1] 156/1 11 [1] 43/2 11.03 [1] 42/25 11.45 [1] 42/24 12 December [1] 129/19 12 years [1] 160/9 13 [1] 78/19 13 May 1983 [1] 105/11 13 September 1982 [1] 103/20</p>	<p>13 years [1] 68/15 140 [1] 53/17 149 [1] 50/15 15 [2] 7/16 163/2 15 months [1] 140/14 15 years [1] 71/20 16 July 1982 [1] 73/6 16,320 [1] 120/5 17 October 1983 [1] 109/7 1930s [1] 133/19 1940s [1] 37/8 1960s [4] 30/12 33/3 37/6 37/24 1968 [1] 2/1 1970s [11] 10/4 11/15 13/11 35/25 36/8 42/16 43/16 56/16 65/22 70/1 71/19 1970s/early [1] 33/17 1973 [4] 2/1 33/2 39/12 39/18 1974 [4] 39/18 39/22 43/9 44/24 1975 [4] 38/7 38/8 38/13 40/5 1976 [5] 2/6 39/23 47/3 47/8 48/5 1977 [5] 43/9 48/10 49/8 49/16 51/3 1978 [8] 43/7 51/6 57/9 57/15 57/19 63/21 63/24 64/7 1978/79 [1] 41/15 1979 [8] 2/6 3/8 6/25 39/3 60/1 60/3 65/24 66/19 1980s [2] 33/17 56/7 1981 [2] 73/12 73/22 1982 [12] 73/6 73/12 76/5 76/12 77/22 78/1 80/4 84/7 103/20 105/14 105/21 142/1 1983 [30] 2/13 3/14 4/15 32/4 78/19 80/4 81/15 81/18 81/19 81/21 81/23 91/15 95/18 98/4 98/5 105/11 105/16 106/21 107/1 109/4 109/4 109/7 110/14 114/22 116/7 118/21 121/25 124/14 135/10 136/7 1983/early [1] 128/16 1984 [22] 6/25 110/7 112/12 112/16 117/20 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<p><b>4</b></p> <p>4.28 pm [1] 172/1 40 [1] 7/15 40 years [3] 14/6 65/8 68/1</p>	<p>45 [3] 42/21 42/23 43/2 45 per cent [1] 40/9 45 years [1] 46/24 48,750 [1] 120/3</p> <hr/> <p><b>5</b></p> <p>5 per cent [2] 120/10 155/20 5,000 [1] 54/4 50 children [1] 134/5 50 per cent [4] 135/25 137/4 138/21 147/5 50 years [1] 142/12 50,000 [1] 21/9 500mls [1] 89/3 51 [1] 45/7</p> <hr/> <p><b>7</b></p> <p>7 February 1984 [1] 117/20 70s [1] 54/9 71 per cent [1] 45/7 79 [1] 41/15 79 times [1] 67/8</p> <hr/> <p><b>8</b></p> <p>80 [1] 53/17</p> <hr/> <p><b>9</b></p> <p>90 per cent [1] 50/25</p> <hr/> <p><b>A</b></p> <p>abandoned [1] 167/3 ability [4] 13/20 97/12 108/9 137/2 able [20] 13/17 13/18 24/8 25/8 25/10 25/18 58/23 69/7 82/1 100/24 117/25 118/24 119/3 123/23 124/16 136/8 136/23 143/1 143/15 159/6 abnormal [10] 10/6 40/10 41/19 52/4 58/15 63/7 65/13 66/13 72/19 72/25 abnormalities [2] 58/20 79/3 abnormality [1] 53/13 abolish [1] 118/9 about [243] above [1] 60/14 absolute [2] 125/16 133/5 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<p><b>A</b></p> <p><b>after... 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