

Friday, 4 February 2022

(10.00 am)

**SIR BRIAN LANGSTAFF:** Good morning, Dr Boulton.**THE WITNESS:** Good morning.**SIR BRIAN LANGSTAFF:** You can hear me then, good. Can you see me?**THE WITNESS:** Yes, I can see you, yes.**SIR BRIAN LANGSTAFF:** There's a slight lag, I think on the connection. You're at home, are you?**THE WITNESS:** I am indeed.**SIR BRIAN LANGSTAFF:** And you're with your wife?**THE WITNESS:** At the moment she's out but she's around.**SIR BRIAN LANGSTAFF:** But in the room at the moment it's just yourself, then?**THE WITNESS:** Yes.**SIR BRIAN LANGSTAFF:** Now you're talking to Aldwych. There's a select group of people here to listen to what you have to say, but your significant audience is that beyond this room. They'll be watching remotely, YouTube or live stream, and there will be something like 100 or thereabouts or more people who want to hear what you have to say. So that's your audience. The questions are going to be asked by Ms Scott. She is also asking them remotely, and so we'll just have to hope that the connection is maintained. We've managed pretty well so

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correct?

**A.** That's correct. The difference in the senior lectureship is that in Liverpool I had NHS consultancy whereas at the London I was not quite of the consultant standard status, but I was an honorary consultant in Liverpool.**Q.** And I'll come back in a moment and ask you a little bit more detail about those posts. Then you took -- moved to Scotland and took up a post as a consultant haematologist at the Edinburgh and South East Scotland Region Blood Transfusion Service, based at the Royal Infirmary of Edinburgh, a post you held from 1980 to 1990, albeit you became deputy director of the transfusion centre in 1982; is that correct?**A.** Correct.**Q.** Then in 1990 you moved to the Wessex Regional Blood Transfusion Service in Southampton, as medical director, a post you held until 1995. And then when the National Blood Authority took over all of the regional transfusion centres, you remained working, as it were, in Southampton, but your post changed to consultant haematologist at the National Blood Authority; is that right?**A.** That's correct. Yes.**Q.** And you retired, I believe, in 2006?

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far. There has been the odd hiccup. If it happens, please forgive us.

In a moment or two I shall ask Mary to ask you to take the oath.

Mary.

Then Ms Scott will ask questions.

**THE WITNESS:** It is actually an affirmation which I have agreed to give, thank you.**SIR BRIAN LANGSTAFF:** The oath is a global term.**DR FRANK ERNEST BOULTON (affirmed)****Questioned by MS SCOTT****SIR BRIAN LANGSTAFF:** Ms Scott.**MS SCOTT:** Dr Boulton, I'm going to start by asking you some questions about your career.

So you were a trainee pathologist at St Thomas' Hospital from 1967 to 1970, and then took up a post in 1971 as a senior registrar in haematology at the London Hospital; is that right?

**A.** Correct.**Q.** You then became a senior lecturer at the London Hospital Medical College, a post you held from 1973 to 1975?**A.** That's correct.**Q.** You then became senior lecturer and honorary consultant haematologist at the University of Liverpool and Royal Liverpool Hospitals between 1975 and 1980; is that

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**A.** Yes, yes.**Q.** You've also been a member of a number of advisory committees and working groups, and just to pick out a few of those, you were a member of the Standing Advisory Committee on Donor Selection, and that was a UK Blood Transfusion Service and a NIBSC committee. You were a member, and then became secretary, and then became chair of that committee; is that right?**A.** That's correct, and the full title that evolved during my time there was the Standing Advisory Committee on the Care and Selection of Donors, the caring bit was important.**Q.** You were also on the Standing Advisory Committee for the UK BTS NIBSC on Clinical Transfusion Medicine. You were a member of the Coagulation Factor Study Group?**A.** Yes.**Q.** You were a member of the SNBTS, Scottish National Blood Transfusion Service, Ethics Committee (Clinical Research and Investigations), and you were a member of the SACTTI Working Group on vCJD and the SACTTI Advisory Group on Blood Parasites, and chair of the British Committee for the Standards in Haematology Blood Transfusion Task Force, and a founder member of the British Blood Transfusion Society, and their president from 2005 to 2007. Is that -- are all of those details correct?

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1 A. That's broadly correct. I'm not quite -- didn't quite  
 2 catch the earlier bit about the Ethics Committee,  
 3 I think you said.  
 4 Q. SNBTS Ethics Committee (Clinical Research and  
 5 Investigations).  
 6 A. I'd forgotten that. Yes.  
 7 Q. July 1986 I've got --  
 8 A. That's correct, yes, yes.  
 9 Q. You also provided both written statements and oral  
 10 evidence to the Penrose Inquiry?  
 11 A. I did. Yes.  
 12 Q. So if I can turn now to your role as senior lecturer --  
 13 sorry, senior registrar and senior lecturer at the  
 14 London Hospital, so that was between 1971 and 1975. Can  
 15 you tell us a little bit your role in those posts over  
 16 that time?  
 17 A. Well, as senior registrar, I was still trainee, so  
 18 consequently I was learning my trade and also preparing  
 19 for the qualifying examinations for the Royal College of  
 20 Pathologists, and also I was -- both at the St Thomas'  
 21 stage and later, I was preparing an MD thesis which got  
 22 accepted in 1974, I think.  
 23 So I was training, studying, learning my trade,  
 24 treating patients, learning the laboratory technology  
 25 of -- in haematology technology, which included

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1 presenting with horrendous bleeding from his bladder,  
 2 which was due to a cancer and he was a haemophilic and,  
 3 at that time, cryoprecipitate had just been discovered,  
 4 and the haematologist at Portsmouth, Dr John O'Brien,  
 5 was able to procure large quantities of plasma for  
 6 cryoprecipitate production from the Royal Navy base in  
 7 Portsmouth.

8 So I had my early experience in cryoprecipitate  
 9 then but I knew about it when I learnt more, when  
 10 I became a trainee at St Thomas', and actually helped  
 11 prepare cryoprecipitate at that time.

12 Q. Now, your witness statement tells us about your work in  
 13 this period, that you began to expand the service to  
 14 local haemophiliacs. I wonder if you could just tell us  
 15 a little bit about what you meant by that.

16 A. Well, we hadn't quite got as far as home therapy  
 17 although that was beginning to develop among the  
 18 haemophilia consultant community, but we were just able  
 19 to procure more cryoprecipitate from the Brentford  
 20 Transfusion Centre, and also just to make available more  
 21 treatment. So there were people who presented to us,  
 22 some of whom I can remember very clearly, who were  
 23 treated effectively as inpatients for their bleeding  
 24 disorders, and that included some really quite difficult  
 25 cases who required surgery. So we were able to support

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1 cross matching of blood, compatibility testing, and  
 2 assaying clotting factors such as Factor VIII.  
 3 Q. There was a Haemophilia Centre there under the  
 4 directorship of Professor Jenkins; is that correct?  
 5 A. Yes, he was not professor then, he became a little  
 6 later, but yes, he was the head of department of  
 7 haematology at the London Hospital, and indeed was  
 8 the -- was my boss, both as senior registrar, and then,  
 9 when the university granted academic status to the  
 10 haematologists, he became the professor -- yeah, he  
 11 became -- sorry, George became the -- in charge of me as  
 12 senior lecturer.  
 13 Q. And were you --  
 14 A. Sorry, that was a little bit garbled, but you're  
 15 correct.  
 16 Q. Were you treating -- providing clinical care to people  
 17 with haemophilia in that period?  
 18 A. There was some incredibly good and very cooperative  
 19 haemophilic men who were patients in that unit, so I was  
 20 both seeing them as outpatients and as inpatients.  
 21 Q. So you had experience, did you at that stage of  
 22 administering cryoprecipitate and factor concentrates?  
 23 A. Indeed. In fact, my very first experience of  
 24 administering cryoprecipitate goes back to my houseman  
 25 days in Portsmouth in 1966/67, when there was a patient

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1 them mostly as inpatients from the London Hospital.

2 Q. You've also told -- you've also recounted an incident in  
 3 your witness statement of a patient who, after receiving  
 4 one batch of commercial product, was infected with both  
 5 hepatitis B and non-A, non-B --

6 A. That is correct.

7 Q. Can you just tell us, again, a little bit about the  
 8 circumstances in which that incident arose and the  
 9 impact it had on you?

10 A. He was a 50-year-old man with mild haemophilia, about  
 11 5 per cent of Factor VIII activity, who had not really  
 12 had very much problem with haemophilia, although he knew  
 13 it all his life that he'd had it, he'd had three other  
 14 brothers who were also affected. And he presented on  
 15 Christmas Eve with a raging toothache and an abscess,  
 16 and this was bleeding, and there was no doubt that he  
 17 needed to have urgent treatment which involved the  
 18 extraction of a tooth. I'm not sure if he was actually  
 19 admitted but he was -- certainly spent some time in the  
 20 hospital.

21 We gave him -- we felt that cryoprecipitate may  
 22 not be sufficient to control the bleeding and, in fact,  
 23 I think there was very little cryoprecipitate in the  
 24 hospital at that time, so we delved into our small  
 25 stocks of commercial Factor VIII, which I cannot

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1 remember the exact variety, but it was there available.  
 2 We got him up to 100 per cent full activity, the tooth  
 3 was extracted without a problem. The abscess was  
 4 drained successfully, the antibiotic course was  
 5 successful and he went home and had a good Christmas.

6 About two months later he presented with a rash  
 7 and mild jaundice and, in fact, we didn't give him any  
 8 treatment. He was mildly affected, mildly symptomatic,  
 9 and went home and recovered. He then had a recurrence  
 10 about two months after that, and I contacted Dr Craske  
 11 at Manchester and he was able to inform me that he  
 12 probably had both forms of what was then called serum  
 13 hepatitis. One was probably hepatitis B, and I think we  
 14 were able just to check that, but the other form was  
 15 neither A nor B and was my first clear-cut experience of  
 16 non-A, non-B hepatitis.

17 He recovered and, for the rest of the time I was  
 18 at the London, I -- he was no problem. I do not know  
 19 what happened to him. It's possible that Dr Colvin, who  
 20 was my successor, may have some knowledge of that.

21 Q. Your witness statement suggests that that incident had  
 22 an impact on your later practice; is that right?

23 A. Yes.

24 Q. Can you tell us about that impact?

25 A. Well, particularly when I went to Liverpool -- I mean,

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1 Centre Director? There's different documents that name  
 2 one, either -- or sometimes both of you as Centre  
 3 Director?

4 A. That's understandable. Professor Bellingham was the  
 5 head of department and, therefore, took nominal  
 6 responsibility for the care of the haemophiliacs, but he  
 7 delegated that entirely to me, so that, for example, the  
 8 purchasing policies that he -- clinical management of  
 9 the haemophiliacs who presented was my responsibility.  
 10 Of course, there were times when I was away, so either  
 11 he or, for the first couple of years of my time there,  
 12 the other senior lecturer, Dr Michael Leyland would take  
 13 over my clinical duties while I was out of hours.

14 But, apart from that, I basically ran the  
 15 haemophilia service and filled in the returns for the  
 16 directors' organisation.

17 Q. What region did the Haemophilia Centre cover?

18 A. Merseyside and North Wales, so it went from the boundary  
 19 between Merseyside and Manchester. So it went from  
 20 Stockport on -- in the north through to the Welsh  
 21 peninsular, including Bangor hospitals. So we actually  
 22 had a significant population from North Wales, as well  
 23 as those in Merseyside. So it included St Helens in  
 24 Lancashire, as well as the -- as well as North Wales,  
 25 and, as I say, the rest of Merseyside.

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1 in fact it was probably not very effective, but going to  
 2 Liverpool and being aware, not least through the World  
 3 in Action Tainted Blood programme that came out in 1976,  
 4 I think, that I was very anxious not to purchase  
 5 American blood products, but if there were blood  
 6 products -- well, there were products available on the  
 7 market that were -- the claim was that they didn't come  
 8 from American donors, although they did come from  
 9 European donors, basically, in Austria, who did -- who  
 10 were paid for their donation but at least it wasn't  
 11 American.

12 So, in that sense, I tried to avoid the risk of  
 13 using American plasma with its, by then, well-known  
 14 association with the transmission of disease and tried  
 15 to avoid it by giving Austrian.

16 In fact, we were let down because, within a couple  
 17 of years, a patient who'd received that Austrian product  
 18 actually developed hepatitis in Liverpool. So,  
 19 consequently, that was a vain tactic but at least  
 20 I tried.

21 Q. So moving on, then, to your time in Liverpool, so just  
 22 reminding ourselves that that was 1975 to 1980, I'm  
 23 going to ask you, first of all, a few questions about  
 24 the arrangements and set-up of the centre itself. Were  
 25 you the Centre Director or was Professor Bellingham the

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1 Q. Is it right to understand that Liverpool -- that the  
 2 Haemophilia Centre in Liverpool was not a reference  
 3 centre; your reference centre was the Manchester Centre?

4 A. That is correct, and we had occasional dealings with  
 5 that, although most of the time we were able to function  
 6 separately.

7 Q. That's my next question. What did, if I can put it this  
 8 way, your reference centre do for you?

9 A. Well, it was another forum for discussion and sharing of  
 10 problems, and understanding. And they were  
 11 professional, helpful colleagues, so spreading the  
 12 burden of responsibility was welcome to me. And there  
 13 were one or two episodes involving a slight confusion  
 14 among some of the north Welsh hospitals, I think Wrexham  
 15 in particular, who clearly thought that they were -- if  
 16 they had a problem with a local haemophilic, which was  
 17 rare, they tended to turn to Manchester. I think  
 18 possibly because the laboratory staff there had more  
 19 experience of the Manchester set-up than the Liverpool  
 20 set-up.

21 But -- so there were occasional cross-references  
 22 but they weren't very often.

23 Q. In --

24 A. And I was able to go to the Haemophilia Directors  
 25 Organisation meetings but not to the meetings of the

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1 reference centres.

2 **Q.** In terms of those discussions with your colleagues in  
3 Manchester, were those formal meetings or was it more  
4 a question of picking up the phone when you've got  
5 a problem and asking somebody for a view?

6 **A.** It was a mixture but there were formal meetings.  
7 I think, actually, to be honest, there were only two or  
8 three meetings during my time there. The rest was by  
9 general conversation, and, of course, we would meet at  
10 other functions, like annual meetings of the British  
11 Society for Haematology. So there was a certain degree  
12 of informality as well as formality.

13 **Q.** Is it right to understand that most, if not all,  
14 children with haemophilia in the Liverpool and  
15 Merseyside area were treated at the Alder Hey Hospital?

16 **A.** They were treated. The -- you use the word "all".  
17 There was an understanding that as boys became teenagers  
18 they were probably in some ways better dealt with in the  
19 adult unit rather than the children's unit, although it  
20 was a bit of a mixed blessing. Some of those young men  
21 were quite challenging, understandably, and it was felt  
22 that -- and I went along with it -- that they would  
23 be -- as they were growing older, it would better for  
24 them to develop links with the adult centre rather than,  
25 say, with the children's centre.

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1 course, we had nurses on the wards who were particularly  
2 skilled with dealing with patients with haemophilia.  
3 And so, again, it was a sort of combined service,  
4 multi-professional in a way, which was important for  
5 these people but particularly important for the children  
6 as they were growing up.

7 **Q.** In terms of the staffing of the centre, were you  
8 dedicated -- was your role entirely taken up by the  
9 centre?

10 **A.** By no means. I would say that the haemophiliacs -- my  
11 haemophilic commitment was about 10 to 15 per cent of my  
12 time. The rest of the time I'd be dealing with the  
13 clinical laboratory, so I was actually the consultant  
14 for the laboratory services, which included the blood  
15 bank, the anaemia services, the leukaemia laboratory  
16 diagnoses, all those aspects as well as the  
17 haemophiliacs. So the haemophiliacs were a very important  
18 part of my job and that's why I was pleased to move to  
19 Liverpool, but they were -- but I was by no means the --  
20 they were by no means my only commitment.

21 The -- it would be fair to say that -- sorry, I've  
22 slightly lost my thread but it would be fair to say that  
23 my commitment was -- because of my interest in  
24 coagulation as a whole, my commitment was spread  
25 a little bit beyond the haemophiliacs and, indeed,

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1 So the age differentiation was a little bit vague.  
2 Somewhere between 14 and 18, a boy would transit from  
3 Alder Hey to the Liverpool Royal Infirmary. But we held  
4 joint clinics with John Martin, who was the consultant  
5 paediatrician in care of the haemophiliacs at Alder Hey,  
6 and so there was, I think, a good understanding of the  
7 transition those boys were transiting from, being young  
8 boys to young adults.

9 **Q.** The joint clinics were in respect of all of the -- all  
10 ages or --

11 **A.** No, the joint -- those were joint clinics for the  
12 children. So John would bring along his nurse  
13 specialist that he would work with it -- although  
14 I think her time was not fully time with the  
15 haemophilia -- he'd also bring along a dentist, and we  
16 had access to social workers, physiotherapists,  
17 occupational therapists, so it was a sort of combined  
18 clinic. And, in that sense, it was really quite  
19 advanced, it was really good thinking on John's part to  
20 actually bring in all the professionals who were dealing  
21 with these children who were growing up and it was a joy  
22 to work with them.

23 In the -- as adults, I ran a service which was  
24 also in conjunction with the physiotherapists,  
25 occupational therapists and social workers and, of

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1 included the Liverpool School of Tropical Medicine which  
2 was next door, which was also interested in disorders of  
3 haemostasis because of the snake venoms with which they  
4 specialised.

5 So my time -- I was very interested in  
6 haemostasis, haemophilia was a big part of that but  
7 there were other aspects, which I would explore too,  
8 which was helpful in the sense that it was -- it gave me  
9 a broader insight into the general nature of haemostasis  
10 problems.

11 **Q.** So is it right to understand that there would have been  
12 no dedicated nurse for the centre or junior member of  
13 staff?

14 **A.** That is actually what I was slightly stumbling over now.  
15 There was no specific building or room with a door that  
16 said on it "Haemophilia Centre". The services were  
17 provided and I was -- I think I could describe myself as  
18 director of the haemophilia services to Liverpool but  
19 the site was split. There were -- there were the  
20 specialist laboratories, part of the laboratory block in  
21 pathology; there were the wards; and there the  
22 outpatients, where I would see the haemophiliacs.

23 So the function was split over several sites, and  
24 that assisted when we moved to the new Royal Liverpool  
25 Hospital in 1978/79, which incidentally was a very

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1 disruptive experience. So consequently my time was --  
2 and that of Professor Bellingham -- was spent very much  
3 on coordinating the move of the laboratory and clinical  
4 services from the old and rather decrepit site to the  
5 new, better site, but there were still problems on the  
6 new site as well. So we had a lot to contend with but  
7 the haemophilics were an important priority for me.

8 **Q.** We see a reference in some of the documents to people  
9 with haemophilia being treated on the tropics ward.  
10 Which hospital was that in; was that in the old or the  
11 new or both?

12 **A.** The old -- the old Liverpool Royal Infirmary, and it was  
13 called "tropics" because in the first part of the  
14 20th century the school -- the Tropical Medicine School  
15 next door would attract people who'd been overseas and  
16 caught horrible diseases like malaria and others which  
17 had a profound effect on the blood.

18 So when they were admitted, they were admitted to  
19 this really rather wonderful ward which was of a unique  
20 design. It was circular, and the 20 beds were spread  
21 around the edge and they were pointing towards the  
22 pillar in the middle. That was partly to dissipate the  
23 risk of transmitting infections from bed to bed, like  
24 the old Nightingale model but this was a different  
25 model, and they were the preserve of the physicians who

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1 antibodies, Christmas disease patients, eight, none with  
2 Factor IX antibodies.

3 Then if we look at down at the table, we can see  
4 that there was no treatment with plasma.

5 Can we have the whole table up? Thank you.

6 Cryoprecipitate was approximately 800,000 units.

7 Then NHS factor concentrate, just over 13,000 units. No  
8 Abbott Factor. Some Armour Factor, 58,000. Quite a lot  
9 of Koate, 207,000. Some Hyland Hemofil, and some Immuno  
10 Kryobulin. And then we can see there NHS Factor IX  
11 Concentrate at 244,000 units.

12 Just trying to understand that, then, we can see  
13 relatively little NHS factor concentrate being used  
14 in 1977. Why was that?

15 **A.** Well, firstly, the handwriting is mine. So I can take  
16 clear ownership.

17 The relative reduced amount of NHS Factor VIII was  
18 simply because it wasn't available in the quantities  
19 which we would have otherwise required, so we were  
20 reliant mostly on the cryoprecipitate, and you can work  
21 out from there I've assumed that each pack of  
22 cryoprecipitate had about 70 international units --  
23 that's the maths -- had about 80 international units.  
24 That's the maths. Later on I think I assumed there were  
25 more like 70 units.

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1 specialised in tropical diseases.

2 As time went on, the instance of tropical diseases  
3 needing inpatient care declined, while the development  
4 of other services in the haematology expanded, not least  
5 the blood bank and then, later, the haemophilia  
6 disorders, but particularly the leukaemia disorders.

7 And so tropics ward was effectively the ward -- the  
8 clinical haematology ward, which included leukaemias in  
9 particular, and some haemophilics.

10 **Q.** Did you have a relationship with Dr Rob at the Walton  
11 Community Hospital?

12 **A.** I knew her quite well, at one stage, but there was never  
13 any real dealings with -- as far as I remember, with the  
14 haemophilic community.

15 **Q.** I'm going to look now at the annual returns with you,  
16 I'm going to look at two of them, 1977 and 1979.  
17 The Inquiry has had a presentation on Liverpool and has  
18 looked at more than that, but if we start with 1977,  
19 that's HCDO0001178.

20 If we start, please, on page 14, we can see at the  
21 top that says "Annual Return for 1977" for Liverpool  
22 Royal Infirmary, and you're noted as the director along  
23 with Professor Bellingham.

24 And we can see there that the number of patients  
25 treated that year were 56, none with Factor VIII

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1 So as far as the cryoprecipitate dosage is  
2 concerned, that is very much approximate depending upon  
3 how much Factor VIII was in each pack, and that could  
4 vary a lot, between about 20 and 100 units.

5 So that's an approximation. But the others are  
6 clear-cut numerals relating to the amount of  
7 international units that those were given.  
8 International unit being the amount of Factor VIII in  
9 1ml of plasma, basically. So that's the sort of  
10 activities that they were given. And yes, there was  
11 a lot of Immuno. That was the -- as far as I remember,  
12 that's the Austrian product, and that's what I was using  
13 mostly that year. But I was already beginning, as you  
14 see, to spread to the others. Basically to spread the  
15 load and make sure that we had enough Factor VIII in  
16 stock to allow for emergencies.

17 The smallest amount there, Hemofil, is the product  
18 that was manufactured by the company that was most  
19 criticised in the World in Action programme. So that's  
20 the small quantity compared with the amount of  
21 Kryobulin. But I do admit that there was a real mixture  
22 of origins of the Factor VIII that was given.

23 **SIR BRIAN LANGSTAFF:** I think you may be in error in  
24 suggesting that the biggest commercial concentrate usage  
25 was Kryobulin, because I think, if you look again at the

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1 figures, the Koate is 207,330 units, isn't it?  
 2 Have I got that right?  
 3 **A.** You are correct. You are correct.  
 4 **SIR BRIAN LANGSTAFF:** So it looks as though Koate was  
 5 essentially just under half of the commercial  
 6 concentrate being used.  
 7 **A.** That is correct, Sir Brian. And indeed the number of  
 8 bottles would confirm that it was -- that was the  
 9 dominant factor that I was using in that year.  
 10 **MS SCOTT:** And the policy you've explained of -- the  
 11 rationale, if I can put it that way, behind the policy  
 12 of having this spread of different types of commercial  
 13 product was to ensure you always had a supply; is that  
 14 right?  
 15 **A.** That's correct.  
 16 **Q.** Because there was a concern that if you just had one  
 17 commercial concentrate, that it may run out and you may  
 18 not be able to get a replacement?  
 19 **A.** That was our thinking.  
 20 **Q.** If we then turn to page 15, we can see -- no, sorry,  
 21 that was the annual return for Christmas disease, but  
 22 that shows as nil.  
 23 Sorry, that's carriers. I didn't mean to go to  
 24 this page. I actually wanted to go to page 13, sorry.  
 25 Can we go to page 13, which shows the von Willebrand's.

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1 others received small amounts of treatment for bleeding  
 2 episodes but one individual, based in North Wales, who  
 3 had severe von Willebrand's disease, was bleeding from  
 4 his vocal chords, and he required a lot of treatment,  
 5 and eventually we managed to control it with large  
 6 amounts of cryoprecipitate. The small amount of  
 7 clotting factor concentrate he was given seemed to make  
 8 no difference. So that was why so much was given in  
 9 that unique circumstance in that year.  
 10 Coming back to what's in front of me now, yes, you  
 11 correctly point out that we were giving some  
 12 cryoprecipitate to patients on home therapy.  
 13 **Q.** Then we can see a small amount of NHS factor concentrate  
 14 given as home therapy. Again, the reason for that was  
 15 because of the limited amount of NHS factor concentrate;  
 16 is that correct?  
 17 **A.** Correct.  
 18 **Q.** Then we see a range of different commercial concentrates  
 19 being given as part of the home therapy treatment. Were  
 20 there -- then, sorry, if we turn -- if we look at the  
 21 bottom of this, below this table, we can see:  
 22 "Comments: These figures include ALL patients  
 23 from Merseyside including children who are normally  
 24 treated by Dr J Martin either at Alder Hey Children's  
 25 Hospital or the Royal Liverpool Children's Hospital.

23

1 Here we go. So we've got "Summary of Patients  
 2 Treated ... 1977 [for] von Willebrand's Disease", and  
 3 you've got three patients there. We can see that they  
 4 were treated primarily by cryoprecipitate, but a small  
 5 two bottles of Immuno Factor VIII concentrate used  
 6 in 1977.  
 7 Can we turn to page 9, because we get some  
 8 information about the home treatment programme in 1977.  
 9 Again, if we look at the top of that page, "Total  
 10 amount of materials supplied during 1977 to  
 11 Haemophilia A Patients on Home Treatment", and we can  
 12 see there that we -- you have 330 bottles  
 13 approximately -- I think that says 23,100 or 28,100  
 14 units you've estimated --  
 15 **SIR BRIAN LANGSTAFF:** I think it's 23,000, if you apply the  
 16 factor of 80.  
 17 **MS SCOTT:** Yes, thank you.  
 18 Just pausing there, so you had a home treatment  
 19 programme in 1977 in which people used -- patients used  
 20 cryoprecipitate?  
 21 **A.** That is correct.  
 22 Could I just go back to your previous one about  
 23 the von Willebrand's patients?  
 24 **Q.** Yes.  
 25 **A.** That treatment was dominated by one individual. Two

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1 There is also one patient included from [North] Wales,  
 2 under the routine management of Dr T ..."  
 3 Korn is that?  
 4 **A.** Korn, K-O-R-N.  
 5 **Q.** So that reflects what you've just told us about the  
 6 arrangements with those centres.  
 7 So the numbers that we see, the number we saw, of  
 8 patients treated in 1977 by a Liverpool Royal Infirmary,  
 9 of 56, includes, does it, the children at Alder Hey and  
 10 the North Wales patients?  
 11 **A.** Yes. And that one patient was the man with  
 12 von Willebrand's syndrome who was mostly treated in  
 13 hospital, but he may have received a little bit of  
 14 cryoprecipitate at home, but I can't confirm that, at  
 15 this stage. My memory is not too clear on that point.  
 16 But I actually do remember the patient very well,  
 17 because he was a very significant problem.  
 18 **Q.** I don't think this form helps us, this document helps us  
 19 with home treatment for von Willebrand's but we do get  
 20 some information about home treatment with ... I beg  
 21 your pardon. Yes, sorry, we do get some treatment for  
 22 patients on home treatment for haemophilia B or  
 23 Christmas disease.  
 24 If we look at page 11, we can see there:  
 25 "Total amount of materials supplied during 1977 to

24

1 Haemophilia B ... Patients on Home Treatment."  
 2 We can see it's all NHS factor concentrates, no  
 3 commercial products used or other products used.  
 4 A. That's correct.  
 5 Q. You tell us in your witness statement that during your  
 6 time at Liverpool the number of patients on home therapy  
 7 increased from 15 to 27. Was there a policy of trying  
 8 to get more patients on home treatment during this  
 9 period?  
 10 A. Yes, I was committed to expanding the already  
 11 established home therapy programme.  
 12 Q. Can we then look at the last page I want to take you to  
 13 on this document, at page 1, please, which gives us  
 14 a breakdown of the treatment by patient, but for each  
 15 patient.  
 16 The patients' names, which have been redacted, and  
 17 dates of birth are on the left-hand side, and then we  
 18 can see various bits of information about their  
 19 condition.  
 20 Then we have, on the right, the type of material  
 21 received during 1977. And we can see that, for many of  
 22 the patients, they received a number of different types  
 23 of commercial concentrate during 1977.  
 24 Is it right to understand from looking at this  
 25 document and the following pages that there was no

25

1 patients, that's just chance, I believe. So some years  
 2 it would be in the high 40s and other years it would be  
 3 in the low 50s. So I don't think there's any great  
 4 significance in the change of numbers of patients  
 5 treated.  
 6 Q. And we can see there number with Factor VIII antibodies,  
 7 two. Total number of Christmas disease patients  
 8 treated, five. And none with Factor IX antibodies.  
 9 Then if we look down the page, we can see that  
 10 there's a figure for the "Cryoprecipitate: Whole region"  
 11 of about 18 million units. You didn't fill out this  
 12 form. Can you help us at all with what that means?  
 13 A. Sorry, could you just repeat that again? The?  
 14 Q. The first entry on the table is "Cryoprecipitate: Whole  
 15 region", and then we've got "Cryoprecipitate (RLH  
 16 only)". Can you help us at all -- I understand you  
 17 didn't fill this out, but can you help us at all to  
 18 understand what "Whole region" might mean?  
 19 A. Also that top line is deleted by whoever prepared it.  
 20 So I can't give a clear explanation of that.  
 21 Q. And then we've got --  
 22 A. I think the fact it's deleted implies that it was  
 23 actually an error.  
 24 Q. Cryoprecipitate (RLH only), 630,000 units;  
 25 NHS Factor VIII concentrate, 220,000; Armour Factor VIII

27

1 policy in 1977 of trying to keep patients on one type of  
 2 commercial concentrate?  
 3 A. Yes, that's correct.  
 4 Q. Can we then turn to the 1979 return, which we find at  
 5 HCDO0001344.  
 6 We can see at the top, "Annual Return for 1979",  
 7 for patients with haemophilia or Christmas disease.  
 8 RLH. The move to the new site. And the director on  
 9 this -- this time is noted to be Professor Bellingham.  
 10 Total number of patients treated during the year  
 11 is 49. Now, the previous year it was 56. Can you help  
 12 us with why there's been a reduction over the two-year  
 13 period of seven patients?  
 14 A. This return was made by my successor sometime in 1980.  
 15 But I had taken care to prepare most of the data before  
 16 I left, so that the -- my successor was not left with  
 17 need to go through all the paperwork involved in filling  
 18 out this data. So by the time this was returned,  
 19 Alistair Bellingham was, in effect, acting as  
 20 the director, at least nominally, but I think that my  
 21 successor would have taken on much of this work. So  
 22 that's why my name is not there. I wasn't there at the  
 23 time of completing this return. But most of those  
 24 figures were worked out by myself.  
 25 As for the reason for the reduction in treated

26

1 Concentrate, 550,000; Hyland, a small amount, 750; and  
 2 Immuno, 150,000.  
 3 Then at the bottom there is "(Oxford)", 177  
 4 bottles, approximately 115,000 units for Christmas --  
 5 for haemophilia B Christmas disease.  
 6 And then "Other Materials" it says "DDAVP".  
 7 Just pausing there on the DDAVP, that is the first  
 8 time we see DDAVP entered onto the annual returns. Can  
 9 we take it from that that DDAVP would not have been used  
 10 before 1979?  
 11 A. Um, no, we were using DDAVP. It became available --  
 12 I think it was licensed for treating haemophiliacs in  
 13 about 1976 or '77. And I remember presenting  
 14 the ability to treat mildly affected haemophiliacs and  
 15 people with von Willebrand's disease with this  
 16 desmopressin, or DDAVP, which could be given  
 17 by injection and would induce an increase in the level  
 18 of Factor VIII, and indeed of von Willebrand's factor,  
 19 in the blood of these mildly affected patients or  
 20 patients with von Willebrand's. So I'm sure I was doing  
 21 that from 1977.  
 22 I think the haemophilia returns did not request  
 23 data about DDAVP until this particular year. So I may  
 24 well not have documented for my successor how much DDAVP  
 25 was used, and so he would be unable to actually complete

28

1 that detail. So that form is a slight victim of  
2 a handover which might have been better, but I was doing  
3 my best to ensure that all was accounted for before  
4 I actually left.

5 **Q.** I'm going to ask Sully, please, to put this -- keep this  
6 page on the screen and to go back to the 1977 document  
7 and have it next to it, so we can see how the  
8 prescribing practice has changed between 1977 and 1979.

9 So Sully, could we please have next to this  
10 page 14 of HCDO0001178.

11 So I hope you can read this, Dr Boulton, but we  
12 can see -- we just looked earlier at the cryoprecipitate  
13 from 1977, approximately 10,000 bottles or  
14 800,000 units. And we can see that that's reduced  
15 somewhat by 1979 down to just over 7,000 bottles or  
16 630,000 units.

17 We can see that the NHS factor concentrate has  
18 gone up from 13,000 units to 220,000 units. Can you  
19 tell us the reason for that?

20 **A.** I believe that BPL had expanded their capacity to  
21 prepare Factor VIII concentrate from English donors of  
22 donations of plasma. So as a result of a building  
23 programme, they're able to supply the whole country with  
24 rather more Factor VIII than they had in earlier years.  
25 So I think that's the explanation.

29

1 So some of this may have been slightly driven by  
2 the preference of the patients or their parents in terms  
3 of the convenience of dissolving the powdered material,  
4 that was kept in their fridge at home, in water that  
5 I advised be not kept in the fridge, of course cold  
6 water didn't dissolve things as well as water at room  
7 temperature. So there was a lot of those little  
8 details. But some of that difference might have been  
9 due to patient preference, and it looks as if that's the  
10 case, that the one product they did prefer was the  
11 Armour Factorate.

12 **Q.** Then just looking at the amounts, by my calculations,  
13 the 1977 number of units for commercial factor  
14 concentrate across those four that we see there comes to  
15 457,320 units and, by 1979, that has increased across  
16 the three commercial products, we see there, to 920,750.

17 So I don't expect you to be able to do the mental  
18 mathematics on the spot, Dr Boulton, but we can see,  
19 looking at it, that there's -- sorry, I think I've got  
20 that figure wrong, I beg your pardon. I think that's  
21 the whole -- sorry, that's the whole of --

22 **A.** It's 700 --

23 **Q.** Yes, thank you.

24 **A.** Yes, it's 700,750 that made up those three.

25 **Q.** It is, and the figures I gave you, I beg your pardon,

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1 **Q.** Then we can see that there's a rather different pattern  
2 of -- well, perhaps not very different, but, rather than  
3 having four commercial concentrates in 1977, there are  
4 three commercial concentrates, although one is --  
5 Hemofil is a small amount, and it's primarily Factorate  
6 at that stage, with some Kryobulin?

7 **A.** Yeah.

8 **Q.** Again, was there a different policy by 1979 in terms of  
9 spreading the concentrate across different manufacturers  
10 or was that just a matter of chance?

11 **A.** I think we were becoming more aware of the need to be  
12 a little less liberal in the resourcing.

13 Each commercial firm was charging roughly the same  
14 amount. I think it was 10p per unit of Factor VIII. So  
15 it wasn't so much a price difference, although there  
16 were occasional tussles that would try to make one more  
17 attractive than the other. But the other thing that was  
18 of significance, and I cannot remember the details, but  
19 the haemophilics themselves, or their mothers who were  
20 treating the children at home, really liked the stuff  
21 that dissolved most quickly. And some of these  
22 preparations, particularly those in 1977, did not  
23 dissolve all that well. And so the same manufacturer  
24 would produce improved batches that dissolved more  
25 easily.

30

1 were not just for commercial concentrate, they were for  
2 concentrate altogether. So the 457,320 was for all the  
3 concentrate, including the NHS factor, and the 92 -- now  
4 I can't read -- 920,750 was for all the concentrate,  
5 including the NHS factor concentrate.

6 So the question I have for you is: is it right to  
7 understand that between 1977 and 1979 there was quite  
8 a considerable increase in the amount of factor  
9 concentrate that was being prescribed by the Centre?

10 **A.** That is correct, and it would be related to the  
11 expanding home treatment programme.

12 **Q.** I'm going to ask you now some questions about the  
13 policies and the rationale for those policies, and how  
14 you made treatment decisions.

15 First of all, I'm going to start on the home  
16 treatment program. What criteria did you use to decide  
17 which patients should go on home treatment and which  
18 patients should not get home treatment?

19 **A.** Well, I personally trained the patients or their parents  
20 usually their mothers. So that would involve physical  
21 face-to-face meetings, discussing, first of all, the  
22 pros and cons of home therapy, and discussing the  
23 practicalities, like did they have a refrigerator, and  
24 what were the conditions like. I don't think I actually  
25 visited their homes, but I -- and that was an option

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1 that could be done, if necessary. But it involved a lot  
2 of close conversations with the people affected and, in  
3 a sense, just to get a feel of how suitable they were,  
4 how well they could cope.

5 Needling veins is always a challenge, and you can  
6 imagine that for a mother faced with a four year old,  
7 five year old little boy, learning to put the needle in  
8 the vein is a very stressful experience. They were very  
9 well motivated and they, on the whole, learnt it very  
10 well, but there needed to be care in the process of  
11 training, advising, and I had to be reasonably satisfied  
12 that they were able to cope.

13 I do remember one occasion with one young man,  
14 I think in his early teens, who said he couldn't  
15 dissolve the Factor VIII in the vial and I found out  
16 that that was actually because he was warming the water  
17 and basically cooking the Factor VIII as he put it in.

18 So that's the sort of thing that would be dealt  
19 with in the course of training these people. So that  
20 was quite a lot of time spent just doing that.

21 But, on the whole, it was worth it, in terms of  
22 the relief of access -- of pain and difficulties.  
23 Although more Factor VIII was used, in the course of the  
24 home therapy programme, what was used is probably used  
25 more effectively in cutting short the time that the

33

1 who are up to 5 per cent; and the milds, more than  
2 5 per cent. As far as I remember, but I can't be  
3 totally accurate on this, none of the mildly affected  
4 haemophiliacs actually needed home therapy, in one sense,  
5 but it is possible that a few of the moderately affected  
6 might have done but I cannot remember. It was  
7 principally directed at those with severe haemophilia.

8 **Q.** Can we just look at a document, then, that you wrote to  
9 Dr Martin about home treatment.

10 So that's WITN0173002. It's a letter that you  
11 wrote to Dr Martin and, when it comes up, we'll see that  
12 it's dated 29 October 1976. Can we go to page 4,  
13 please, of that document. We can see at the second  
14 paragraph down:

15 "Because of recent queries from the Central and  
16 Southern District Administration concerning the expense  
17 of buying commercial clotting factor concentrate, I feel  
18 that wherever possible we must initiate home therapy  
19 programmes on the basis of Cryoprecipitate. Mrs [X] has  
20 a deep freeze, but is not sure of its temperature range.  
21 However, if this turns out to be satisfactory (and of  
22 course the BTS will have to be satisfied with this)  
23 I think we should encourage her to continue on the basis  
24 of Cryoprecipitate at home, although we can get powdered  
25 concentrate for travel.

35

1 people were actually bleeding, if you're bleeding into  
2 a knee joint very painful. If it took an hour or two to  
3 come to the hospital, prepare the cryoprecipitate and --  
4 or Factor VIII and administer, there was still a few  
5 hours of quite intense pain.

6 At home, the patient would say, "I've got  
7 something in my knee I know it's going to bleed", and  
8 they would be able to treat it much more effectively,  
9 and so, consequently, although more was used, it was  
10 also used more efficaciously.

11 So the training programme was important in order  
12 to do that. So, consequently, I did develop a fairly  
13 close relationship on those terms with the patients and  
14 their parents.

15 **Q.** So were all the people on home treatment severe  
16 haemophiliacs?

17 **A.** Sorry, I missed a little bit of that.

18 **Q.** Were all the people on home treatment people with severe  
19 haemophilia?

20 **A.** Yes, yes.

21 **Q.** What about people with moderate haemophilia, would they  
22 be put on home treatment?

23 **A.** I don't think I offered home therapy for those with  
24 moderate -- we're having a distinction here, aren't we?  
25 There's the severe, less than 1 per cent; the moderates,

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1 "I have not made a further appointment, but have  
2 asked Mrs [X] to bring" --

3 **SIR BRIAN LANGSTAFF:** Just pause there. We've lost the bit  
4 on the screen because of the highlighting.

5 **MS SCOTT:** I beg your pardon, sorry.

6 **SIR BRIAN LANGSTAFF:** Sully, can we move the --  
7 Thank you.

8 **MS SCOTT:** Thank you, sir.

9 "I have not made a further appointment, but have  
10 asked Mrs [X] to bring [presumably her son] to Tropics  
11 on the next bleeding occasion so I can be satisfied that  
12 a) she can needle properly, and b) she is confident  
13 about re-constitution of Cryoprecipitate."

14 So we can see from this the process of you  
15 consulting with Dr Martin in relation to a child  
16 patient; is that right?

17 **A.** That is correct. Can I just offer my profound apologies  
18 for the somewhat *maladroit* wording of the first  
19 paragraph? Those are words which I would not use these  
20 days about people having "slight histrionics". So  
21 I regret that particular use, it was not appropriate.

22 This was a lady who was clearly concerned for her  
23 son who was then, as I say, a remarkably lively little  
24 chap so, clearly, I warmed to him as a person, as  
25 a little boy, and she was exhibiting the very

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straightforward and understandable anxieties about the future of her son.

So, on behalf of us as professionals, I would say I regret that wording. Of course, it's quite extraordinary how one's past catches up with one and something you think is confidential, will never be revealed to the public, that's a lesson that I think is very profound for the whole of this Inquiry. The amount of confidential material that was inappropriately confidential and which hampered communications was quite profound. But I do apologise for that.

As for the rest of the letter, I was -- I only saw this a week or so ago, and I have to say that, apart from that first sentence, as far as this letter was concerned, I was quite gratified to be reminded of this particular episode, which I had otherwise almost completely forgotten and it is rewarding to have even a little bit of feedback from a patient, even though, as I see from the rest of the document, it was the beginnings of a really rather tragic experience for this man.

But, nevertheless, it did confirm that we were training people to give cryoprecipitate at home, although I developed reservations about that later on because of the nature of the material and of the

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number of donors who contributed to that cryoprecipitate pack, which might even just be one, or maybe two or three people. But, as they grew up and their blood volumes got bigger and they needed much bigger doses, one was sometimes forced to use materials that they could inject more easily, because the concentrate was made up in much smaller volumes of water, so that an adult may only need to inject 10 or 20ml of liquid that contained commercial concentrate, compared with the equivalent volume for Factor VIII content of cryoprecipitate.

So children were more tolerant, in a way, of receiving cryoprecipitate but, as they get older, needing more, we had to resort to the more concentrated forms of commercial concentrate.

**Q.** Can you recall how many of your patients you had on home treatment with cryoprecipitate?

**A.** I can't recall with any accuracy -- seeing this reinforced what was on the earlier displays that you showed -- that cryoprecipitate was being used. But I cannot remember how many patients. It was probably not a large number. By which I mean, you know, half a dozen or so, I think. But I have no clear memory of how many people I would be treating with cryoprecipitate at home.

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alternatives that could be given. But, in those days, when there was very little NHS Factor VIII around, if one had to give Factor VIII it was either commercial or cryo, and cryo was obviously, at that time, an option I preferred for certain types of people and that included this mother and child.

**Q.** You set out there that the pressure, if I can put it that way, on you as a prescriber, in terms of paying for commercial clotting factor and that --

**A.** Yeah, we were given a budget, and it was a fairly tight budget, and I was very keen to keep to it. And the budget was about £40,000 a year to buy commercial Factor VIII, and I think in that particular year I spent £50,000 and the treasurer was actually pleased that I hadn't spent any more. He was expecting a hugely bigger sum but we were trying to keep within reasonable bounds.

But, nevertheless, there were certain financial constraints and that's why, for certain patients, I felt that cryoprecipitate was a good option.

**Q.** So you were reserving the more expensive commercial concentrate for this patient for when cryoprecipitate really couldn't be used, for travel, and so on?

**A.** I think that's right. I mean, children would respond -- you didn't need to give much cryoprecipitate in terms of volume to a child, so that child was only exposed to the

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**Q.** For those patients that you considered to be appropriate to -- and would be able to manage cryoprecipitate, did it work reasonably well as a method of home treatment?

**A.** Well, I think it's the patients and their parents themselves who are more qualified to answer that question, mainly because of my lack of memory. But the fact that it was documented in the returns of 1977 that we were doing it, as well as this particular child receiving it, confirms that some people were able to use it and, presumably, with some satisfaction, although I think it wouldn't be surprising if sometimes the -- we had to resort, even for those children, for concentrates. And I think that is what happened to this particular boy.

**Q.** Now, you've just told us that one of the factors that was important when deciding whether a patient should get cryoprecipitate or factor concentrates was the age of the patient. Were there any other factors that you took into account when making that decision?

**A.** Well, apart from the social circumstances that the child or their family or the patient were actually living in, which was quite an important factor in advising how to care, I think probably the cryoprecipitate was more reserved for the smaller people, which would be basically children.

40

1 Q. What about when you were making that decision for  
2 a treatment -- for a patient who was coming into  
3 hospital for treatment, say somebody that's not on home  
4 treatment? What factors would you take into account  
5 when deciding whether or not to give them  
6 cryoprecipitate or factor concentrate?

7 A. I think cryoprecipitate was preferred for most of those  
8 who attended the hospital. Either for a day treatment  
9 or for -- admitted for several days. Those  
10 circumstances, although I've described it was time  
11 consuming and people would be in some pain, we -- if we  
12 heard in advance that a patient was coming, we would  
13 have time to start forming and preparing the  
14 cryoprecipitate in advance.

15 So, consequently, we would be able to prepare the  
16 cryoprecipitate ready for them to use -- to be given,  
17 and also we, ourselves, were reconstituting the  
18 cryoprecipitate under controlled circumstances; we,  
19 ourselves, would be putting the needle, although  
20 sometimes the patient still preferred to needle  
21 themselves, once they'd got expert at doing it.

22 But it was done under more controlled  
23 circumstances in a health setting, which lowered the  
24 threshold, if you like, for using cryoprecipitate.

25 The other thing about cryoprecipitate that is

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1 with concentrate, what criteria did you use or how did  
2 you decide whether or not that patient should get  
3 commercial concentrate or NHS factor concentrate?  
4 A. Well -- and I think this mostly applies to the latter  
5 year, so -- because that's when we had a more  
6 substantial amount of NHS Factor VIII. One important  
7 thing is: why were they admitted? If it was for surgery  
8 and we were, you know, giving -- there were patients who  
9 required surgical episodes, either urgent or planned.  
10 The occasional orthopaedic surgeon would be required to  
11 do something for patients for a haemophilic joint.  
12 Under those circumstances, we required large amounts of  
13 Factor VIII and the most readily available sources would  
14 be the commercial.

15 For other episodes, for example dental extractions  
16 that could be done at home, these -- some dental  
17 extractions that could be done in an outpatient  
18 department of the hospital or the dentistry, we would  
19 possibly give either NHS Factor VIII or cryoprecipitate,  
20 accompanied by antibiotics and also antifibrinolytic  
21 agents to stop the clot dissolving. So, in those  
22 circumstances, we might be able to avoid the use of  
23 commercial Factor VIII but, quite honestly, I cannot  
24 recall any details.

25 These are something of a supposition from what

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1 important is that it was accompanied by a significant  
2 frequency of adverse reactions, mostly fever and  
3 headache. And, somehow, the children seemed to be more  
4 resilient, I think, for this, whereas the older children  
5 and adults were more prone to having these adverse  
6 events.

7 And it was much easier to deal with those adverse  
8 events when they were actually in the direct care of the  
9 nurses and doctors administering the Factor VIII. So,  
10 in many ways, cryoprecipitate was reserved for hospital  
11 care because we could keep a closer eye on the  
12 circumstances of the actual infusion, whereas at home we  
13 would be less able to keep a close eye, that would have  
14 required a standard of training, a standard of trust,  
15 a confidence among the parents that they were able to  
16 infuse the cryoprecipitate, and a confidence among the  
17 parents that they were able to infuse the more  
18 concentrated Factor VIII in dissolving it and preparing  
19 it for infusion.

20 So it's quite a long and complicated process.  
21 It's not just an easy thing to say "home therapy"; it  
22 involves an awful lot. And, actually, Peter Jones's  
23 book on *Living with Haemophilia* was immensely helpful in  
24 that particular regard.

25 Q. When you are faced with a patient who you want to treat

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1 I can recollect about what our general policies for  
2 treatment were at that time and I don't think we can  
3 place too much reliability on what I've just said about  
4 whether we would choose to use NHS factor concentrate or  
5 commercial Factor VIII. But clearly there was more  
6 commercial Factor VIII around and so, consequently, they  
7 were used for patients as a sort of second resource,  
8 with the NHS Factor VIII being the first resource of  
9 choice but I cannot make an accurate comment on those  
10 policies going back 40-odd years.

11 Q. Did you introduce a prophylactic programme of treatment  
12 at Liverpool?

13 A. No, I didn't. I know that there were advocates of home  
14 therapy, but I felt that -- sorry, of prophylaxis and  
15 home therapy prophylaxis, but I felt that the home  
16 therapy programme was adequate in aborting the early  
17 stages of a bleed that the patients knew was going to be  
18 painful. And that was not a form of prophylaxis, but it  
19 was a form of treatment, a preventative treatment  
20 stopping an established bleed getting bigger. But I did  
21 not introduce a prophylactic programme in patients who  
22 were not experiencing a bleed who nevertheless inject  
23 themselves with enough Factor VIII to tide them over the  
24 next few days so that if they did have some sort of  
25 accident, the blood -- their blood would clot normally

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(11) Pages 41 - 44



1 within them. I did not do that as a prophylactic  
 2 programme.  
 3 Q. So just drawing this together before we break, can we  
 4 look at a paragraph in your witness statement,  
 5 WITN3456002, page 28 of that witness statement, to  
 6 understand what the treatment policies were during your  
 7 time in Liverpool for people with mild haemophilia.  
 8 At the bottom of that page, you're asked:  
 9 "To what extent, and why, were people with mild or  
 10 moderate bleeding disorders treated with factor  
 11 concentrates?"  
 12 And then you say at paragraph 72:  
 13 "In 1977, of ten patients: one had only DDAVP; 8  
 14 had cryo; one had 'Koate'."  
 15 And if we go over the page, please:  
 16 "In 1978, of five patients, all had just  
 17 cryoprecipitate.  
 18 "74. In 1979, of seven patients: three had just  
 19 cryo; 2 had cryo [plus] DDAVP; one had cryo plus  
 20 'factorate'; one had just 'factorate'. I cannot recall  
 21 the clinical circumstances."  
 22 So from that, do we understand that, certainly  
 23 from 1977, the primary -- the preferred course of  
 24 treatment for somebody with mild haemophilia was  
 25 cryoprecipitate, and cryoprecipitate and DDAVP?

45

1 A. To be honest, I don't think that the patients were  
 2 offered much of a choice of concentrate. In other  
 3 words, I don't think they had an opportunity to say,  
 4 "Could I have the NHS one, please?" Maybe that is  
 5 regrettable, but for much of the time there wasn't much  
 6 NHS around until the last year. So it was a little bit  
 7 of sort of Hobson's choice. But nevertheless, on  
 8 reflection, it would have been good practice to have  
 9 reserved the NHS Factor VIII for some of the most needy  
 10 cases, for whom -- who perhaps didn't require treatment  
 11 quite so often.  
 12 That's a little bit of a contradiction, I realise,  
 13 but there were some patients who were severely affected  
 14 in terms of their Factor VIII content in their blood,  
 15 the Factor VIII activity in their blood, but who didn't  
 16 present very often, and if they needed therapy, they  
 17 needed it properly.  
 18 There's no -- you couldn't go halves on this, and  
 19 that's also true for people with mild haemophilia. If  
 20 they needed a large amount of Factor VIII, because DDAVP  
 21 would only give a boost and it wouldn't last -- and you  
 22 couldn't give it the next day. You couldn't give  
 23 repeated courses of DDAVP, it was the first dose that  
 24 was the most effective, it was a sort of exhaustion  
 25 effect of the stores of Factor VIII in the body.

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1 A. I think so. This data in my witness statement is based  
 2 entirely on the returns, which we've already shown. So  
 3 I really cannot add any more details to this  
 4 description. So I think I have to leave it at that.  
 5 But yes, for mild haemophilia, and indeed  
 6 von Willebrand's disease, when DDAVP became available,  
 7 that was the matter of choice. As again, particularly  
 8 if they needed a dental extraction, in which case we  
 9 would also give, as I say, antibiotics and  
 10 antifibrinolytics. Saliva has enzymes that dissolve  
 11 clots, so it was important to try to inhibit that. So  
 12 that was part of our treatment programme, including  
 13 DDAVP.  
 14 I think that's all I can really say.  
 15 Q. And again, drawing together what you've told us about  
 16 those with severe haemophilia, is it right to say that  
 17 it's not really necessarily possible to identify a first  
 18 line of preferred treatment for all of those severe with  
 19 haemophilia, it would depend on their age and their  
 20 circumstances as to whether they should have  
 21 cryoprecipitate or factor concentrates, and if they're  
 22 to have factor concentrates it might depend on their own  
 23 preference, or availability, as to whether they have  
 24 NHS factor concentrates, commercial factor concentrates,  
 25 and if commercial, which commercial?

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1 But patients with mild haemophilia, as far as  
 2 their activities were concerned, if they started  
 3 bleeding, they could bleed very heavily and they needed  
 4 quite a lot of Factor VIII. So perhaps for them, the  
 5 first choice should have been NHS Factor VIII, but  
 6 I cannot remember the details of my policy at that stage  
 7 in 1979 in the Liverpool Haemophilia Centre.  
 8 So I can only give general comments and not  
 9 perhaps what I actually did.  
 10 MS SCOTT: Sir, I note the time. Would now be  
 11 an appropriate time to take a break?  
 12 SIR BRIAN LANGSTAFF: Yes, it would. We'll take a break  
 13 until 11.50.  
 14 We're just starting a break, Dr Boulton. Let me  
 15 tell you what I say to all witnesses at this stage.  
 16 It's this: you're giving evidence, you must not discuss  
 17 anything you've said in evidence with anyone, your wife,  
 18 anyone else; you must not discuss anything which you  
 19 think you may yet be asked to give evidence about but  
 20 you can talk about anything else you like. I'll see you  
 21 back on screen at 11.50.  
 22 A. Thank you very much, I take all those points.  
 23 (11.21 am)  
 24 (A short break)  
 25 (11.49 am)

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1 **SIR BRIAN LANGSTAFF:** Yes, Ms Scott?  
 2 **MS SCOTT:** Dr Boulton, I'm going to move on now to ask you  
 3 some questions about your knowledge of risk of  
 4 hepatitis.  
 5 Is it right to understand that you have known  
 6 since you started practice that there was a risk of  
 7 hepatitis B being transmitted by blood and  
 8 blood products?  
 9 **A.** From the start of my practice, I'm not sure when to  
 10 define that, but certainly as students we were taught  
 11 about serum homologous hepatitis, the fact there are two  
 12 sorts of hepatitis, which became known as A and B, and  
 13 the B was the homologous serum hepatitis that could be  
 14 transmitted by, for example, injections using shared  
 15 needles, as in vaccinations, for example.  
 16 As my training proceeded, we got more specifically  
 17 aware, and while I was senior registrar at the  
 18 London Hospital, I spent five months at the Brentwood  
 19 Transfusion Centre, which is where I first learnt  
 20 specifically about the tests for the hepatitis B surface  
 21 antigen, which was still known then as Australia  
 22 antigen, had been known about 10 years. But the testing  
 23 was introduced for blood donors in the early 1970s, and  
 24 I was actually taught by the scientists who performed  
 25 those assays how to do them back in about 1972.

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1 the hepatitis B virus. But it has a propensity in most  
 2 people to over-produce that and it makes it very  
 3 obvious. So it's easy to detect a person -- most people  
 4 who are at the stage of carrying hepatitis B virus  
 5 either because they've been acutely infected or because  
 6 they're one of the minority who become a chronic  
 7 carrier. And the chronic carrier state is quite  
 8 important to us in transfusion, because those are people  
 9 who are entirely healthy, well, asymptomatic, but do  
 10 transmit the infection.  
 11 So we were aware that hepatitis B was an  
 12 extraordinary virus, easy to detect, but not always  
 13 foolproof. There were some people who, infected, did  
 14 not exhibit this particular overproduction phenomenon,  
 15 and also sometimes the carriers would go through phases  
 16 with very low production of surface antigen, so it would  
 17 still be quite possible for someone to test negative  
 18 with those tests but still actually be infectious. And  
 19 we knew that.  
 20 **Q.** You tell us in your statement that you understood from  
 21 a very early on in your career the importance of  
 22 pool size in determining the infectivity or potential  
 23 infectivity of a blood product; is that right?  
 24 **A.** Absolutely, yes. There was some excellent early work  
 25 done in the war, and actually I've also just seen

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1 **Q.** Is it also right to understand that from the time that  
 2 you were at the Royal London, that you understood that  
 3 screening process did not screen out all cases of  
 4 hepatitis B?  
 5 **A.** Um, I obviously learnt from the experience I recounted  
 6 earlier that there was more than one form of serum  
 7 hepatitis. So that, in a sense, one was not surprised  
 8 to hear that others were aware of this particular  
 9 situation. Dr Craske in Manchester in particular was  
 10 very helpful in improving my understanding of that  
 11 situation.  
 12 So yes, from the early 1970s, we were aware that  
 13 not only was there other forms of infectious hepatitis,  
 14 like hepatitis A, but other forms of hepatitis that  
 15 could be transmitted by "serum", which included B but  
 16 then other forms, which initially were called  
 17 non-A, non-B.  
 18 **Q.** And that the screening processes for hepatitis B didn't  
 19 pick up all of the hepatitis B infections, some of them  
 20 still --  
 21 **A.** Yes, that's also true. Yes. That's also true.  
 22 Hepatitis B is a strange virus in that it has of the  
 23 habit in most people it infects of going through a phase  
 24 of vast overproduction of this protein called the  
 25 surface antigen, which is the protein on the surface of

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1 a paper that came out in 1949 by Dr Lehane, who became  
 2 the director of the Liverpool Centre, which also  
 3 indicated the impacts of pooling. In those days they  
 4 called large pools of the order of 300 donations in  
 5 a pool, which is very much smaller than the pools that  
 6 we became more familiar with in the preparation of  
 7 Factor VIII concentrates.  
 8 **Q.** So is it fair to say that you have always known that  
 9 there is a risk of getting a transfusion-transmitted  
 10 infection from concentrate and that that risk was  
 11 significant?  
 12 **A.** Yes, we -- that was well recognised by not only myself  
 13 but all my colleagues. But -- and you may be coming on  
 14 to this -- the consensus of opinion in the 1970s among  
 15 haemophilia doctors, and indeed among many other  
 16 physicians, was that the non-A, non-B form of hepatitis  
 17 was often mild, even asymptomatic, and people might get  
 18 an infection from it, but only be slightly ill, if ill  
 19 at all, and in time would completely recover.  
 20 It was that complete recovery that in the end came  
 21 to -- back to bite us, because we obviously learnt in  
 22 time that most people with non-A, non-B hepatitis --  
 23 that became labelled as hepatitis C still -- were still  
 24 affected for the rest of their lives, and their livers  
 25 gradually deteriorated.

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1 Q. Just for the transcript, you mentioned some work that  
 2 came out in the war relating to pool size. I think you  
 3 might have been referring to the work of Dr Vaughan  
 4 in 1946, and for the transcript, that is RLIT0000052.  
 5 I'm afraid don't have the transcript reference for the  
 6 Lehane article that you --

7 A. No, that was very recent. I can send that.

8 Q. As I understand your evidence, you were aware, were you,  
 9 of the publication of Professor Preston's study in  
 10 The Lancet in 1978 in which he had carried out biopsies  
 11 on asymptomatic people with haemophilia, and discovered  
 12 a wide range of quite serious liver disease.  
 13 You're nodding. The transcript --

14 A. Yes, I will -- I mean, that was a remarkable piece of  
 15 work. That was received in some quarters, including  
 16 myself, with some incredulity at first. Partly because  
 17 I think there was a sort of wishful thinking, partly  
 18 because there were some criticisms about -- well, many  
 19 of his patients, and there were eight biopsied, were  
 20 middle-aged men, and there are lots of causes for  
 21 cirrhosis in middle-aged men, particularly alcohol. So  
 22 we were -- there was a certain amount of scepticism  
 23 which, on reflection, was completely unjustified. Of  
 24 course that is an incredibly bold piece of work.  
 25 There is also -- I know these things shouldn't

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1 biopsies indicated.  
 2 It's a classical case of looking at the patient,  
 3 seeing how they are, and then noting what the laboratory  
 4 investigations say without necessarily linking the two.  
 5 So a bit of self-denial among the haemophilia doctors  
 6 community. And I include myself in that. And we were  
 7 wrong. There's little doubt of that.

8 Q. When you say you should have taken more notice of that  
 9 paper, are you referring there to amending your  
 10 prescribing practice to turn away from factor  
 11 concentrates back towards cryoprecipitate?

12 A. There was a lot of talk, not so much then, but I think  
 13 in the early '80s and particularly with the onset of --  
 14 of HIV/AIDS, that these infections -- these diseases  
 15 that were caused by infections in the Factors that were  
 16 being transfused to these people should have made us  
 17 think more than twice about expanding the use of those  
 18 concentrates. But the power of persuasion of those who  
 19 witnessed -- and that's not just the families but the  
 20 doctors -- who witnessed the instantaneous relief of the  
 21 suffering that could be -- that could follow, that did  
 22 follow the treatment of the haemophilic bleeding episode  
 23 with these concentrates, it was -- this was miraculous.  
 24 I mean, haemophiles before the 1960s had to lead  
 25 an extraordinarily limited life. They were crippled and

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1 happen to the clear-cut academic mind, but nevertheless  
 2 there was some reason to note the irony of the need to  
 3 insert large needles through the skin into people's  
 4 livers in order to get a bit of tissue. And if you do  
 5 that to anybody, they will bleed. And if you've got  
 6 a haemophilic there, then of course they will bleed even  
 7 more. But Eric took the precaution of transfusing them  
 8 with Factor VIII -- and I don't know where it came from,  
 9 but I wouldn't be surprised if some of it was  
 10 commercial -- to raise the activity of Factor VIII in  
 11 those patients' plasma to normality,  
 12 one hundred per cent. And that's a lot of Factor VIII,  
 13 you had to give three to 4,000 units, and it only lasts  
 14 for about 12 hours, it starts deteriorating immediately.  
 15 So he was giving the very materials that were  
 16 potentially causing the problem to people with -- by  
 17 doing the liver biopsy.  
 18 And so there was a sort of atmosphere of  
 19 incredulity about the whole thing. But Eric is a very  
 20 fine scientist, as is the tradition from Sheffield  
 21 anyway, and we should have taken more notice of that.  
 22 We still rather hoped that even if there were signs of  
 23 cirrhosis, if the people were asymptomatic and leading  
 24 normal lives, they were -- the actual clinical  
 25 consequences would not be quite so severe as the

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1 their life expectancy was short. And I think others to  
 2 the Inquiry have given witness to that. And certainly  
 3 those haemophiles who I saw as a student at St Thomas'  
 4 were brave young men already incredibly disabled.  
 5 So the prospect of being able to reduce or even  
 6 prevent that degree of crippling by a relatively simple  
 7 procedure of intravenous injection, that people could  
 8 learn, sometimes even the patient themselves could  
 9 learn, offered a bright future for these young men. And  
 10 the persuasive power of that image -- it wasn't just an  
 11 image, it was direct experience of the -- not just of  
 12 the patients but of those treating the haemophiles --  
 13 was very, if I can put it that way, seductive. So we  
 14 felt, as a community, that it would be wrong to  
 15 radically alter the approach.  
 16 There were stages when people thought about  
 17 reducing it a bit and reducing the commercial doses  
 18 a bit and improving the cryoprecipitate a bit, but  
 19 actually, these were quite difficult to enact on a large  
 20 scale.

21 Q. Would you agree, as a matter of principle, that patients  
 22 being treated with factor concentrates should have been  
 23 told that a risk of that treatment was contracting  
 24 non-A, non-B hepatitis when you were practising in  
 25 Liverpool?

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1 A. Yes, that is a fundamental principle. And, to my  
2 recollection, we did as doctors, try to -- well, we  
3 did -- we did not deny and we actually did assert at  
4 opportunities that there was a risk of infection in the  
5 materials. But in the late 1970s, even after Eric's  
6 paper, which is why I say we should have learnt more,  
7 there was still a feeling that that risk was acceptable  
8 because the infection symptoms were short lived and, as  
9 far as we could see, the long-term effects were minimal,  
10 so consequently the short-term disadvantage of a short  
11 period of relatively mild jaundice -- although some  
12 actually became quite ill -- that short-term effect was  
13 outweighed by the long-term benefits of not being  
14 disabled as their predecessors had been.

15 So I think we did tell patients and their families  
16 but we almost certainly underplayed it. I can certainly  
17 remember speaking to the haemophiliacs in Liverpool in  
18 the newly formed branch of the Haemophilia Society about  
19 the prospects of treatment and the patients were excited  
20 about the possibility of leading a life like diabetics,  
21 who were injecting themselves every day with insulin,  
22 and I sort of acknowledged the validity of that  
23 aspiration, but -- and I think others may need to be  
24 asked about this -- but my recollection is that I did  
25 say that little bit of a "but": there is a risk

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1 A. Well, as I said earlier, it's because the visible  
2 benefits and the relief of suffering that these  
3 concentrates were able to produce seemed so much greater  
4 than the apparently minor adverse reaction of suffering  
5 from a short-term burst of hepatitis. So we got the  
6 balance wrong. So basically, as I said, the good news  
7 suppressed the understanding of the bad news.

8 Q. Were your patients subject to liver function tests at  
9 appointments?

10 A. No, I don't think they were, not as a routine. If they  
11 showed signs of jaundice, then they would have been  
12 conducted. But not as a routine.

13 Q. If you suspected that a patient had been infected with  
14 non-A, non-B, would it have been your practice to tell  
15 them that?

16 A. Or indeed with hepatitis B, yes.

17 Q. Well, yes, so you would have -- if you'd got abnormal  
18 liver function test results back and suspected  
19 non-A, non-B, you would have told the patient that under  
20 your practice?

21 A. Well, I think it worked like we had regular follow-up  
22 clinics, so roughly every three/six months, or so, for  
23 an individual haemophilic. So they would come, we would  
24 ask "How are you getting on? How are you managing your  
25 home therapy?" et cetera, and they would answer. If in

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1 associated with every injection and that could include  
2 infection.

3 But I, almost certainly -- in fact, I'm sure  
4 I did -- underplay that particular risk, and so the good  
5 news suppressed the bad news in practically everybody's  
6 mind.

7 Q. Just unpacking some of what you've said there, is it  
8 right to understand that the primary way of patients  
9 being informed of risk from treatment came through  
10 contact with the Haemophilia Society, rather than being  
11 told on a one-to-one basis when they were getting their  
12 treatment from you as their clinician?

13 A. I think it was both. It so happened that the  
14 Haemophilia Society branch in Liverpool, the setting of  
15 that was encouraged by myself, but not every haemophilic  
16 attended meetings of the societies so, consequently, it  
17 would have been quite easy for them to have missed  
18 information. So it was incumbent upon us to actually  
19 inform every patient that there was a risk. But how  
20 well that was done, I have doubts. I think it was --  
21 probably the message was transmitted by me rather than  
22 inadequately in retrospect, looking at what we now know.

23 Q. You have said that you almost certainly underplayed it  
24 and you've used the word "inadequate"; why was that?  
25 Why was that approach taken?

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1 that conversation there was apparently "I felt a bit  
2 ill, I felt a bit funny the other day or last week", at  
3 that point we might do -- include tests of liver  
4 function for those patients and, if they were abnormal,  
5 we would (a) test further specifically for hepatitis B,  
6 because that was -- that test was available, obviously  
7 no test available for hepatitis C. It wasn't even  
8 called that then.

9 So the combination of disordered liver function  
10 and hepatitis B was certainly [audio disruption] worth  
11 passing on. And I imagine that we did so. But I have  
12 no recollection of precise conversations of that nature  
13 in the clinics. But that's what the follow-up clinics  
14 were for, to check not only how they were coping with  
15 the haemophilia, but how they were -- what their general  
16 state of health was.

17 So there were ways in which we could be informed  
18 but I don't think we regularly -- I don't think we  
19 conducted liver function tests on patients at every  
20 clinic they came to.

21 Q. Would you accept, as a matter of principle, that if you  
22 had made a diagnosis of non-A, non-B, to the extent that  
23 it could be made, a diagnosis could be made, given the  
24 limitations, would you accept, as a matter of principle,  
25 that the patient should have been told?

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1 A. Yes.

2 Q. Do you have any recollection of giving advice to

3 patients about lifestyle and infecting others, if you

4 had made a diagnosis of non-A, non-B?

5 A. Which would include reference to their sex lives, for

6 example?

7 Q. Precisely.

8 A. I think probably not on a regularly basis. I mean, the

9 attitudes to those personal lifestyle matters were very

10 much more constrained in those days, although obviously

11 people working in the -- the staff working in sexually

12 transmitted disease clinics would have a very different

13 take. But I think -- and particularly with mothers and

14 young children -- we would not really be referring very

15 much to those lifestyle aspects.

16 And certainly in Liverpool, the attitude towards

17 those lifestyle factors, and including injecting drug

18 use -- and, by the way, it's much better to use the term

19 "injecting drug use" than "intravenous", because some

20 drug users don't intravenously, they actually do it by

21 cutaneous injection. But we rarely, if ever, touched in

22 any detail on that aspect of the lifestyles of the

23 haemophiles and their families, back in the 1970s.

24 Q. In your statement you have suggested that some

25 information was given about the risk of needle-stick

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1 and how much it was due just to the undesirability of

2 an unfortunate accident like that, in general -- you

3 don't want to hurt yourself unnecessarily -- I cannot

4 really accurately recount. So it may well be that the

5 mums didn't really understand -- excuse me using that

6 phrase -- that the parents giving the injection didn't

7 really understand the risk was in the materials they

8 were giving.

9 They were much more concerned about the benefits

10 from the materials they were giving and the risks was,

11 sort of, put in the background, and probably my training

12 schemes didn't emphasise that aspect to them as much as

13 probably it should have done. So that's the way it

14 went. As time went on, we learnt much more about how to

15 deal with these things. But that was a difficult phase,

16 at that particular time in the '70s, when home therapy

17 was expanding, because the benefits were so obvious, and

18 the disadvantages were much more obscure.

19 Q. Were referrals made to hepatologists for those that had

20 a diagnosis of hepatitis B and a diagnosis of

21 non-A, non-B?

22 A. Um, when the -- patients who developed jaundice, whether

23 it was identified as hepatitis B related or not, would

24 have been seen by a physician, referred to in the

25 hospitals, both in the children's hospital and in the

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1 injury, for example, for a patient that had hepatic

2 illness or hepatic virus, but you say that you had no

3 evidence to suggest that the parents, when you were

4 giving this information, understood the risks that --

5 understood what you were getting at -- I paraphrase, but

6 can you tell us a little bit more about that?

7 A. I think so. I think I can. I'm not sure if the risk of

8 infection was specifically identified. So, in other

9 words, when training a mother how to inject her son, we

10 would have said, you know: take care about these

11 needles, of course they are sharp, that's why you have

12 to be careful about your technique of injecting your

13 child. But I am not sure if the specific risk of

14 hepatitis transmission from the contents that they were

15 injecting, how much that was emphasised.

16 But, clearly, the risk was that the concentrate

17 was reconstituted in water at home, taken up into the

18 syringe through the needle, so that needle was obviously

19 then -- it was -- it contained the therapeutic

20 materials. It was then injected into the child and if,

21 in the meantime, a mishap occurred, and the mum

22 scratched herself with that needle while giving the

23 injection, that was an undesirable event.

24 Whether I stressed that the undesirability was as

25 much to do with the contents of the vial being at risk

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1 adult hospital.

2 But actually it was really quite rare. There were

3 a few, as you will see from the tables, about up to six

4 different people, although sometimes there was some

5 double counting, who in my time did develop clinical

6 jaundice. They would not only have had their liver

7 function tests determined but they would have been

8 referred to a physician, and also their GPs informed.

9 But I honestly cannot remember specific episodes of such

10 referrals.

11 Q. What role -- you touched on this to an extent, the role

12 that patients had in choosing their treatment at the

13 time you were in Liverpool, and I think you said they

14 didn't get a choice between NHS concentrate and

15 commercial concentrate but, as I understood what you

16 were saying, if they had a preference for a particular

17 type of commercial, that may have -- they may have had

18 a say in whether they wanted a particular type of

19 commercial if they found one easier to use than another?

20 Is that a fair assessment of -- a fair summary of what

21 you have said about their --

22 A. It may be a slight overinterpretation because all these

23 things come from a memory, which is of events of more

24 than 40 years ago. But I do remember conversation, not

25 least at the meetings of the Haemophilia Society group

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which I met, of discussions about the problems and the choices that they had of giving Factor VIII concentrates. I think all of them would have preferred the NHS, had that been available. But, even in 1979, even though there was considerable increase in the productivity from the BPL laboratories, it was still in short supplier.

So I think, in many cases, they just had to accept what was made available to them. So there wasn't that much choice about it, although there could well have been preferences.

**Q.** Would you agree, as a matter of general principle, that treatment decisions for patients involved weighing up the risks and benefits of one product against another?

**A.** Among commercials, I don't think there was much differentiation. But I think people, on principle, would have probably preferred the NHS, had that been available in the quantities that were required.

So I think the dividing line in choices would have been between NHS concentrates and any of the commercials, the latter being given roughly the same degree of acceptance compared with the rather greater desirability of the NHS concentrates, for reasons which they understood on terms of pool sizes and where the materials came from. In other words, often

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circumstances. It may well be that my performance, had anybody been around to witness it and document it accurately at that time, was not up to the ideals which I have perhaps currently said. So I do have to point out that the ideology which we've all been able to develop since may not have been fulfilled quite so much in practice -- in my practice -- for the haemophilic communities in the late 1970s.

**Q.** I've just got one more topic to ask you about before we move on to your time in Edinburgh, and that's record keeping.

What was the system for recording products received and batches used? Were records kept as part of the patient's medical records or were they kept separately?

**A.** I think there were two systems of recordings.

The main one would be in a patient's notes. Every time a patient received a blood transfusion or transfusion of blood products, the requirement for the doctors writing in a patient's notes, sometimes with the help of the nurses, was to document not just the fact that they'd been transfused but with the specific donation number of the transfusate.

And it is sometimes accompanied by laboratory forms that were sent back to the ward, including those

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North America for the commercial stuff, but only British people -- people donating in Britain for the NHS concentrate.

**Q.** And they knew the risk, the difference in the risks between the NHS commercial and -- the NHS and the commercial because you had told them that or because it was generally well known, amongst the haemophilia --

**A.** I think it was generally well known among the haemophilia community, but -- because probably out of a sense of, as much as anything else, a national loyalty to what the NHS was able to do. So if the NHS was able to produce something that worked compared with a commercial company that was being paid, then ideologically, the -- everybody, including the patients, would have preferred the NHS.

But it was a sort of in -- ill-defined as that.

When it actually came to the hard facts, data, that here was something that could save your life, stop your bleeding, and -- save your life, stop you from bleeding to death, there was a sort of more pragmatic approach about -- what they wanted was something that worked, rather than where it came from.

Now, I have to emphasise that these are recollections and impressions and what I, in a sense, would like to think I would have done under those

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precise identification markers. So those should have been inserted in the patient's notes every time.

Obviously with a haemophilic, receiving lots of treatment, they would have been -- they would have accumulated and got a very thick set of notes, but that was the accepted.

So that's what should have happened, and I'm pretty sure it did happen in Liverpool.

The other set of records would, of course, be in the laboratories, where there was patient data associated with the laboratory findings, because quite often -- not always, but quite often -- particularly when covering surgical procedures, the samples were taken for assay, those assay details were recorded and kept on record in the laboratory files. So those would be less complete but there would still be records.

And I would imagine after I left Liverpool, those two sets of records still formed the principal of data access for subsequent searches.

**Q.** What about home treatment records? Were patients or patients' families expected to keep those and return them to the centre?

**A.** They were expected to return the -- well, yeah. Sorry, let me just go back on that.

I honestly can't remember exactly what the home

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1 therapy patients in Liverpool were -- what instructions  
2 they received about disposing of the waste materials,  
3 the products and needles, et cetera.

4 I think this would be the days before sinbins, so  
5 they were still instructed to take care about the  
6 disposal of the needles and that goes back to my  
7 previous recollection that I think that the people who  
8 were doing home therapy were certainly advised to take  
9 care about the disposal of the waste products.

10 The batch numbers of all the materials they were  
11 given should have been recorded in the patient's notes,  
12 whether that was the case or not, I cannot honestly  
13 answer, but they should have been recorded in the  
14 patient's notes. And that would have been the main  
15 record, because the ward would have had a refrigerator  
16 where these materials were kept. So, although they came  
17 from the blood bank and the blood bank would also have  
18 kept details of the batch numbers, the ward would have  
19 known -- would have been able to identify those that  
20 they were giving to the patient.

21 So, ideally, there should have been a record of  
22 the batch numbers on every bottle of Factor VIII  
23 concentrate that was given. But I honestly cannot  
24 recollect the details of how that system worked.

25 Q. Can we look at a document, it's HCDO0001093. It's

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1 draw your attention to. You say:

2 "[The] man was treated with a batch of Kryobulin  
3 to cover a vasectomy, but unfortunately the doctors who  
4 with do the material failed to observe the departmental  
5 rule of the registration of batch numbers, etc. This  
6 has been a salutary lesson to me and I have tightened up  
7 our recording procedures but I must comment that, with  
8 the best will in the world, little can be done about  
9 doctors who fail to observe the rules."

10 So, just pausing there, then. There seem to have  
11 been two problems that you've identified in this letter,  
12 first of all problems with the recording procedures,  
13 which you've just told us about, and having to tighten  
14 up the rules and, at the beginning of that letter, the  
15 records have an annoying habit of going missing. This  
16 letter might give an impression of a somewhat chaotic  
17 recording and record-making system at Liverpool at the  
18 time you were there. Is that a fair conclusion to draw  
19 from this letter?

20 A. I think it's fair in one sense that it was highly  
21 undesirable, but this is not a unique experience,  
22 particularly for patients who were regular attendants at  
23 the clinics and on the wards. There would frequently --  
24 they would go missing in transit. So the wards had  
25 their record collections, the outpatient clinic would

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1 a document we've already looked at. It's the 1977  
2 returns.

3 Sully, can we go to page 3 of that document,  
4 please. This is a letter from you to Ms Spooner at the  
5 Oxford Haemophilia Centre, dated 23 September 1977, and  
6 you say this at paragraph 1:

7 "I recall, rather shamefacedly, that when I saw  
8 you in Oxford on the day of Dr Biggs's retirement  
9 I promised to send you our Annual Return at our earliest  
10 opportunity. All I can say is that the final  
11 compilation has not been quite so easy as some of our  
12 medical records have the annoying habit of going missing  
13 just when they are wanted."

14 Then the next paragraph you say:

15 "However this is the best I can offer you at this  
16 stage. As you will remember from a telephone call some  
17 months ago I feel I am not able to take part in  
18 Dr Kirk's jaundice survey and this is a bit regrettable  
19 as two of our patients have had some form of hepatitis  
20 during 1976/1977."

21 Then you say:

22 "I would like to amplify a bit on those two  
23 cases."

24 Then you refer to one case, and it's just the  
25 first part of that in relation to records that I want to

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1 require those records to be available to me when I saw  
2 the patients, and after I saw the patients and made my  
3 extra notes, I would put them on one side for them to be  
4 returned to the ward when possible.

5 With the best will in the world, sometimes it  
6 would be some days, or even occasionally weeks, when the  
7 records were not locateable with any great ease.

8 I think that was a day-to-day experience in many  
9 hospitals up and down the country in many specialties,  
10 so it wasn't unique. It's fair to comment on the chaos  
11 that surrounded that particular system, but I am sure  
12 this was not a unique experience, one of those that we  
13 sort of shrugged our shoulders and got on with.

14 It was difficult, it made life difficult to make  
15 accurate records at the appropriate time and, therefore,  
16 would prejudice the quality of those records. But these  
17 are busy hospitals, with regular recurring patients and  
18 ever-growing notes and finding pages missing in the  
19 notes was all much more difficult.

20 That's the problem with paper records. Similarly  
21 with donor records, when computerised systems became  
22 available, theoretically they should have been much more  
23 accessible through local devices, but those were the  
24 days of intensive paperwork, and depended upon the  
25 commitments of the -- those who were working and writing

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the notes and keeping them as to how they would be used, and made available to others.

So it was a sort of standard expectation but -- and it was chaotic, but I think not more chaotic than was often found throughout the health services.

**Q.** I'm going to move on now to ask you some questions about your time in Edinburgh. Just to remind ourselves of the chronology, we're now in 1980 and you spent 10 years in Edinburgh, first of all as a consultant, and then 1982 as the deputy director of the Edinburgh and South East Scotland Centre.

Now, we've heard oral evidence from both Dr Gillon and Dr Brian McClelland, who have covered some of the issues and events during the time that you were there, so I'm going to just pick up some specific issues with you, rather than run through all of the matters that are set out in your witness statement.

First of all, I'm going to ask you some questions about the centre itself and the role that it had. You describe to the Penrose Inquiry the South East Scottish Transfusion Centre being a transfusion centre that also had an active clinical base. What did you mean by that?

**A.** One of the reasons why I was attracted to the Edinburgh post was that, unlike the standard system in England, where you have a Regional Transfusion Centre that is

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the donors who were anaemic, so we were able to do blood counts but, in Edinburgh, not only were we able to do blood counts, we could do platelet counts on donors and we could do also clotting factor assays on donor plasma.

Also, this laboratory was available -- serviced the hospitals, and particularly the Royal Infirmary, for patients who had acquired bleeding disorders or thrombotic disorders as a result of an acquired condition, often surgery or some other illness, including liver failure. And so we were able to investigate those patients. So there was a rather greater availability to the hospital clinicians of investigations, laboratory investigations, for patients, conducted in the transfusion centre which in other places would have been conducted in the haematology laboratories.

I was given that responsibility for the clinical advice from that extra laboratory and particularly for the clotting factors associated with patients, because it wasn't just haemophiliacs who had abnormalities and clotting factors. So, although Christopher's laboratory would also have been able to and did the assays of Factor VIII and clotting investigations, particularly on the haemophiliacs, there was a sort of competition between the two, and I wouldn't blame Christopher at all

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separate from the hospital activities, sometimes in the same grounds as the hospital but actually organised as a separate unit, and sometimes quite remote from the working hospitals.

So the Transfusion Centre would be solely concerned with the collection and testing of blood donations with -- there would be reference laboratories that would do the specialist investigations mostly on rare blood group types for suitability of a transfusion to patients. So the patient contact was much less from the English centres, and I think -- well, in fact, I know the same really occurred at Glasgow when the centre was at Law Hospital, which was like 20 miles away from the main Glasgow hospitals. Whereas in Edinburgh, and the other centres in the east of Scotland, the centre was not only within the geographic hospital, but also directly issued blood for patients who were identified and crossmatched in the labs of the Transfusion Centre and not in the labs of the haematology laboratories, which is the case in most other hospitals.

But furthermore, in the Edinburgh Centre, there was a laboratory for haemostasis and blood counts. Blood counts were standard in Transfusion Centres, of course we needed to have some sort of investigation into

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if he felt that we were intruding on his territory.

But, for me, that was one of the reasons I came up. I was advised by Dr Cash when I came that this facility was available and I found it very attractive. It enabled me, for example, to participate actively in audits around the hospital of blood usage, and particularly useful, and I think this has also been commented by others, for the cardiac surgery. When I arrived, the cardiac surgeons basically wanted 10 pints of fresh blood for every open heart surgery operation they conducted.

By the time I left, partly due to my work but also partly due to increasing awareness among the surgeons and particularly the anaesthetists, the use of blood was much more rational, much more use of red cell concentrates and much less emphasis on the freshness of the blood, which actually caused quite a hurdle in the provision of services, because it does take time, when a transfusion centre has received the blood from a donor, to get it tested for and suitable for transmission, usually two days at least between receipt and availability for issue. And those -- the virtue of the freshness of the blood would disappear within those two days, according to the surgeons.

And there was some justification of that

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particular thinking. But as a result of my close contact with the clinicians, physicians and particularly the surgeons, we were able to develop an audit system. And that was all to the good of the standard of practice within the hospital.

But that explains a little bit sometimes of the interactions between Christopher and myself that went on.

Christopher was also very busy looking after other patients. Again, for him, only part of his service was to do with haemophilia, although it was a very important -- and he was very committed to that, but we were both busy doctors doing other things, but ultimately, very committed to high-quality standard patient care. And I, having left Liverpool, knew that I was deserting, if you like, the haemophiliacs there, about which I felt quite bad, not least because I never had to face up to the difficult conversations with those haemophiliacs in the -- and their families -- in the 1980s. And I felt bad about that.

But I was, therefore, an experienced haemophilia doctor in the hospital, but I did take care to intrude minimally on Christopher's practice. It was his job, and my -- I had a different job. And I think I said that to the Penrose. So that we respected each other's

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A. Well, we were an immunohaematological unit, blood transfusion is sometimes described as immunohaematology, so I'm not quite sure what you mean about the -- what you were referring to?

Q. It's a question I've been asked to ask you, so perhaps we -- so perhaps we can -- I can get some more detail --

A. Well, we were doing tissue types for patients in relation to the organ transplantation. We were looking at lymphocyte subtypes. That was part of the immunological aspects of the work in the Centre. So we were pretty thoroughly involved in immunohaematological investigations.

Q. We heard evidence yesterday from -- as -- we'll come back to some of those issues, but, just before we do, we heard evidence yesterday from Dr Gabra, who said that in Glasgow they were heating plasma over many years, and he thought that the same was happening in Edinburgh.

Do you have any -- can you assist us with whether that was taking place in Edinburgh or, to your knowledge, in Glasgow?

A. I didn't know about the heating of plasmas in Glasgow. We didn't do any heating of plasmas in Edinburgh. What was going on in Glasgow, which was intriguing, was that they were freeze drying units of cryoprecipitate, in other words they were exposing donations of plasma

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interests and commitments, and indeed what we were expected to do, but there were times when we had to have open, friendly, frank conversations about how we actually approached a particular deal. And that came particularly for when it came to assaying haemophiliacs who were receiving the new heat-treated products to see how effective they were, not just clinically but also by the lab tests.

And so there was a real need for Christopher and I to work together, as well as the need to work together on ensuring he got adequate supplies for his own expanding home therapy program.

Q. Dr Boulton, we'll come on to look at some of those issues you have just told us about in a little bit more detail, perhaps by reference to some documents.

Just picking up, then, on the work done by the centre, did the centre do ALT or AST testing of people with bleeding disorders?

A. No, I don't think we did. Just as in Liverpool, the Edinburgh Centre would have referred those samples to the local laboratories in clinical chemistry, I think, for those particular determinations. So I don't think we had a lab in the Centre that would do those tests.

Q. And what about white cell or immunological testing?

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collected -- that were decanted into bottles, and treating it in a freeze dryer in a way analogous to that which was developed at the Protein Fractionation Centre for freeze drying the fractionated concentrates. So Glasgow was keen and had been doing for a long time a freeze drying of plasmas, and they extended it, I believe, in the 1970s, to the freeze drying of cryoprecipitate.

I think -- and the idea there would be that we could have bottles of cryoprecipitate that, instead of expiring within hours, unless it was deep frozen, these were cryoprecipitate preparations that could be stored for months or years, and then reconstituted in a few minutes by adding water in the same way that the Factor VIII concentrates were being reconstituted.

So those were being prepared from the Glasgow Centre. They may have been heated, I just don't know.

My understanding is that the -- sadly, the freeze drying apparatus in Glasgow, which was of Second World War time vintage, by the 1970s had become -- it had failed the standards of Good Manufacturing Practice required by the Medicines Inspectorate. So, consequently, the process of making and distributing freeze-dried cryoprecipitate for the use of haemophiliacs

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1 within Scotland, or even in Glasgow, I think it never  
 2 really got off the ground in the way that the Glasgow  
 3 Centre Directors hoped. But that was certainly a valid  
 4 aspiration, and it was worth trying to do.

5 But what happened in Edinburgh, of course, is the  
 6 Protein Fractionation Centre moved out to  
 7 Liberton Hospital sometime in the mid-1970s and took  
 8 with them the equipment, including the freeze dryer. So  
 9 the Edinburgh Centre was never in the position itself of  
 10 freeze drying plasma or cryoprecipitate in quite the  
 11 same way that Glasgow was hoping to do.

12 Q. I'm going to pick up now on some of the points you  
 13 mentioned earlier in terms of consultation and  
 14 discussion with your clinical colleagues about the use  
 15 of blood and so on, and the audit of the use of blood.

16 We've heard from other witnesses the use of blood  
 17 ordering schedules. Is that a practice that was used in  
 18 Edinburgh?

19 A. Yes, we did. We developed the MbSOs, and I -- that was  
 20 developed in quite -- in quite some strengths.

21 Q. And you have made reference to having various  
 22 relationships with clinical colleagues. Was the audit  
 23 and the training and discussions that you were having  
 24 limited to those colleagues in the Edinburgh Royal  
 25 Infirmary or was that work you did throughout the whole

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1 Similarly for the more remote hospitals in Melrose  
 2 and in Livingston in West Lothian.

3 So consequently -- and also, I think, in the  
 4 Kirkcaldy hospitals, because I think I forgot to say,  
 5 but the others would have said, that the Edinburgh  
 6 Centre also distributed hospital blood to hospitals in  
 7 the south of Fife, across the Forth.

8 So consequently, although we in Edinburgh were  
 9 crossmatching blood for -- mostly for the -- although  
 10 the blood we distributed was -- went to several other  
 11 hospitals, most of it went to the Royal Infirmary but  
 12 the Royal Infirmary also had satellite hospitals, and  
 13 our efforts on blood ordering schedules would have been  
 14 concentrated mostly on the practitioners in the  
 15 Edinburgh Royal Infirmary.

16 That, of course, was facilitated considerably when  
 17 the realignment of hospitals to the new Royal Infirmary  
 18 occurred, somewhat after my time.

19 But yes, it -- we were doing the services, we were  
 20 doing it for surgeons and for some of the physicians as  
 21 well, but it was -- it came to be more expanded as the  
 22 services within Edinburgh also got modified with the new  
 23 hospital buildings.

24 Q. I'm going to come on to ask you some questions about  
 25 your role in terms of procuring PFC concentrate for

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1 area covered by the Edinburgh and South East Scotland  
 2 Centre?

3 A. Well, I understand what you're saying, because the --  
 4 but just to clarify, which I think you've already got,  
 5 the blood bank provided by the Edinburgh Blood  
 6 Transfusion Centre, sited in the main Royal Infirmary,  
 7 also supplied blood to small peripheral hospitals that  
 8 have long since closed, the Elsie Inglis, the  
 9 Bruntsfield Hospital, and others that are scattered  
 10 around Edinburgh that had an interesting history  
 11 providing specific services -- Bruntsfield for women in  
 12 particular, for example. So only about 70 per cent of  
 13 the blood which we distributed to the Edinburgh  
 14 hospitals was distributed to the Royal Infirmary.

15 There was the other major hospital in Edinburgh  
 16 called the Western General Hospital, which was also  
 17 staffed by haematologists -- an excellent haematologist,  
 18 Dr Norman Allan -- who had their own blood bank, so we  
 19 would supply the blood to them but they did the cross  
 20 matching. They did not treat, as far as I'm aware, any  
 21 haemophiliacs at all. That was specifically for us in  
 22 the Royal.

23 But the -- that hospital was a significant user of  
 24 blood and they would have been drawing up their own  
 25 blood ordering schedules.

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1 Dr Ludlam in the Edinburgh Haemophilia Centre, and  
 2 discussions with him about the use and prescribing of  
 3 that. But now I'm going to ask you some questions  
 4 about -- and you've already touched on this in your  
 5 answers earlier -- your role and your input with those  
 6 people with haemophilia being treated at the Haemophilia  
 7 Centre in Edinburgh.

8 We heard evidence from Dr Brian McClelland who  
 9 told us that it was his impression or his view that  
 10 those patients were, to use his phrase, jealously  
 11 guarded by Dr Ludlam, and that you hadn't got -- didn't  
 12 have a chance to have any direct dealings with them. Is  
 13 that correct as a matter of fact, that you didn't have  
 14 face-to-face dealings with the patients being treated in  
 15 the Edinburgh Haemophilia Centre?

16 A. Brian was immensely supportive of me. He was a great  
 17 colleague. And so, consequently, he would have been  
 18 prepared to, sort of, defend me in those sort of -- any  
 19 of those sort of situations. I'm not sure I would use  
 20 the words "jealously guarded". I mean, Christopher did  
 21 allow me to speak to his patients at one meeting of  
 22 a Haemophilia Society gathering there. I was well known  
 23 to the laboratory scientists in his department, and that  
 24 included in the haemophilia laboratories. They knew me.  
 25 We also knew some of the -- were working with some of

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the senior registrars who actually rotated through the blood transfusion centre, so it's not as if there was a brick wall between us.

The departments were next-door neighbours. So it was inevitable that there'd be some informal, quite a lot of informal contact. So yes. There was -- Christopher was very keen to make it clear that he was the one who was now running the Haemophilia Centre. I had no difficulty with that. He had every right to expect that, and also to expect that [audio disruption], and say, "Ooh, I think you've got that bit wrong". So, Christopher and I met within two weeks. We were both new, and I knew that he was wanting to expand his home therapy programme. Was fully supportive of that and always was.

As time went on, within two or three years, the expanding programme caused stresses on the supply, and so I was called in to advise Christopher. I think the words in my letters were "warn", which is a bit unfortunate. I think it would have been better to use the words "inform and advise" but, basically, I needed to clear with Christopher the degree of -- how the Transfusion Service and particularly how PFC could best respond to his requirements.

So it did require a regular set of meetings and we

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between Christopher and the transfusion directors from which -- which I didn't attend. And I understood that.

Brian briefed me as much as he could about those meetings, otherwise I couldn't have done my job, but it was a little bit of a barrier from that side, but it wasn't as if the Transfusion Centre's meetings were jealously guarded. But even less so did I think that "jealously guarding" is really the best way of describing Christopher's attitudes.

So he and I needed to work together, we both recognised that, and, yes, it caused, you know, a little bit of blood pressure raising occasionally in the way that these conversations do, but it was a dialogue. It was not a debate.

And so, consequently, we, on the whole, got on amicably, and I would still say that if I were to meet Christopher again today, and I don't quite know when I last met him, we would be on the best of friends terms. So that's the sort of memory that I've got and that's how I think we behaved at the time.

But it was not always easy, I do have to say.

**Q.** So just picking up, then, on the role that you played between -- with the Haemophilia Centre Directors, and -- with -- sorry, the Haemophilia Centre. We'll look at some of the correspondence but would it be fair to say

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had them and some of them are documented and the correspondence around them are documented in the Inquiry's files.

So we developed a working relationship, which I think worked well for him, and particularly even more importantly, for the haemophiliacs. Some tragically developed inhibitors, others tragically developed hepatitis, others developed AIDS, and that was awful, and I think you've gone through that episode in November 1984 when, to our horror, in the Transfusion Services, and also Christopher's own horror, a batch of PFC Factor VIII concentrate was contaminated with the HIV virus and transmitted it to, I think, at least 16 or even 17 patients, and one or two possibly in Glasgow.

So that was -- and it may -- whether it's one donor or two or three we never quite got round to, but it was probably a very small number of donors over those years, you know, giving hundreds of thousands of donations, who infected that batch. An absolute tragedy. And we never quite got to the bottom of how that transpired, but it was awful. For us, for Christopher, and in particular for the patients.

So that degree of cross-communication was vital.

I was under a bit of disadvantage, which Brian did his best to alleviate, in that there were meetings

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that you were doing two things, really. On the one hand, you were providing Dr Ludlam with the PFC product, the Factor VIII product from PFC that he wanted and sometimes having to borrow and beg it from other areas because he had exceeded what you'd already given him; and, at the same time, telling him -- or you use the word "warning" or whatever the correct word is -- telling him, warning him, reminding him, to prescribe within the Edinburgh -- the South East Scottish Regional Transfusion Centre's allocation of PFC product.

**A.** I think that's correct, yes. And I think the correspondence speaks for itself.

**Q.** So, in a sense, you are almost carrying out a coordinating role between, on the one hand, PFC and, on the other, the Edinburgh Haemophilia Centre, and there's you representing the South East Scotland Regional Transfusion Centre and/or the SNBTS in the middle, coordinating between those two?

**A.** Yes, and the most valuable part of that coordination was the trialling of the various heat-treated products from PFC to see how effective they were, both clinically and with regards to the testing, and apart from the one episode which we may not need to refer to, when there was a misunderstanding, that was carried out with cordiality, cooperation, not least from the patients,

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1 who needed lots of needlings to get the samples, and  
 2 that was, in my opinion, highly successful and very  
 3 satisfactory work, to actually be able to demonstrate  
 4 that these materials were actually working.  
 5 We were not able really to test how safe they were  
 6 hepatitis-wise or HIV-wise, apart from the *in vitro*  
 7 tests on those materials to see how well they were  
 8 inactivating viruses. So part of those trials did not  
 9 really include a detailed study of their liver function;  
 10 it was more directed toward the haemostatic functions  
 11 and that was carried out in some detail with schedules  
 12 that Christopher helped me draw up. So this was  
 13 collaborative work of a very satisfying nature.  
 14 **Q.** We see you being appointed or taking on the role of  
 15 coordinator of some of those research or clinical  
 16 investigations.  
 17 **A.** And not just with Christopher but with outsiders such as  
 18 Dr Mayne in Belfast and, indeed, Dr Bloom in Cardiff.  
 19 **MS SCOTT:** Sir, I'm about to look -- on the same topic but  
 20 look at a couple of documents, and I note the time.  
 21 I don't know whether it's appropriate to continue now  
 22 for -- which will take us probably until 1.05 or  
 23 possibly 1.10, or to take a break now.  
 24 **SIR BRIAN LANGSTAFF:** All right, let's take a break now, and  
 25 come back at 2.00.

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1 That's helpful, thank you.  
 2 **A.** Well, thank you.  
 3 Yes, this table is compiled entirely from the  
 4 records which [audio disruption] that I was sent in  
 5 advance, but I'm sure they are authentic and they are --  
 6 they're a distillate of the separate returns to -- which  
 7 we discussed earlier.  
 8 I think this shows a bit more clearly, perhaps,  
 9 and I took some time preparing this, and although I'm  
 10 fairly -- I am very confident about the numbers -- one  
 11 or two may be slightly exceptional, but they show,  
 12 I think, a very clear indication of [audio disruption]  
 13 developing uses.  
 14 First of all, the number of patients treated is  
 15 different from year to year a bit, so that's the degree  
 16 of variation. I think that by 1979 a couple of the  
 17 adult haemophiliacs had died, I think one of a brain  
 18 haemorrhage and one in a road traffic accident, so  
 19 that's one of the reasons that numbers vary. And of  
 20 course new ones present.  
 21 The amount of cryoprecipitate that was used was  
 22 quite substantial, and it increased from 1976, and  
 23 that 700,000 represents, to my calculation, about  
 24 10,000 packs of cryoprecipitate, which would be  
 25 a significant output from the Liverpool Transfusion

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1 So 2.00.  
 2 **A.** Thank you.  
 3 (12.59 pm)  
 4 (The Luncheon Adjournment)  
 5 (2.00 pm)  
 6 **SIR BRIAN LANGSTAFF:** Yes, Ms Scott?  
 7 **MS SCOTT:** Before I return to my questions in relation to  
 8 Dr Boulton's time at Edinburgh, he has asked me to bring  
 9 up a table that he has put into his witness statement.  
 10 He wants to say something about that.  
 11 It's WITN3456002 and it's page 26.  
 12 So here, Dr Boulton, we've got a table that you've  
 13 put into your witness statement. The beginning of the  
 14 table is on page 26. The table's titled "Liverpool  
 15 Royal Infirmary Haemophilia Centre, numbers of patients  
 16 treated and therapeutic materials used 1976-1979".  
 17 And you've put a note there:  
 18 "... some paediatric patients were treated at  
 19 Alder Hey Children's Hospital."  
 20 And the table starts here and it goes over to  
 21 page 27.  
 22 Could we have page 27, please.  
 23 And it continues there.  
 24 What would you like to say about that?  
 25 Can we try to get both pages up at the same time?

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1 Centre.  
 2 Then when it comes to the next row, the  
 3 NHS Factor VIII use for haemophiliacs, you can see pretty  
 4 clearly the very substantial increase in 1979, which is  
 5 the result of BPL's success in increasing their general  
 6 outputs.  
 7 And I rather assume that there are similar  
 8 patterns from other centres.  
 9 If you go to the next page, you can see that  
 10 in 1976 -- well, it starts off with the number 387,665  
 11 of the amounts of units used of the various commercial  
 12 factors -- you can see that although in 1976 it's a bit  
 13 higgledy-piggledy, it was Immuno Kryoglobulin, which was  
 14 the Austrian product, which was dominating in 1976. But  
 15 that was associated with the outbreak of hepatitis  
 16 I believe in the patient who had a vasectomy under cover  
 17 of Kryoglobulin, and he got the -- he was found to have  
 18 hepatitis, and so we dropped it. So the next year is  
 19 considerably less and I think the residual in 1979,  
 20 that's 750, possibly represents the remaining bottles in  
 21 the bank before they expired.  
 22 You can see that the most important, most  
 23 significant replacer was the Armour product which  
 24 dominated in 1978 and 1979, while at the same time of  
 25 course the NHS product increased, and in that row

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1 towards the end, "Total [Factor] VIII given", you can  
 2 see how it almost doubled in total from 1976 to 1979.  
 3 I think that gives a fairly clear summary of the  
 4 changing patterns of use in the Haemophilia Centre at --  
 5 by the haemophilics in Liverpool and at Alder Hey during  
 6 that period, and I think that might be quite useful,  
 7 I hope, to the Inquiry.  
 8 **Q.** Thank you.  
 9 **SIR BRIAN LANGSTAFF:** Just one question on these documents.  
 10 It's really an arithmetical question, I think.  
 11 Can we just go back, Ms Scott, to the 1979 returns  
 12 which we looked at earlier.  
 13 **MS SCOTT:** Yes. The 1979 return is at HCDO0001344.  
 14 **SIR BRIAN LANGSTAFF:** Yes. You see there the  
 15 cryoprecipitate which is 7,000, roughly. Now  
 16 630,000 units, that I think works out at 90 per bottle.  
 17 If you go back, please, to what we've just been looking  
 18 at.  
 19 **MS SCOTT:** That's WITN3456002. I've already forgotten the  
 20 page number, I beg your pardon.  
 21 **SIR BRIAN LANGSTAFF:** Yes, 3456002.  
 22 **MS SCOTT:** Dr Boulton, can you recall the page number?  
 23 **A.** I can't recall the page number I'm afraid.  
 24 But Sir Brian, you're absolutely right. The maths  
 25 do differ a bit.

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1 variable. And my later experience, I think in  
 2 Edinburgh, indicated that the average per donation was  
 3 about 70. But it could be anywhere between 20 and 120,  
 4 depending upon the volume collected, the way it was  
 5 processed, the temperature it was stored at, and indeed  
 6 blood groups have an impact as well, because people of  
 7 blood group O have distinctly lower Factor VIII levels  
 8 than people of blood group A, 90 per cent compared with  
 9 110 per cent, for example. So there is variability in  
 10 the potency. And I have shown 70 per cent arbitrarily  
 11 across all, so that although in the returns it's a bit  
 12 variable, sometimes 90 and I think others were 80, this  
 13 table has the virtue, if you like, of consistency,  
 14 although it is bedevilled by the variable  
 15 characteristics of cryoprecipitate.  
 16 So, yes, there will be an impact on the  
 17 interpretation of the absolute values as recorded here,  
 18 by that particular variable.  
 19 So, once again, it shows one of those problems  
 20 with cryoprecipitate that made it a little bit more  
 21 difficult to use. The patients -- or at least I never  
 22 knew exactly how much Factor VIII the patients were  
 23 getting, so we had to do a certain amount of guesswork.  
 24 And that's, again, one of the reasons why  
 25 cryoprecipitate was often pooled, even in maybe only

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1 **SIR BRIAN LANGSTAFF:** The reason I mention that --  
 2 **A.** -- (overspeaking) --  
 3 **SIR BRIAN LANGSTAFF:** Sorry, the reason I'm mentioning  
 4 that is on your table you say that you're assuming that  
 5 it's 70 per bottle.  
 6 **A.** Yes.  
 7 **SIR BRIAN LANGSTAFF:** And obviously that doesn't work out,  
 8 does it? There's a slight inaccuracy there.  
 9 **A.** You're absolutely right.  
 10 **SIR BRIAN LANGSTAFF:** I wouldn't have --  
 11 **A.** It --  
 12 **SIR BRIAN LANGSTAFF:** -- drawn your attention to it if it  
 13 hadn't perhaps been that as a result it looks as though  
 14 there's been more cryoprecipitate than any other single  
 15 product in that year, whereas actually, on your figures,  
 16 it looks as though there's actually been more of the --  
 17 what is it? Let me just find where I am.  
 18 **A.** The Armour?  
 19 **SIR BRIAN LANGSTAFF:** Yes, I think that's the Armour.  
 20 That's it. Thank you.  
 21 **A.** Sir Brian, you're absolutely right. I have made one or  
 22 two assumptions here, but it does illustrate the rather  
 23 irregular characteristic of cryoprecipitate. Whereas  
 24 all the concentrates were meticulously and accurately  
 25 determined, their potency, cryoprecipitate is highly

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1 three, because three would be just a little bit nearer  
 2 the average -- you know, a third of the total value of  
 3 three would be a little bit nearer the average of,  
 4 I chose 70, compared with others. And later  
 5 cryoprecipitates, when more plasma was taken from each  
 6 donation, would have been a bit more powerful, because  
 7 more plasma was taken from each donation for making into  
 8 cryoprecipitate.  
 9 So I'm sorry, this is a fairly long-winded answer,  
 10 but the cryoprecipitate is useful for a comparison, but  
 11 not too much reliance should be placed on it for the  
 12 actual units that were given. Of course, they were not  
 13 directly assessed, whereas for all the others, the  
 14 concentrates, commercial and NHS, they were [audio  
 15 disruption]. Thank you.  
 16 **SIR BRIAN LANGSTAFF:** We have, I think, elsewhere seen, in  
 17 respect of some of the commercial products, that what it  
 18 said on the bottle was not necessarily what you got if  
 19 it was assayed in the lab. Am I right about that too?  
 20 **A.** You could be but the lab's assays were just as  
 21 vulnerable to variation, not error, but the -- what  
 22 you're assuming is that the lab's performances are  
 23 within, say, 95 per cent of what it says. There are  
 24 different ways of assaying, there's one stage and two  
 25 stage. There are different conditions under which those

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assays are conducted. I had the advantage over some of the witnesses of actually performing assays of Factor VIII and IX in plasmas during my training, I learned how to do it. And it's an intriguing technique.

And furthermore, there are other techniques that involve what's called chromogenic, colour generation from precursors. These all tend to give slightly different absolute value, so it's one of those important features of laboratory medicine to realise that there is a variability on the values of the factors. And people themselves vary. So it would be fair to say that you couldn't totally rely on the number on the label of the bottle.

But I really doubt that the commercial manufacturers exaggerated the amount in there. Quite apart from anything else, they were subject to inspections. The Americans, the FDA was quite a fierce body, the federal drugs authority. So I think that they would have been very wary about massaging the numbers on the bottle.

But -- no, they might have done, but I rather doubt it. But there are other reasons. They would come back, if they were challenged, with all those points I have just made.

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it's PRSE0003044. When it comes up on the screen we'll see it's a letter you wrote to Dr Ludlam, dated 10 May 1982. You start in the first paragraph by saying:

"Please find enclosed our Table of Haemophilia Home Therapy Patients and the amount of Factor VIII that they were ..."

**A.** "... that they were issued [with] for home therapy ..."

**Q.** Thank you, I couldn't read that:

"... in the first quarter of this year."

Then you go down into the second paragraph and you say:

"My concern is the amount of Factor VIII that has been issued."

Then you set out some detail about this, in terms of what's been issued and what's been -- what's been issued by Dr Ludlam, and you say at the end:

"This means that for each of the 20 patients, the average annual consumption would be 41.360 [sic] units -- or 34,467 units if you include all 24."

24 patients, I presume.

**A.** Yes.

**Q.** "These figures are obviously pretty close to the UK national average."

Then you say:

So biology is not physics. Physics you can do an exact measurement and, of course, it's very mathematical. Biology is real life, with all its variety and diversity. So that's where I leave it, Sir Brian.

**SIR BRIAN LANGSTAFF:** So the bottom line is these tables give you a spurious sense of absolute accuracy. The truth is they're a pretty good indication. Is that a fair summary?

**A.** Yes.

**SIR BRIAN LANGSTAFF:** Thank you.

**A.** Pinch of salt is very reasonable in that but I do think they give a reasonable representation of the varying patterns of usage, and the almost doubling amounts of Factor VIII given between '76 and '79. I think that is a reasonable assumption. It may not have been exactly 860,000 to 1,550,000, but it would be somewhere between, you know, 800 and 1,500, or 700 and 1,600, or whatever. So I think you can take it that that's a reasonable assumption, reasonable indicator, but not an absolute. Thank you.

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

**MS SCOTT:** Dr Boulton, I'm going to pick up now where we left off before lunch. I'm going to turn first to a document, a letter that you wrote to Dr Ludlam, and

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"However, the amount of Factor VIII that we were officially issued in the first quarter of this year was only 261,530 units, although we did get some ... from Inverness [for a particular patient]."

"Hence, you will see that your home therapy programme alone has accounted for about 80% of our allocation from PFC."

"As you know, this allocation is actually based on the amount of plasma we supply to PFC."

Then you set out what that runs to, and what that will produce in terms of PFC stocks.

So just pausing there before we go over the page, is it right to understand this letter to be saying to Dr Ludlam: look, there's a problem, we've been allocated this X amount, you've used 80 per cent of X amount. You seem to be specifically saying, "Your prescribing figures are actually pretty close to the UK national average", so you don't seem to be making a point there about how much Factor VIII Dr Ludlam is prescribing to his patients, but there's a problem because of what we've been allocated from PFC; is that a fair summary of this part of the letter?

**A.** I think it is. The numbers at the top are subject to the same caveat as we've just been talking about but, again, I think they're reliable enough to indicate the

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1 trend. And there was indeed what the English call the  
2 *pro rata* system, that the regions got back the amount of  
3 Factor VIII that would have been extracted from the  
4 kilograms of plasma that they were -- the PFC was sent  
5 from the centres and, in this case, we were clearly  
6 dependent upon an extra burst from Inverness.

7 So, in terms of its comparison with the national  
8 average, I'm at a disadvantage here in not having a copy  
9 either of the list of patients or indeed what the  
10 current practice was in the rest of the UK. But your  
11 surmise of the message I was giving is accurate.

12 Q. So can we then turn over, please, to page 2. You say  
13 this.

14 A. Next page.

15 Q. Ah, page 3, it's my fault.

16 "I think that the SNBTS as a whole can just about  
17 hold your requirements as long as the following points  
18 are borne in mind:

19 "1) Maximum use is made of the Cryoprecipitate  
20 Programme ..."

21 Pausing there, what was the cryoprecipitate  
22 programme?

23 A. Thank you for putting me on the spot there. That's  
24 basically the -- I don't know whether it was agreed --  
25 negotiated beforehand, but the understanding of the

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1 lower haemophilic loads, particularly if we are treating  
2 'their' patients;  
3 "Some of the heaviest users are counselled to use  
4 less."

5 You then go on at the paragraph below, if we can  
6 just miss out that next paragraph, and say:

7 "I feel therefore that you should be warned that  
8 we are now very definitely at the limits of our  
9 production for home therapy and therefore you may  
10 consider the necessity for buying some commercial  
11 product."

12 Then you set out future plans for increasing  
13 plasma procurement.

14 So what you're doing here is you're effectively  
15 setting out to Dr Ludlam a plan, a way in which you can  
16 just about cope with the home therapy programme and the  
17 amount of Factor VIII that he is prescribing by taking,  
18 as you've just described to us, these steps, some of  
19 which are pretty serious, and making it very clear to  
20 him that the alternative is purchasing commercial,  
21 because there's no more PFC; is that right?

22 A. I think that's correct. It was a real dilemma, and so  
23 putting Christopher on the spot was -- I felt I had to  
24 do, but tried to do it in the most constructive way.  
25 And, possibly, although this would be, again, a bit of

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1 amount of cryoprecipitate that would be made available  
2 for the haemophilics -- haemophiliacs in Edinburgh. So  
3 I can't remember the precise details of that programme,  
4 but it clearly was -- I assume it was a programme that  
5 was guiding the amount of Factor VIII that would be  
6 available in the form of cryoprecipitate for their  
7 patients.

8 Q. Then:

9 "No more patients are put on home therapy;

10 "No patients are put on the cold operating

11 lists ..."

12 If you just explain to us what the cold operating  
13 lists are?

14 A. Elective surgery. So that if, for example a patient had  
15 a disordered joint, an elbow joint, or knee joint, or  
16 hip joint that would justify surgery, it would be -- the  
17 suggestion was that they might have to wait a bit. Now,  
18 that's a very significant thing to say, because I think  
19 in general we're all aware, particularly these days, of  
20 the impact of waiting lists. So, in many ways, this was  
21 a bit of cheek from me to ask Christopher to do all this  
22 but, nevertheless, there was a problem and we had to  
23 look at ways of alleviating it.

24 Q. Then you go on:

25 "We try to borrow from other Regions who may have

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1 a cheek on my part, my experience as a director in  
2 Liverpool may have given me a little bit of authenticity  
3 in making these suggestions, but I am not in any way  
4 belittling the significance of those suggestions. They  
5 are quite profound and so, consequently, not to be taken  
6 lightly.

7 So I had a lot of sympathy for what Christopher  
8 was faced with, and I would have loved to have been able  
9 to give him more PFC Factor VIII but there were -- there  
10 was a limit to what they could produce and so there  
11 was -- we were in that very unfortunate dilemma of  
12 limiting the service to patients, which was a thing we  
13 hate doing, we hated it even more in those days than  
14 perhaps now is sometimes the case. But, nevertheless,  
15 it was important that we tried to work through those  
16 particular problems if we could.

17 Q. Can you recall what the response from Professor Ludlam  
18 was to those -- your suggested plan?

19 A. I can't remember, to be honest. I wouldn't be at all  
20 surprised if, on opening the letter, he uttered a sigh  
21 of exasperation. But we did have further meetings, you  
22 know, down the line and we were able to continue a level  
23 of supply. I think he may have acquired some commercial  
24 Factor VIII and tried to put them aside for specific  
25 patients, rather different from the higgledy-piggledy

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fashion which I was practising in Liverpool in 1976 for example, because he was very conscious of the need to rationalise the use of these products.

And I nearly used the unsayable word in healthcare, which is "ration". That's, in a sense, what we were having to do, but it's not a concept that either the public or the healthcare professionals like to consider. So that was -- it was a difficult time. I can't remember his exact response but I'm sure he was going to do his best, what he thought was best for his patients.

**Q.** Can we then look at a later letter from February '83, PRSE0003653. This is a letter we looked at with Dr McClelland and when it comes up you will see it's not a letter from or to you, but it's a letter cc'd to you. It is, in fact, a letter, as we can see, from Dr McClelland to Dr Cash dated 2 February 1983.

In the second paragraph he is updating Professor Cash, or Dr Cash as he then was, about the discussions that you had had with Dr Professor Ludlam about the PFC -- the supply problem. And then it's in the third paragraph that I want to draw your attention to and ask you a question:

"My conclusion is that while I'm more than happy to meet with you and Chris (and Frank) to attempt to

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among the Scottish haemophilia directors. Of course I don't think I would have been involved in it.

I think Brian felt that I was the appropriate person to deal with Chris, because the beginning of this letter indicates that if I couldn't sort it out, John Cash was thinking that perhaps Brian could sort it out. But Brian was basically saying he didn't think he could sort it out because this needed a more -- a wider approach, and if anybody in the Edinburgh BTS had some understanding of the actual practical problems, it would be me rather than Chris, because of my previous experience.

So I think your analysis is correct that we were really approaching the brink of supply now, ahead of a period of trying to work out how to inactivate the viruses in the products, in the Scottish products, and so consequently there was a real concern that we might run out and there may have to be major recourse to commercial materials. Which in Scotland was anathema. Particularly for John Cash, because he was committed, as was Brian, and indeed myself, to the so-called self-sufficiency, whereby we didn't have to buy anything from other sources but obtain it within our own system.

So I think a peer review is a very nice idea from the outside. Practical difficulties from within, but --

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resolve the problems, this really isn't the whole answer to the difficulties. I would suggest that there is a need for a peer review by the Haemophilia Directors producing some clear guidance as to a reasonable level of consumption for the SE haemophiliac population."

So is it right to understand, this letter, that matters had moved on somewhat from the letter we just looked at, where you weren't expressing a concern about the levels at which Dr Ludlam was using Factor VIII for his patients, because you had noted that it was along the national average, but by the time it comes to February 1983, having set out the plan that -- the workable plan, you're saying something rather different. You're saying, "Actually, there may be a problem now with whether or not there is a reasonable level of consumption for the South East haemophiliac population"?

**A.** Yes, I do actually remember this letter, and seeing it again a few weeks ago reminded me.

This was a difficult period, in more ways than one. And the idea of a peer review by the haemophilia directors is one which I'm sure Christopher would in principle welcome, so long as it was shared among all the haemophilia directors and was not targeted at particular ones.

I honestly don't know if there was a peer review

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but I'm pretty sure that Christopher would have welcomed the concept of sharing experiences among the Haemophilia Directors and trying to get some consistency across the level of demand.

But again, this is biology, it's not mathematics, and variables occur all the time. Nevertheless, this is on a background of increasing demand to supply factor to a population group who were very much in need of the best that could be made available.

So I have sympathy on all sides. But whether that peer review was conducted and how effective it was, I cannot really remember.

**Q.** Did you have discussions with haemophilia clinicians in the South East of Scotland and hear their views about PFC products, Factor VIII products, Factor IX products?

**A.** Not with the haemophilia directors as a community. It would have been mostly with Christopher. I did know the Directors in -- of the adult haemophiliacs in Glasgow, and indeed the paediatricians as well, but I don't think we had detailed discussions about the significance of the supply -- you know, significance in terms of not just numbers but the concept of plasma coming from products being made and supplied from the PFC.

So my main contact with the Scottish haemophilic community in that sense would have been with

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1 Christopher. But I mean he was a very informed person,  
2 so his opinion was pretty sort of -- I think he was  
3 a bit of a leader among the haemophilia doctor community  
4 actually in the UK, quite apart from Scotland. So his  
5 feelings were very important to understand.

6 Q. But did you gain an impression either from him or from,  
7 as you say, any of the other clinicians that you were in  
8 contact with about what their view was of the SNBTS  
9 intermediate product that was available between  
10 '83 and '84?

11 A. Well, their opinion and our opinion would have been very  
12 much influenced and shaken by the discovery of  
13 a contaminated batch or a batch or two in November 1984,  
14 because until then there had been a hope -- I don't  
15 think it was complacent hope, but a hope -- that blood  
16 donated in Scotland from a carefully selected group of  
17 donors would not be contaminated with the AIDS virus.  
18 The fact that that was -- unfortunately proved to be  
19 misguided by this contamination was indeed a shattering  
20 blow, as I said earlier, and may well have had an  
21 impact. But until then, I think there was a real hope  
22 that Scotland would be more or less HIV --  
23 Scottish-derived blood products, not just Factor VIII  
24 but the donations, would be pretty well free of the  
25 HIV virus.

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1 the contamination was not due to an infected organism  
2 but was due, as I think I said in one of the other  
3 meetings, due to a concatenation of inflammatory  
4 experiences and lifetime experiences that put a strain  
5 on the immune profile of the people who were most likely  
6 to get AIDS as a result of their lifestyle.

7 It is too glib to say, but someone did say to me  
8 once, that what we are transfusing -- "We're not  
9 transfusing lifestyle, we're transfusing particles".  
10 That's too glib a response, but it gives a flavour of  
11 the difference of hopes and attitudes at that crucial  
12 time in May.

13 But we in Edinburgh were working our socks off in  
14 trying to produce a way of excluding donors who might be  
15 at risk from donating, even if it was at the cost of  
16 less blood being donated.

17 So we were working hard at that angle, and -- so  
18 to come across a requirement that implied some sort of  
19 attitude to the PFC products, that's where we came from.

20 The experience in November would undoubtedly have  
21 changed the attitudes of the haemophilia community in  
22 Scotland about the safety and reliably (sic) of the  
23 product. The other thing of course going on at the same  
24 time was the virus inactivation programme, which took  
25 two or three years to mature.

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1 This is an interesting period, because that  
2 donation was probably collected in 1983, which was the  
3 year, the crunch year, in many ways, for the country,  
4 and particularly in Scotland, because Brian in  
5 particular, Brian McClelland, and his -- our colleague  
6 Anne Smith, were working very hard on preparing the  
7 leaflets for donors to understand the significance of  
8 the impending HIV/AIDS epidemic, as it became, and would  
9 therefore refrain from donating. And this was  
10 because we felt -- and I shared this with Brian and with  
11 Anne -- that the most likely explanation for the rise of  
12 HIV that was beginning to appear among the haemophiliacs  
13 in America and then beginning over here, could only  
14 really be explained by infectious organism.

15 I do know that Christopher also accepted that as  
16 a probability, but [audio disruption] was, along with  
17 others in the English centres -- and I -- as you know,  
18 I had correspondence with others, including  
19 Professor Bloom and Peter Jones, in which, in the  
20 middle, in May 1983, they were still of the opinion that  
21 the chances of HIV actually being an infectious disorder  
22 and indeed, if it was, of it arriving in Britain, was  
23 sufficiently dubious for them not to abandon the use of  
24 American product.

25 In other words, they were hoping against hope that

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1 So we were working very hard in the donation  
2 community to deal with that particular threat, but that  
3 window period of 1981 to -- well, actually, late 70s  
4 through to the mid-80s, was the crucial one, and it's  
5 during that period in particular that patients may well  
6 have been at most risk of acquiring HIV through blood  
7 products, which did cast a significant question over the  
8 reliability of the Scottish products. Which was  
9 a shame, shattering, but nevertheless understandable and  
10 inevitable.

11 Q. So that response you've just given me brings me on to my  
12 next topic of questions, which is AIDS.

13 As I understand your witness statement, you were  
14 aware of the July 1982 MMWR report reporting on the  
15 infection of three people with haemophilia with AIDS.  
16 And you say in your statement that that was, to you, the  
17 first clear-cut evidence that haemophiliacs were  
18 affected by AIDS.

19 Is that when you, July 1982, put your  
20 understanding that there was -- the most likely  
21 explanation for AIDS was a transmissible agent carried  
22 by blood?

23 A. I have to say, on reflection, that I'm not too confident  
24 about the July date. I am confident that later, at the  
25 end of 1982, we were pretty -- we felt it very likely

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1 that it was a transmissible agent. I -- on reflecting  
2 my Penrose Inquiry statement, I see that I was pretty  
3 firm about that July date. I'd been thinking more about  
4 that and, quite apart from anything else, it took  
5 a little time for the MMWR reports to reach us. You  
6 know, a few weeks. And it may well have been a little  
7 later in that year.

8 I think it's fairly likely that we were aware  
9 enough of this particular risk, before the Edinburgh  
10 Festival of 1982, which of course was a very significant  
11 event in Edinburgh -- in Edinburgh life, but I don't  
12 think I could totally I say with certainty how much that  
13 impacted us for 1982.

14 We wouldn't know what to do, really, at that  
15 stage. By 1983 it was much more evident and so we  
16 worked very hard at that particular time. But I am  
17 confident by December 1982 we were of the opinion, in  
18 the Edinburgh and South East Transfusion Centre medical  
19 community that the most likely explanation of the  
20 increasing number of haemophilics -- in early 1983 there  
21 were some in Britain as well -- would have been due to  
22 an infectious particle with an epidemiology resembling  
23 that of hepatitis B, although probably a very different  
24 kind of particle. Different kind of virus, different  
25 kind of organism. May not even have been a virus but it

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1 took you by -- I think took you by surprise. Does that  
2 help you date your knowledge of AIDS being caused by  
3 a transmissible agent?

4 **A.** Yes, that did. And, in fact, I probably understated in  
5 that report. I think you've been reading between the  
6 lines successfully. I think I understated in that  
7 report my attitude to the way the English directors were  
8 reacting to this particular oncoming challenge. That's  
9 why I said I wasn't quite sure, I couldn't be quite  
10 confident of the June date, I'm not quite sure how soon  
11 after that June date I actually saw that report but,  
12 certainly by the end of that year, there was enough  
13 around in my head, and probably discussed with Brian as  
14 well, because Brian would have been very, very aware of  
15 the implications there.

16 So I think there was a sort of split between the  
17 transfusion doctor community and the  
18 haemophilia-treating doctor community about the  
19 significance of this oncoming set of findings, and we  
20 were seeing dark clouds over the horizon, where perhaps  
21 they were trying to look for some sort of relief beyond  
22 that particular challenge. So there was an important  
23 difference of emphasis among the carers.

24 But that's why, in particular in Scotland, the  
25 transfusion community was working very hard to find

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1 would have been a specific organism.

2 **Q.** In your -- forgive me while I just try to find a file.  
3 In your witness statement you refer to a -- wait  
4 a minute, that's not the right -- let me just find the  
5 right reference.

6 **A.** I think I know what you're referring to.

7 **Q.** The meeting -- ah, sorry, found it. Okay, I've got too  
8 many files here. Here we go.

9 Right. In your witness statement you refer to  
10 a meeting that took place in September 1982 of UK  
11 Haemophilia Centre Directors in Manchester that you  
12 attended. I don't think we need to go to it but, for  
13 the transcript, the reference is CBLA0001619. Your  
14 witness statement tells us that, in the discussion about  
15 AIDS, and in the minute there is a discussion about the  
16 MMWR report about the three haemophiliacs who were  
17 diagnosed with AIDS, and you comment on the fact that  
18 the minutes say, "It appeared that there was a remote  
19 possibility that commercial blood products had been  
20 involved", and then Dr Craske asked the directors to let  
21 him know if they have any cases of the AIDS syndrome.

22 In your witness statement, you make it clear that,  
23 at that meeting, you were surprised, troubled, noticed,  
24 that this was being underplayed by, as you saw it then,  
25 the English Haemophilia Centre Directors, in a way that

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1 an appropriate set of wording for the leaflets, and  
2 Brian and Anne were really working hard to get the  
3 communications right, talking to the Scottish -- it  
4 wasn't, I think, the Terrence Higgins Trust, it was the  
5 Scottish Homosexual Rights Group that they were talking  
6 to and to the GP Roy Robertson, and those sort of  
7 people, in order to get to the community to discourage  
8 them from donating.

9 And that's why it was so shattering to find in  
10 November 1984 that, probably during that period, one or  
11 two donors were infected with HIV and the result was 16  
12 haemophilics getting it, and suffering as a result.

13 **Q.** Can we turn to a document, a memo that you wrote to  
14 Dr McClelland in May 1983, PRSE0003709, and when it  
15 comes up on the screen we'll see that it's dated  
16 30 May 1983.

17 **A.** Yes.

18 **Q.** It says:

19 "Dear Brian

20 "Just to let you know I telephoned Peter Jones on  
21 Tuesday 24 May, on the subject of AIDS. I was basically  
22 following what he was claimed to have said on the  
23 Nationwide Programme the previous week about  
24 non-rejection of gay donors.

25 "He told me that what he actually said was that

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1 there should be no discrimination against anyone who  
 2 wished to donate blood and in particular there should be  
 3 no questions into their sex lives. However, literature  
 4 should be provided, to include definition of high risk  
 5 categories etc."

6 Then if we jump down to the penultimate paragraph:  
 7 "He also claimed that there is a lot of doubt  
 8 about the diagnosis of all the AIDS cases in the UK" --

9 **SIR BRIAN LANGSTAFF:** We haven't got the right bit up on the  
 10 screen.

11 **MS SCOTT:** Thank you.

12 "He also claimed that there is a lot of doubt  
 13 about the diagnosis of all the AIDS cases in the UK, and  
 14 in particular the haemophiliacs. I felt he was ...  
 15 being somewhat less than cautious in his attitude, but  
 16 this is not unexpected given his interests etc."

17 So is this an example of what you were describing,  
 18 a reticence on the part -- or reluctance on the part of  
 19 haemophilia clinicians to accept what you saw as clear,  
 20 even as late as May 1983?

21 **A.** Yes, that is the case. I think -- Peter Jones, I knew  
 22 very well. I'd met him, I think, during my time at  
 23 Liverpool and he was a leading author on the care of --  
 24 *Living with Haemophilia* was his book, which came out in  
 25 several editions, and he was a very informed and

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1 The second part, which you've still got up, about  
 2 diagnosis, this is precisely what I was saying. There  
 3 was what we thought, even then, a sense of wishful  
 4 thinking among the haemophilia-treating community that  
 5 this awful condition was not due to an infection but  
 6 might go away because it was not very common yet at all  
 7 in the UK.

8 So that's basically the thinking that we had. So  
 9 we were not convinced by Peter's argument that this  
 10 might not be an infectious disease after all.

11 **Q.** The degree of wishful thinking that you've described, is  
 12 it right to understand, from what you said earlier, that  
 13 this was exhibited not only by the haemophilia  
 14 clinicians in England but also in Scotland? I think you  
 15 included Dr Ludlam in that camp, if I can put it that  
 16 way.

17 **A.** Yes. Yes, I think that would be fair. I'm sure that,  
 18 intellectually, Christopher accepted the probability of  
 19 infection but, emotionally, the implications of that  
 20 were so vast, in terms of potential withdrawal of  
 21 treatment for patients, that, in a sense, it was almost  
 22 unthinkable. So he, poor chap, was faced with that  
 23 particular dilemma. For us, it was a little bit easier,  
 24 in that, although there were other patients than  
 25 haemophiliacs who would suffer as a result of

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1 concerned clinician, concerned for the welfare of his  
 2 patients.

3 So I sort of heard secondhand about what he was  
 4 alleged to have said on that Nationwide programme and  
 5 I wanted to check with him what he actually said, and he  
 6 gave his answer, which, I have to say, I don't find  
 7 totally satisfactory, partly because I felt he was  
 8 trying to tell us how to do our job in donor selection,  
 9 when we were working so hard on it already, partly  
 10 because there was no guarantee that any donor turning up  
 11 at a session would read a document like that and, in  
 12 fact, later on we tried to initiate a system whereby  
 13 donors would sign that they'd read up. All very  
 14 difficult, contentious stuff.

15 So we were definitely doing rather more than he,  
 16 I think, was assuming. So, as I say, he was sort of, in  
 17 a sense, trying to tell us how to do our job.

18 I mean, he had a good point because donor sessions  
 19 were difficult and confidential conversations with  
 20 a haemophilic about their sex lives would have been very  
 21 difficult but, nevertheless, a leaflet, we felt, was not  
 22 sufficient, and we needed to do rather more than just  
 23 the techniques which he was saying it was important to  
 24 try to get this -- a more thorough aspect, and coyness  
 25 about sex lives is not necessarily the best way ahead.

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1 contamination of blood -- and we certainly know that  
 2 from later experience -- but -- nevertheless, this is  
 3 the value of a sort of dialogue situation which both  
 4 sides can discuss their viewpoints in and come to the  
 5 understanding of the other viewpoint.

6 I think in May we were not there yet and so,  
 7 consequently, it wasn't until even more data became  
 8 available from the MMW reports, and also occasions like  
 9 Dr Galbraith's descriptions of a patient in Cardiff,  
 10 which I think became more and more convincing, that this  
 11 was not a condition that could be passed on by  
 12 a concatenation of environmental circumstances or  
 13 lifestyle, but actually, did represent the outcome of  
 14 an infectious organism contaminating the blood donation  
 15 and persisting in the end product even though it had  
 16 been diluted more than 1,000 fold.

17 **Q.** I'm going to ask you about a different document now.  
 18 Can we have up, please, PRSE0003845.  
 19 It's a document, when it comes up, that's dated  
 20 27 June 1986. It's a letter from you to Dr Perry, and  
 21 you say:  
 22 "May I pass onto you a couple of verbal comments  
 23 about blood products from Christopher Ludlam."  
 24 It's the second paragraph I want to take you to:  
 25 "A young haemophiliac who previously had minimal

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therapy with factor VIII received an infusion of the current heat-treated product a month ago. He now shows signs of liver enzyme rises indicating non-A non-B hepatitis. Christopher is a bit ruthless with his own staff about this because he feels that his patient should have received VIII Y or an equivalent product. However, the patient is apparently quite well clinically."

Did you discuss this case with Dr Ludlam? This incident?

A. I think the letter indicates that that indeed was the case. This is the value of -- I think this was at a formal meeting, which was, nevertheless, not really minuted but these were verbal descriptions, reports to me, by Christopher of his experience. So the first one is a good experience, Factor IX that was heat treated, seemed not to transmit infections, but the last paragraph refers to the product which would be known as VIII Y, which was a product that had received enough treatment to inactivate home hopefully the HIV virus, HTLV-III virus, but there was some doubt about whether it was able to inactivate the non-A, non-B hepatitis viruses, and this was informative, in that this patient's experience indicated that that process that Dr Perry was -- the unit in the PFC was exercising on

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somehow, that were implicated, which is probably a bit unfair because I think it was a shared responsibility between the Transfusion Centre staff and the haematology/haemophilia staff in the laboratory there.

But, nevertheless, Christopher regretted this particular episode, and possibly felt that the staff were responsible.

Now, Christopher would have to answer that for himself. This may be a misinterpretation on my part, but that's the impression I think I got from that particular meeting. Apportioning blame is always a bit easy when you think about a situation like this, and it would be a more complicated episode than perhaps immediately meets the eye.

Q. I'm going to ask you some questions now about some correspondence on 7 July 1986. Yes, that's correct. The first document -- I'm going to go to both of them and then ask you the questions.

The first document is PRSE0003814, which is a letter from Dr Perry to you, dated 7 July 1986, "Factor VIII Trials". It refers to a note of 4 July which we don't have and makes a couple of comments, and says:

"The PFC phase IV product (very high purity, non-infective as assessed by model virus studies etc) is

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this particular batch of Factor VIII -- VIII Y, was indeed not sufficiently treated to inactivate the non-A, non-B viruses, although it probably was able to inactivate the HTLV-III viruses.

So -- but also note the little point about the patient being apparently quite well clinically. This would be characteristic of the usual sort of course of non-A, non-B patients.

So this was a very informative exercise, and this illustrates the value of the meetings that Christopher and I were holding. And this is three years after the previous correspondence that we had and nearly two years after the dreadful experience of November 1984. So this is a useful bit of information to pass on to Bob.

Q. The use of the term "ruthful" in the letter, does that suggest that Dr Ludlam had thought there'd been some mismanagement of the situation by his staff?

A. I have to say I don't quite know what "ruthful" means. It's obviously the opposite of "ruthless", but basically he was a bit cross with his own staff about this, because he felt that they should have selected this 8Y, rather than, I think, the previous product was NY. I think it was NY that they gave him and, somehow, the selection of products system had gone wrong, and he didn't blame me for that, but it was his own staff,

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planned for production in January '87", and hope that there will be supply by September '87, and saying that after they've:

"... used up the stocks of Phase III product. This product is more than equivalent to 8Y [the BPL product 8Y], it's much better!"

Then:

"While there will be no PFC product virucidally comparable to 8Y until September '86, after that time it would be my intention to supply the Phase III product to 'virgins' since we hope to demonstrate by that time that it is virucidally equivalent thus removing the need to go South. However, in the immediate future (July-September '86), we could probably get supplies of 8Y for special cases. It would of course be preferable if these were obtained and supplied through PFC."

The other letter I wanted to take you to is PRSE0004097, which is a letter of the same date -- I think you suggest in your witness statement that these would have crossed -- and it's a letter from you to Dr Perry. And it starts off saying:

"Sorry to be pestering you again."

It says:

"Last week, Dr Ludlam wrote to Brian asking if it would be possible to obtain some of the BPL products for

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1 use if a previously untreated haemophilic presented for  
 2 replacement therapy".  
 3 Then you say in the third -- miss out the next  
 4 paragraph, and then you say:  
 5 "Before I write back to Christopher, would it be  
 6 possible for you to obtain perhaps 10,000 -- ie 50 vials  
 7 which would at least enable us to cover the initial  
 8 injection for such a case ..."  
 9 We can see from subsequent correspondence that  
 10 indeed you did manage to get some 8Y from England, and  
 11 it was provided on the basis that it was still in  
 12 clinical trial, and so information had to be provided to  
 13 BPL. Is that right?  
 14 You're nodding.  
 15 A. Yes, that's so. I think that's so. The previous  
 16 letter, the top paragraph, the high purity product  
 17 was -- that was -- later became known as Z8. And  
 18 actually, I think there was some delay in the  
 19 production. I think they ran into some technical  
 20 problems when upscaling the production for this Z8  
 21 product when it came to the freeze drying process,  
 22 which, as I alluded to earlier, is a delicate procedure  
 23 and, when upscaled, it probably needed a further  
 24 tweaking to ensure that the freeze drying was completely  
 25 freeze dried, because it had to be completely freeze

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1 new patients; in the case of need, was available from us  
 2 in the Blood Transfusion Service.  
 3 So in summary, that's correct.  
 4 Q. And did you understand that Dr Ludlam's request for this  
 5 safe 8Y product was triggered by the episode we  
 6 looked at in the correspondence from June, the minimally  
 7 treated patient who had been infected with non-A, non-B?  
 8 A. I think so. That sounds likely.  
 9 Q. Would there have been any impediment to you making  
 10 a request of BPL for a supply of 8Y earlier than you  
 11 did?  
 12 A. Well, we know that BPL were also facing up to the same  
 13 problem of quantity and supply. And we were loath to  
 14 put them under extra pressure. In fact, the -- I think  
 15 one would have understood that BPL may have thought:  
 16 well, the Scottish haemophiles are getting quite a good  
 17 service already, why would we have to give them some of  
 18 our stocks to -- which might prejudice our own ability?  
 19 Now I'm sort of over-stating the case because the  
 20 relationship between the Scottish PFC and the  
 21 English BPL was one I think I'd described as cordial  
 22 rivalry, in which they shared ideas about production,  
 23 and there was sort of a lot of cross-talk between them  
 24 and indeed mutual benefit. But the way these things go,  
 25 at various stages, one centre would be ahead of another

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1 dried in order to dissolve on reconstitution easily.  
 2 So it took a little longer to come out than they  
 3 had initially hoped. But in the meantime it was known  
 4 that BPL had this product, 8Y, whereas the product  
 5 I think that was usually distributed from PFC was NY.  
 6 Now, I get confused by these various acronyms, but  
 7 I think the NY was the one that inactivated HTLV-III,  
 8 but may not have inactivated the hepatitis viruses,  
 9 whereas the 8Y and Z8 inactivated both.  
 10 Z8, there was great hope for, because that was  
 11 very pure, and that purity would also be a factor  
 12 enabling its constitution in small volumes, very  
 13 powerful and good to administer. So that was  
 14 the ambition.  
 15 So in the meantime there was a gap, and  
 16 Christopher needed reassurance that he could get hold of  
 17 NHS produced [audio disruption] that would be -- that  
 18 would be effectively virus-inactivated. So we managed  
 19 to procure 50 for him. Actually, I sort of beat him  
 20 down. I think I beat him down from 500 to 50, which  
 21 would have been quite difficult for him, but the 500  
 22 would have been quite difficult for us to have taken  
 23 from BPL.  
 24 But nevertheless, we did come to an amicable  
 25 arrangement whereby some was available for Christopher's

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1 centre in terms of the quality of the products it was  
 2 making.  
 3 It's not possible to just transfer one technology  
 4 from one place to another in toto, because there would  
 5 be different scales, different degrees of equipment  
 6 design and that sort of thing, but nevertheless, there  
 7 was a cordial relationship. And, okay, there was a bit  
 8 of a barrier. We would be reluctant, because, quite  
 9 apart from anything else, it would indicate that the  
 10 Scottish system was failing, possibly. But we did  
 11 recognise that there was a value in this product  
 12 from BPL, and it would be better to offer that to the  
 13 Edinburgh haemophiles than, for example, commercial  
 14 concentrate. So BPL were very willing to help us out on  
 15 that to the extent that they actually did.  
 16 Q. And then last document from me in your time in Scotland  
 17 is PRSE0003825. And when that comes up on screen we  
 18 will see that is a letter from Dr Ludlam to you dated  
 19 11 June 1987, and it's in relation to the treatment of  
 20 his patients with the Z8 product that you were just  
 21 talking about. And he says:  
 22 "I'm led to believe that the issue of Z8 patients  
 23 has begun. I was aware that the standard product was  
 24 running short ..."  
 25 Just pausing there, the standard product, is that

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1 the NY product? Is that your understanding?  
 2 A. Yes, I think so, yeah.  
 3 Q. "... was running short and that we had agreed to discuss  
 4 the further evaluation of the new material but I was  
 5 under the impression that there were several weeks'  
 6 supply left. I do not recall that I agreed that  
 7 patients should be treated with this material. So far  
 8 as I am aware it does not have a Product Licence from  
 9 the CSM nor a Clinical Trials Exemption Certificate.  
 10 I am unclear on what legal basis it is being issued and  
 11 who is responsible for any adverse side effects."  
 12 And then he says at the bottom of the letter, the  
 13 last paragraph -- or penultimate paragraph he says:  
 14 "As you know one patient who received Z8 developed  
 15 central chest tightness ... and I am naturally very  
 16 worried that this material has been issued without any  
 17 agreed monitoring arrangements.  
 18 Then in the last paragraph he says:  
 19 "I am now faced with a fait accompli over Z8.  
 20 This has comprised my position and reduced the clinical  
 21 options open to me; ie either to accept the situation  
 22 and hope for the best or to go over to the purchase of  
 23 commercial factor VIII."  
 24 Now, just bearing in mind the letter we saw from  
 25 Dr Perry earlier, who said that the plan was to start

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1 validated, the better. And this was in a period when  
 2 Christopher was away out of the country, and therefore  
 3 not able to keep a close eye on things.  
 4 I actually remember some aspects of this episode  
 5 quite well because I know that I actually went into  
 6 the ward with the registrars who were conducting the  
 7 infusion and I actually spoke to the patient, but  
 8 I didn't in any way actually participate in any  
 9 procedure directly, I didn't put the needle in or  
 10 anything like that, but I was in conversation with them.  
 11 One thing about the reaction he had, which  
 12 I witnessed, he himself said, "Oh, I've had this before,  
 13 with other products". So he wasn't by any means  
 14 a previously untreated patient. He'd received previous  
 15 products. And he wasn't particularly concerned about  
 16 the reaction he had. Although Christopher was already  
 17 aware that if there were adverse reactions in any of  
 18 these patients, and if the product they were receiving  
 19 hadn't been properly validated or licensed, then we were  
 20 all on thin ice.  
 21 So he was absolutely valid in that concern.  
 22 I -- as I say, I was somewhat a bit piggy in the  
 23 middle. I thought that the product we were giving had  
 24 been approved. Christopher thinks it had not been  
 25 approved, and so consequently he was on thin ice and, as

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1 issuing the Z8 once the NY had been used up, was that  
 2 the situation: that in fact there was no more NY, which  
 3 was why the Z8 was being issued?  
 4 A. I believe that was the case. I've gone through this  
 5 particular correspondence in great detail, because it's  
 6 significant and an indication of how seriously, and  
 7 rightly, Christopher took his responsibilities.  
 8 So that is my understanding.  
 9 The other thing is, that I didn't -- wasn't aware  
 10 of at the time, is that there were detailed negotiations  
 11 going on between the Scottish haemophilia doctors,  
 12 I think in a sense led by Christopher, and the  
 13 Scottish Home & Health Department about the licensing of  
 14 these modified products from the Protein Fractionation  
 15 Centre. And I was actually not aware of the depth of  
 16 those discussions. I think they were going on for  
 17 months. And the Scottish office were not really -- they  
 18 weren't satisfying Christopher, and at one stage there  
 19 was a meeting, the minutes of which Christopher actually  
 20 disagreed, and I think that's among -- on record,  
 21 certainly in the Penrose Inquiry, and I guess it'll be  
 22 on your records as well. So consequently, I was, again,  
 23 sort of piggy in the middle, expected to activate these  
 24 particular investigations into Z8, because it was the  
 25 product of the future and the more quickly it could be

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1 I said, his situation was compromised and he was faced  
 2 with a fait accompli.  
 3 Very regrettable, very upsetting for him. As far  
 4 as I was concerned, this was obviously an important  
 5 matter, but I was relieved (a) that the patients didn't  
 6 suffer any extra degree of adverse effect than he'd  
 7 already experienced, and in fact within a few hours was  
 8 entirely well. That's not to minimise the significance  
 9 of an adverse effect of this nature but nevertheless  
 10 that was a little bit reassuring.  
 11 And I also feel that, in the long run, this was  
 12 a very unfortunate episode, but it didn't impair the  
 13 further work that we were doing, and that indeed I was  
 14 doing with the other Haemophilia Directors I've already  
 15 alluded to, Dr Mayne in Belfast and Professor Bloom in  
 16 Cardiff, about further trials of these materials.  
 17 So actually, we were able to ensure the clinical  
 18 validity of Z8 over the course of the next few months,  
 19 and this very regrettable episode fortunately didn't  
 20 impair that but it certainly was a lesson learnt, that  
 21 I learnt in particular, about the need to be absolutely  
 22 sure that the products you were giving were properly  
 23 approved.  
 24 I cannot blame Dr Perry and the PFC staff for  
 25 issuing it, and I cannot blame Dr Ludlam for his

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1 complaint. If there is any person to blame at all, it's  
2 myself for not being sufficiently aware of the  
3 background to what was going on to be able to say, "Hang  
4 on a bit, we shouldn't do it just yet". But in the  
5 event this episode happened, and it did not impair the  
6 professional relationship that I continued to enjoy with  
7 Christopher for the rest of my time in Edinburgh.

8 **Q.** This letter gives an impression that the Haemophilia  
9 Centre is a passive party in the process of getting  
10 products into patients, that actually it's you that is  
11 making -- you, as in the blood transfusion centre --  
12 that's making the decision about what products they get,  
13 and so therefore what products they give their patients.  
14 Is that in reality how it worked?

15 **A.** Well, I think that sort of happened in this particular  
16 instant because Christopher wasn't round, the registrars  
17 didn't know what was happening, the blood bank staff in  
18 my department knew we had this product waiting by, and  
19 so consequently the procedure was activated, possibly  
20 against the better judgment of those registrars, but  
21 they hadn't actually received enough -- they weren't  
22 confident enough about that. And possibly, although  
23 unintentionally, they may have been reassured by my  
24 presence that it was an okay thing to do.

25 Regrettably, they didn't ask Dr Alistair Parker,

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1 1970, 1969 or so, and was to be run by the Wessex  
2 Regional Health Authority, which was a sort of carve-out  
3 of the south-west bit of south Thames and the southeast  
4 bit of Bristol, to produce the region of Wessex, and  
5 a parallel thing happened for the Transfusion Service.  
6 So there was a decision to build a new transfusion  
7 centre in -- to open in about 1970.

8 And that was also in the background of  
9 Southampton University becoming an undergraduate school  
10 of medicine, so medical students started arriving to be  
11 trained in medicine around that time, and it was  
12 thought, I would say on good grounds, that to have  
13 a regional transfusion centre sited in the teaching  
14 hospital grounds of -- of the new teaching hospital,  
15 which was also being rebuilt, with lots of money, was  
16 a good thing.

17 So it all fitted together that there should be  
18 a nice new shiny transfusion centre that was distinctly  
19 post-war to be built in Wessex at that time. And  
20 I think the Centre opened in about 1971.

21 Regrettably, it had not escaped the whole style of  
22 the past, in that the main feature in the building was  
23 a bottle -- glass bottle washing plant expected to wash  
24 bottles analogous to a milk dairy in order to prepare.  
25 Because until -- during the war and afterwards, for the

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1 who was standing in for Christopher at the time, and  
2 possibly, had they done that, there may have been  
3 a different outcome.

4 I don't think what you've said, Ms Scott, just  
5 recently, just now, about the force of choice is true on  
6 a total basis. I think on this particular episode there  
7 was perhaps an undue pressure put on those registrars to  
8 actually give this product in a way that ultimately  
9 their own boss did not approve.

10 **Q.** I'm going to move now to your time at the Wessex  
11 Regional Transfusion Centre in Southampton in England.

12 When you arrived there, as Centre Director, is it  
13 right to understand that the previous holder of that  
14 post, Dr Don Smith, who had been in post since 1969, had  
15 retired in 1978 (sic) or 1988, so a couple of years  
16 before you arrived, and there had been no director in  
17 that two/three-year period?

18 **A.** That is correct. 1988, when he retired.

19 I think he was persuaded by the region to stay on  
20 for another year. So consequently, you know, he was  
21 still around. And indeed, those returns which I've seen  
22 were signed by him and -- including the return for 1988  
23 to 1989.

24 But yes, Don was very experienced. The history of  
25 the Wessex Transfusion Centre is that it was created in

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1 first couple of decades, blood was supplied in bottles.  
2 In fact the first blood transfusion I undertook to -- as  
3 medical student to patients was conducted with -- from  
4 blood in glass bottles.

5 These were transitioning during the 1960s and 70s  
6 to plastic. So most of the regions in the UK by 1970  
7 were almost entirely using plastic for collecting blood,  
8 which was a great advance. Wessex wasn't there, and it  
9 didn't really get to a -- full plastic equipment until  
10 well into the 1970s. But that was the thinking of the  
11 Wessex Centre at that particular time.

12 And Dr Smith did retire, but there was a vacancy  
13 for the directorship. I saw the first advert in 1988  
14 and decided not to apply because I wasn't getting good  
15 signals from Wessex, from the rest of the transfusion  
16 [audio disruption] centre about what Wessex was like.  
17 And, also, I was nowhere near ready in 1988 to actually  
18 consider a move. So when they readvertised in 1990,  
19 I was surprised because I thought the post had been  
20 filled. And when I went to visit the Centre in about  
21 April 1990, in order to consider whether to apply, he  
22 wasn't there. The only consultant there was Dr Andrew  
23 Herborn who did not want -- expressly did not want to be  
24 appointed as director because he felt that being  
25 a director would take him away from the hands-on bench

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1 job that he was actually doing as a consultant, mostly  
2 involved with blood donation procedures.

3 And Andrew was a very conscientious and good  
4 consultant, utterly reliable in his work and I can sort  
5 of understand why he did not want to take on the extra  
6 responsibilities of being a director.

7 So the place had been devoid of a medical  
8 director. The region had appointed a senior  
9 administrator/manager, whose name is Jim Smith -- there  
10 were lots of Smiths around at this time. Jim Smith was  
11 appointed from the region to be the administrator of the  
12 centre and, without making too great a play on this, it  
13 was everybody's opinion within a few months that this  
14 was a disaster and that he was not really leading the  
15 Centre in the direction it should have been. And that  
16 came from the senior staff there, not particularly  
17 Andrew, but from the senior scientific and nursing staff  
18 there, who felt that Mr Smith didn't really understand  
19 the business, felt -- underestimated the degree of work  
20 involved in running a transfusion centre.

21 So when I came, I was appointed to be his  
22 co-director, so I didn't take the post of director  
23 directly, I was required to work with Mr Smith. So when  
24 I went to visit them, I had a conversation with him and,  
25 never having met him before, I didn't really get to

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1 there were lots of interesting people to meet in public  
2 health and it was an attractive way of working. It  
3 wasn't to last. That particular link was disrupted in  
4 two stages so that by 1995, the Regional Transfusion  
5 Centre -- there was no Regional Health Authority and the  
6 workings of the Regional Transfusion Centre were  
7 transferred to the National Blood Authority.

8 So that, in a nutshell, is the history of my  
9 appointment, the working which I took on, the  
10 relationships I had to develop, and how it went from  
11 there. But after Mr Smith's departure, the region were  
12 extraordinarily helpful [audio disruption].

13 They were 12 miles up the road in Winchester, and  
14 we were in Southampton and I honestly think that for  
15 most of the 1970s and '80s, after the initial flush of  
16 opening the centre, Dr Smith was more or less neglected  
17 by the region in many meaningful way to help him cope.  
18 When I arrived at the centre I found that there were  
19 five different bank accounts. That was quickly  
20 rationalised by me, in the course of the year, into one,  
21 when we took on a new treasurer for the Centre.

22 The region supported us very well, Dr Winyard  
23 supported me, as did Ken Jarrold, a very senior figure  
24 in the NHS management structure nationally. So,  
25 consequently, we were well supported for the last two or

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1 grips with his own particular abilities. He was able to  
2 say all of the right words, so I didn't see beyond that.

3 So I applied, was appointed, somewhat to my  
4 surprise -- of course, there are other good candidates  
5 as well -- took on the post, and within two or three  
6 months realised that I was working with a man who was  
7 impossible to work with. He sort of countermanded  
8 everything that I instructed the staff to do.

9 And, eventually, other people, not in other -- the  
10 clinicians, the haematologists, not so much in  
11 Southampton, but in Portsmouth, and in Bournemouth, and  
12 in Winchester, went to Dr Winyard in the region and  
13 said, "You've got to give Frank the freedom to do what  
14 he wants to do because he's got all the right ideas and  
15 is not being allowed to do that".

16 Now, I didn't say that to anybody. They were able  
17 to discern that from the activities in the centre. So  
18 Jim Smith was reabsorbed into the Regional Health  
19 Authority, and Graham Winyard funded me to go on  
20 a King's Fund course in medical management in order to  
21 be prepared to take up the post of what he rather  
22 grandiosely described as chief executive officer of the  
23 Wessex Regional Blood Transfusion Service.

24 Naturally, I was a bit flattered by that,  
25 I enjoyed working with the Regional Health Authority,

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1 three years of my time, which enabled to us develop  
2 a good comprehensive computerised system and, even  
3 better, a really spanking up-to-date blood processing  
4 operation, which I think was, in 1994/1995, would be  
5 among the best in England by that time, because we'd  
6 learnt the lessons from so many of the other centres.

7 So that was my beginning at Wessex and quite  
8 understanding why Dr Herborn didn't want to be director,  
9 he was doing a fine job as consultant and the two of us  
10 did get on very well.

11 We did take on a third consultant for a few years  
12 and that was less of a success because I think there  
13 were some aspects of the job that were taken over by the  
14 National Blood Authority so, consequently, what happened  
15 then is that Dr Herborn moved to Birmingham, I think, in  
16 about the year 2000, or so, or the late 1990s, and so it  
17 was left with me and Bob, really, to continue to be the  
18 medical staff at the Southampton centre. But, by that  
19 time, neither of us were directors because the National  
20 Blood Authority had taken on the principle role of the  
21 Wessex service from a more central base, actually a base  
22 in Bristol. Of course, we were part of the Supra South  
23 West Region.

24 I've gone on at length about that but that's  
25 a quick summary of the development of the Wessex

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1 Transfusion Centre during -- before, during and after  
 2 my -- well, before and during my time.  
 3 **Q.** Just a couple of points -- of details I want to pick up  
 4 with you, so the area that you described, some of the  
 5 area that the centre covered but, importantly, it  
 6 included the Lord Mayor Treloar school; is that right?  
 7 **A.** Yes.  
 8 **Q.** You set out in your witness statement -- I don't think  
 9 we need to go to it -- the urgent priorities that you  
 10 needed to address when you arrived at the station, which  
 11 included the fact that donor records were completely  
 12 paper based, and you've described that that was the  
 13 system of computerisation that came in; and the research  
 14 scientists had not received any guidance for developing  
 15 research programmes; session organisations needed  
 16 reappraisal; and the blood products facility needed  
 17 updating, and you explained that that did, in fact, take  
 18 place; and the stores which had been operating  
 19 traditionally as a repository of equipment needed  
 20 updating.  
 21 So those were your urgent priorities when you  
 22 first arrived; is that right?  
 23 **A.** You don't need to go to my statement. Those are --  
 24 that's an accurate summary. It was a more challenging  
 25 job, in many ways, that I went to but I did get a little

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1 I just want to at that for the record.  
 2 But the other points that you've made are entirely  
 3 valid. Those are the areas that needed improvement.  
 4 **Q.** Just for the transcript, that's paragraph 178 of your  
 5 witness statement.  
 6 **MS SCOTT:** Sir, I note that I've gone on rather longer than  
 7 3.15. I've got at least half an hour left of questions  
 8 to ask Dr Boulton about Wessex. I don't know whether  
 9 now would be an appropriate time to take a break.  
 10 **SIR BRIAN LANGSTAFF:** I think if you've got half an hour,  
 11 yes, it would. So we'll take a short break, shall we,  
 12 until 3.45, if that's okay, and come back then and  
 13 finish off your questions.  
 14 Dr Boulton, there will then be a short break again  
 15 while those who have been watching remotely have  
 16 a chance to put questions through Ms Scott to you in  
 17 what will then be the final session of the day. So  
 18 I can't tell you yet how soon you will be finished, how  
 19 soon we'll be finished. We'll have to wait and see.  
 20 3.45.  
 21 **A.** I understand, yes. Thank you.  
 22 (3.26 pm)  
 23 (A short break)  
 24 (3.44 pm)  
 25 **SIR BRIAN LANGSTAFF:** Yes, Ms Scott?

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1 bit of forewarning about that. I have to say that, in  
 2 spite of the lack of leadership, the staff were very  
 3 conscientious. Although it was a paper-based record, it  
 4 was meticulously maintained. For that, Dr Herborn  
 5 deserves a lot of credit. So when it actually came to  
 6 computerisation, the data that was transferred was  
 7 pretty reliable and so, consequently, we were -- we'd  
 8 jumped from being the back -- the least developed to one  
 9 of the most developed computerised centres by about  
 10 1993. So that is to the credit of the staff there.  
 11 The sessions -- one of the things that helped us,  
 12 and I didn't put this anywhere, I'd just like to add it,  
 13 for the record. One of the things that was obtained  
 14 during my time was a new bus: donor services bus. There  
 15 had been an old one which had got -- become dilapidated  
 16 and it was replaced at a cost of over £100,000 in,  
 17 I think, 1992/3 with a bus that travelled with the team  
 18 to, usually, industrial sites and was able to collect  
 19 something of the order of 100 units of donations a day  
 20 from that bus, which was a considerable contribution.  
 21 It was a new bus, it was actually a left-hand  
 22 drive, because it was American designed, and that was  
 23 very good for the drivers. They enjoyed doing it. It  
 24 certainly enhanced our ability to get good quality of  
 25 blood donated and collected and sent to the centre so

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1 **MS SCOTT:** Dr Boulton, just to orientate you and those  
 2 listening to what I'm going to ask you in relation  
 3 to Wessex, I'm going to ask you some questions about  
 4 your relationship with clinical colleagues and then I'm  
 5 going to ask you some questions about hepatitis C  
 6 testing and the arrangements were put in place for that,  
 7 and the hepatitis C look-back programme, and then about  
 8 record keeping.  
 9 Just on my first topic, on the relationship you  
 10 had with clinical colleagues when you were at Wessex, is  
 11 it right to understand that when you arrived in Wessex  
 12 there was no hospital transfusion committee in place,  
 13 but there was a regional association of haematologists  
 14 which met every three months?  
 15 **A.** That is correct.  
 16 **Q.** And what was discussed at that three-monthly meeting?  
 17 Was a topic of conversation the safer use of blood, the  
 18 better use of blood, reduction in use of blood, in so  
 19 much as it could be safely reduced?  
 20 **A.** I cannot remember precisely what went on. I don't have  
 21 minutes of those particular meetings. But I do know,  
 22 and remember very clearly, that I developed in the  
 23 course of that time a real sense of the need to, as  
 24 I say, cut off my nose to spite my face. That is  
 25 because we had gone into a system of cross-charging,

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1 about which I knew from the time that I'd applied for  
2 the job that was going to come in in the English  
3 Services, that there was an -- an internal market was  
4 going to develop in England, it did not in Scotland, but  
5 an internal market whereby the users of blood, the  
6 hospitals, the users of blood and blood products, would  
7 pay at a fixed price for each product, and that that  
8 money would be used to fund the workings of the  
9 transfusion centre.

10 It wasn't cash, it was a transfer of funds, if you  
11 like, from one source to another, so it was  
12 a translation of the use of the internal markets for  
13 using -- for funding the blood services.

14 The problem with that, as I saw it, was that if  
15 one took a purely commercial capitalist [audio  
16 disruption] my job would be to sell as much blood as  
17 I could, and that was professionally profoundly  
18 distasteful, because it was already becoming apparent  
19 that in order to improve the safety of the Service, we  
20 had to look very carefully at the indications for blood  
21 transfusion.

22 So I regarded part of my job as going round the  
23 hospitals, talking to the consultants, where I could,  
24 and talking to the laboratory staff as well, so that  
25 they were on board with the concept that it doesn't

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1 disruption]. But nevertheless, the use of blood did  
2 slowly come down and, slightly to my chagrin, I felt  
3 that the marketing that -- the commercial -- the fact  
4 that they had to buy it sent a fairly powerful message  
5 to those in charge of hospital laboratory budgets.

6 But in the end it meant the same thing: that we  
7 were looking carefully at the proper use of blood.

8 **Q.** And did there come a time when there were hospital  
9 transfusion committees in the hospitals that the Wessex  
10 Centre served?

11 **A.** Yes, and some hospitals were better than others.

12 To my regret, the Southampton General Hospital was  
13 not among the leaders of this particular trend, whereas  
14 some of the smaller hospitals, particularly the  
15 Dorchester hospitals, were much more open to that sort  
16 of thinking.

17 **Q.** I'm going to turn now to hepatitis C testing.

18 It's right to understand, isn't it, that you  
19 weren't involved in any of the national English forums,  
20 such as the ACTTD and the ACVSB, in which decisions  
21 about the national introduction of hepatitis C testing  
22 were determined or were decided?

23 **A.** No, although I was kept somewhat informed about those  
24 developments, and although -- and indeed, I fairly  
25 quickly formed contact with the Donor Selection

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1 matter what you -- what the prices are, what you need to  
2 do is to cut down your use for the benefit of  
3 the patients.

4 So in a sense, as I say, cutting off my nose to  
5 spite my face. I did not regard myself as a salesman.

6 Unfortunately, one or two of the hospitals did  
7 think that with the takeover, a few years later, by the  
8 National Blood Authority, that's precisely what we had  
9 become. That was one of the problems that we had to  
10 cope with. But that was my ideology, that there needed  
11 to be a rational, clinically justifiable system for the  
12 use of any blood or blood products that was entering  
13 a patient's veins.

14 So that --

15 **Q.** Did that --

16 **A.** So the consequence of that was, indeed, a series of  
17 largely informal meetings hoping to get the message home  
18 that it was a good thing to pay attention to the use of  
19 blood.

20 Ironically I began to realise after a time  
21 that it didn't matter what I said. What really counted  
22 was when they saw the bills. And -- it was the bills.  
23 But the bills were held by the haematology departments,  
24 not by the surgeons or by the ward users, so it was  
25 not all -- in a way, not all that successful [audio

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1 Committee, which I later joined and took on a role on  
2 their committees, and also aware of the Transfusion  
3 Transmitted infections. That was on a UK basis rather  
4 than an English basis, so that I was less involved with,  
5 if you like, the nitty gritty of the work being done to  
6 introduce the testing of HCV.

7 I might just add that, personally, I was in favour  
8 of introducing these specific tests for HCV at the  
9 earliest possible moment, and I think I'm on record  
10 as -- before I came to Wessex as advocating quite  
11 strongly the need for the UK to introduce specific  
12 HCV testing as soon as possible, especially as the  
13 technology was actually coming online.

14 And in the event, somewhat to our shame the UK was  
15 among the latest countries in Europe to actually  
16 introduce the testing. And that was singularly  
17 unfortunate, because I felt that there was an ethical  
18 need to introduce it at the earliest opportunity.  
19 That's the specific testing of -- for the HCV virus.

20 **Q.** And that letter is at PRSE0001562.

21 Could we have that up, please, Sully, just to have  
22 a look at what you were saying.

23 When we get it up, we'll see that it's a letter  
24 that you wrote to Professor Cash on 21 February 1990.  
25 And you say in the main paragraph of the letter:

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"Could I just add that in spite of obvious difficulties with the current Ortho Elisa assay (susceptibility to 'stickiness', unreliable of predictive value with heat treated samples, etc) I have developed a very strong feeling that the screening of donors for HCV antibodies should be introduced at the earliest possible opportunity. This is not because of the 'science', but because there appears to be little doubt that people have contracted HCV as a result of transfusions which they would not have received had these transfusions been screened for HCV antibody. Furthermore there are apparently five known cases of HCC due to PTH. The reason, therefore, from my proposing this view is actually one based on future litigation. I am pretty convinced that the NBTS and SNBTS will find legal action taken against them in about 10 years' time from persons who have sustained post transfusion hepatitis as a result of receiving HCV antibody containing blood which was presumably infectious for HCV at that time."

So that's your view expressed, as you say, quite forcefully in February 1990, before coming to England, to Professor Cash.

And it's right to understand that, is it, that although you recognised some -- that the testing wasn't

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So that was the background. This is a personal feeling I developed. And in a way, I'm pleased that I -- that this [audio disruption] letter is on the record, because it did reflect a real anxiety at that time, although some would say that my anxiety was based on only tenuous grounds at that particular time, because of the difficulties of developing that test, the stickiness and all those sort of technical problems that were getting in the way of developing a usable test for screening.

Screening tests are very different from diagnostic tests, and that's one thing that should be recognised. You can diagnose individual people on the basis of a test that may be not particularly easy to perform but as long as it's carefully conducted on that basis by skilled technicians, then that's reliable.

Screening -- screening hundreds of samples a day is a very much -- is a very different kettle of fish, and you need to have well proven technologies for that in order to reduce the false positive and false negative readings. So I'm not belittling the problems in developing an assay but nevertheless, the assays were well on the way to being developed, and I felt it was very important that those developments should be expedited as quickly as possible.

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perfect, you nevertheless -- the science of the testing wasn't perfect -- you nevertheless thought it should still be implemented?

A. That is pretty correct.

Just one little point of clarification for a potential ambiguity. The acronym "HCC" that's about two-thirds of the way down in that paragraph, is hepatocellular carcinoma. It's not a misprint. That's a deliberate HCC, because people with cirrhosis have a high risk of developing cancer of the liver, so it's -- hepatocellular carcinoma is what that stands for.

Yes, this was actually as a result of my attendance at meetings, and there were -- I think there was a meeting in New York and around about the same time there was a meeting in London, and I attended the London one, and there was a lot of talk about this. And I -- my -- the actual reports of that meeting don't really reflect the sentiment that I'm expressing in this letter. But I was sort of picking up vibes, or maybe my antennae were attenuated because -- well, sensitive to this, possibly because of my experience with HIV back in 1983 when -- and indeed the introduction of the tests in 1985, how important it was to get this done as quickly as possible.

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Q. Then once you had taken up your post in Wessex and there was -- the Inquiry has seen the correspondence and discussions going back and forth between Dr Gunson and the Directors about when the screening date -- when screening should be implemented on a national basis, and the date keeps getting put back, and Dr Lloyd effectively goes early, and there's a correspondence from you to Dr Lloyd in which you are saying to Dr Lloyd, and we can look at it if we need to, but you're saying that you think that the -- everybody should go together, and that to break ranks in the way that he is is not conducive to the image of a coordinated service. And the reference for that for the transcript is NHBT0000074\_021.

So is it right to say that in around May '91, when these discussions were taking place, you -- your view at that point was that it was more important for screening to be rolled out nationally than it was for screening to be introduced early on a piecemeal basis?

A. That's correct, although I would like to add a caveat or two.

This is definitely a -- reality hitting me when I got to Southampton, because the letter that's still up -- I don't think it needs to be up anymore, but the letter that's still up about me advocating an early

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adoption of tests was strongly felt at the time, and I think possibly justified. But the ground -- hitting the ground at Wessex in 1991, one faced reality in that although the laboratory was very well run, by some conscientious scientists, Wessex was not one of those centres that had been participating in any of the preliminary programmes, and the -- neither the region nor the hospitals were particularly willing to put up the extra bit of money when it came to introducing the new tests, which was like an extra pound per test.

And there was quite a lot of correspondence between me and the region, and some of the hospitals, about the funding of these particular tests. And at the end of the day Wessex was only funded by the RHA rather grudgingly, who felt that the hospitals were not paying their -- pulling their weight in this.

Again, this is the sort of typical narrow insight that accompanies the thinking of the market. I think it is profoundly regrettable that this situation was arising, which resulted in a delay of the implementation of the tests in England.

The other slight mitigation for me is that I was not party to any of the detailed discussions about the timing of the introduction. I've seen them since, from Harold Gunson, from John Cash and others, and

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together, we -- and people breaking ranks were making life difficult for the others.

Well, really now I would say that was an unfortunate attitude. We should have been -- we should, I think, have been able to introduce the test earlier. But there were all sorts of other little things that -- the virologists being picky about the quality of the tests and all that sort of thing, so there was a lot going on. But it was, I think, wrong to delay it until September or so in 1991. It should have been introduced earlier that year, if not actually in late 1990, which I could see might have been a bit more difficult, but nevertheless, that was an unfortunate episode. Which is why the look-back period later on was so important.

**Q.** Would Wessex have been able to implement testing earlier? We know from your witness statement that you had to undertake some building works. Were those complete, for example, by the time you'd arrived at Wessex?

**A.** Yeah, I think part of the problem was that people like Jim Smith squashed those sort of thinkings in the time they were there. The letter that -- many were aware that such tests were going to be needed but just couldn't get anywhere with the -- with what was then the hierarchy within the Centre. So the Centre was poorly

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I know that Huw was given a rough ride for his decision to introduce in June.

I now feel quite strongly that Huw was right although at the time, because I didn't know the full picture, I felt that he was -- by breaking ranks, was disrupting the Service and introducing a sort of postcode lottery for donors and patients living in certain areas.

What I hadn't really fully appreciated was quite a lot of English centres were already testing. They were describing it as trials rather than some screening, but nevertheless, a lot was already going on.

So I was a bit naive at that stage. So I feel that my initial instinct back in early 1990 was still right. The delays were unnecessary in the end. We could have introduced the technology, because -- well, I think one of the reasons was that the technology that was going to be introduced in the late year, September, October, was significantly better and easier than the Phase I technologies being used earlier that year, but experience turned out that there was really very little to choose. I may be wrong on this, but that's my impression, that there wasn't all that much difference between the standard of the two tests, but the -- but at the time it was felt that, yeah, we should all stand

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prepared to take that on, even though I had written to Andrew Herborn before I started, saying what's going on about HCV testing?

**Q.** And the reference for that letter, we don't need to go to it, but for the transcript, the letter you wrote to Andrew Herborn on 26 June 1990 is NHBT0000189.

You also make clear in your witness statement that you were only -- Wessex was only given three weeks' notice of the date for testing having to be rolled out nationally, and I just wanted to read out a paragraph from your witness statement. I don't think we need to have it up on the screen.

Well, in fact perhaps we should have it up on screen. It's WITN3456002.

In which you set out the impact on Wessex of that short notice period.

Could we have, please, page 148. And it's paragraph 410 of your witness statement. You're asked what happened to all the unscreened blood that had been collected prior to the HCV testing being implemented and you say this:

"In order for all blood issued after 31st August 1991 to be negative for HCV, all the blood in stock from the 1st September would have been tested -- which is why early stocking of test kits was

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needed so that donations issued to hospitals during August 1991 would be HCV negative. I cannot be confident that this was the case given that Centres had at the most, 3 weeks (before 1st September) in which to introduce the systems. Hence, some untested blood may well have been issued during the first week or two after the tests were implemented. Although usually most blood was issued to hospitals within three weeks of donation, the expiry time of four or five weeks would indicate that a few HCV untested units may have been issued. I have no data on how many untested units were issued or even transfused after August 31st."

So you put the fact that there may have been untested blood being issued post-1 September down to the very short period of time that you -- the very short period of notice that Wessex were given to get testing up and running?

A. That's my understanding now of that time, which is 30 years ago, but nevertheless, it was an important development that I was faced with when I arrived.

I have to say that -- just be a bit cautious -- my -- this is another example in my memory not necessarily being totally accurate, and I don't have any papers backing this particular attitude, but nevertheless, this is a sort of -- I'm painting

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So.

A. Yes.

Q. This is a letter that you wrote to -- it seems to name and shame the hospitals that you were asking to trace the potentially infected products from the HCV infected donors. And what you seem to have done here is done a sort of table, a league of shame to try to get those that had provided you with no feedback and done no investigations, to do so. Is that how to understand this letter?

A. That's correct. I might say that this, of course, is the sort of master copy of the letter, and the details of the people I was posting it to would be occupying that top left-hand corner.

I cannot be absolutely certain how many of them received it, but I do remember bringing the subject up at a Wessex regional haematologists meeting, of which there was two or three each year, usually held at Salisbury, and I remember talking about this. So they certainly were familiar -- or had no reason not to know about this name and shame league table. And I'm afraid that the reaction from most of them at the bottom there was a mere shrug of the shoulders. It was deeply unsatisfying.

Q. And you say in the letter on that last paragraph:

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deliberately a worst-case scenario here, in that if people -- if someone was able to say to me that someone was transfused in a Wessex hospital in, say, October 1991 and then developed hepatitis C, the last thing I could say is, "Well, it wasn't due to the blood."

My understanding now of the situation at the time was there was quite a lot of uncertainty about what we were doing, and I have no real means now of checking that up. But I did remember at the time feeling a little bit nervous about the possibility of HCV emerging among some of our recipients.

Q. I'm going to ask you now to move on to the look-back for hepatitis C.

If we can go, please, to NHB0087650.

There's a letter that you have written to the hospitals served by the Centre. Now, rather curiously, this is only the first page of the letter, and the second page of the letter -- Sully, I wondered if we could have that up by the side, please -- is -- oh, there is a second page. There we go. Thank you.

We don't need them both up at the same time, it was just that on my copy it's a different document reference. But clearly not.

So if we can just look at page 1 of that, please.

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"Levity aside, I must confess to a profound sense of disappointment, particularly as I had visited all the hospitals and spoken to haematologists in April about the need to progress the HCV Lookback programme."

What do you think it was that some of the hospitals simply didn't engage with the look-back?

A. Well, this is September 1995. By which time Wessex had been taken over, as you'll see in the top right-hand corner, by the National Blood Service. And to some -- some of the consultants -- not the scientific staff, not the nurses, this would be a consultant-led attitude -- felt that we had been downgraded in Wessex. We were no longer a regional centre. So consequently, our credibility was a bit sort of -- we'd lost a bit of credibility. And I think that's one particular thing.

The other thing is the smaller hospitals seemed able to cope better, you know, like Poole, which had a good result, Bournemouth less so. The really big hospitals at Queen Alexandra in Portsmouth, which was not a particularly big hospital, but the St Mary's in Portsmouth and Southampton General, those were big hospitals. And, indeed, the Portsmouth haematologists were generally very supportive of me, but this particular message went down like a lead balloon, and I don't think any of them really picked up on that.

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1 I think the response to this was still very poor.  
 2 So my powers of persuasion were tested and  
 3 basically unsuccessful. I think, it's an unfortunate  
 4 reflection of the sense of priorities. And the other  
 5 thing is, as I referred to earlier, this was quite  
 6 an expensive exercise, and they were sort of expected to  
 7 take this on without being funded. This meant going  
 8 into the hospital records, the patient records and, as  
 9 I think I said in my witness statement, that I did, on  
 10 one occasion, somewhat linked to this, but more linked  
 11 to an HIV Inquiry, visit the records of the -- in  
 12 Southampton General and they were in a dreadful state.  
 13 I can also say that the records for the Regional  
 14 Transfusion Service under the management of the RHA in  
 15 the early '90s, when I was there, was also in a very  
 16 disgraceful state.  
 17 So, on the whole, paper records of this nature  
 18 were basically disregarded or forgotten about, put on  
 19 one side, and it was too inconvenient for them to go  
 20 back into the basement and dig out this data. So I felt  
 21 that this -- this is why I was disappointed. Because  
 22 I was prepared to do this work, why weren't they?  
 23 Q. Can we then look at NHBT0036757. This is on the second  
 24 page, it's a table that's provided to you by  
 25 Tim Wallington.

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1 Either the others were just as bad as Southampton  
 2 or Southampton happened to have rather more people.  
 3 I just don't know. Certainly Southampton, you know,  
 4 those figures indicate that there was a look-back, but  
 5 how effective it really was in Southampton, based on the  
 6 previous slide, I've told you, I am unconvinced that  
 7 those are really accurate figures. I think they may  
 8 well be underestimates.  
 9 Q. So my reading of this, and it may be that I'm wrong, was  
 10 that Southampton referred to the work that you were  
 11 doing in the old Wessex Centre, rather than the work  
 12 that was being done by the Southampton Hospital. Is  
 13 that --  
 14 A. Yes. Yes.  
 15 Q. Is that how you read it?  
 16 A. Yes, this is the Southampton Centre not the Southampton  
 17 hospitals. Yes, I'm pretty sure that it would be  
 18 referring to the Wessex centre, not the Southampton  
 19 General Hospital.  
 20 Q. Then the last document from me before we have a break  
 21 for further questions from Core Participants is  
 22 DHSC0004180\_052. I'm going to be asking some questions  
 23 about records. So this is a letter from -- if we go  
 24 over to page 2, we don't need it -- it's from you to  
 25 Dr Rejman, dated 15 --

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1 And if we go over to page 2, we can see the  
 2 numbers for Southampton on that column at the end. So  
 3 we see that number 1, the 95 number is number of donors  
 4 identified who have given blood pre-1991, presumably who  
 5 are HCV positive -- 95; number of relevant donations  
 6 identified, 630; number of donations notified to  
 7 hospitals, 306; number of recipients identified by  
 8 hospitals, 173; number of recipients followed up, 176,  
 9 slightly curiously more followed up than had been  
 10 identified.  
 11 A. Yeah.  
 12 Q. Number of recipients counselled and tested, 34; number  
 13 of recipients tested positive, 19; number of recipients  
 14 tested negative, 12; and number of recipients who had  
 15 died, 128.  
 16 Does that chime with your recollection of the  
 17 sorts of figures that we're looking at?  
 18 A. Well, I don't -- I only recollect this retrospectively  
 19 now; I'd forgotten this particular thing. I do suspect  
 20 that the Southampton columns are an under -- that they  
 21 would be reflecting -- reflected in the analysis that  
 22 Tim's staff were doing on this, but I suspect that those  
 23 numbers are an underestimate, even though row 5, the  
 24 number of recipients followed up, it looked as if  
 25 Southampton was doing more than any of the others.

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1 A. Rejman [clarified pronunciation].  
 2 Q. Rejman, sorry. If we go back to the first page,  
 3 15 October, 1992, and you say, at the beginning of the  
 4 letter:  
 5 "Thank you for your letter of 12th October 1992,  
 6 requesting information regarding the above patients."  
 7 There are two patients listed there:  
 8 "I apologise for the lack of response to this  
 9 matter so far ..."  
 10 Then the next paragraph down, you say:  
 11 "We instituted a search of our records concerning  
 12 Mr [X] shortly after receiving your first letter on  
 13 20th July; and indeed my predecessors had kept  
 14 a detailed file. However, the information is very  
 15 incomplete and I cannot state with any certainty from  
 16 the records that are now available to me, that any of  
 17 the four unit numbers involved [then you set those out]  
 18 which were transfused in April 1984, can be traced with  
 19 certainty to a donor subsequently found to be HIV  
 20 positive."  
 21 Then if we could just go over the page, and go  
 22 halfway down that second page, to the sentence that  
 23 starts -- the paragraph that starts "I think" so below  
 24 the crossing out:  
 25 "I think you will appreciate this has been

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an extremely difficult investigation; our time since the receipt of your first letter in July has been spent exhaustively combing through our files for further evidence which has been entirely unrewarding. I feel that some of the difficulties have arisen through a desire to maintain confidentiality of records of the donors, and indeed some of the documents which would have enabled us to provide the link have gone missing. Also, there has been no storage of any blood samples taken from donors in 1984, which now could be tested."

I think I probably should have said at the beginning, the context of this letter is a request from the Department of Health to you to see whether or not two particular patients had been infected with HIV blood or tissue transfer, in order to see whether or not they met the requirement to receive payments from a Department of Health scheme.

So two issues that arise in relation to this, the first of which is the issue about generally the state of the records at Wessex, and I'll ask you to give us your views about that. But first, perhaps, while we've got this up in front of us, the second page, the second point that arises is this point that you make about the desire to maintain confidentiality in records of donors, causing problems to those that come back to read the

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might have been contaminated with HIV, whatever the reason might be. But the biggest reason that we were worried about was multiple men having multiple sexual encounters with other men, as the biggest risk factor.

And this was a very difficult subject and we were still getting round how to communicate with the donors about this. So it wouldn't be particularly surprising to me -- and this is well before my time, but both these patients were well before my time, and I happened to be around when Andrzej Rejman came up and asked us about this and I had two good conversations with him, but yeah, it's distinctly possible. But people didn't know how to record the suspicion of a high-risk behaviour on a donor card, or they may have put some squiggle on it that was a code, but the significance of that code was lost in a few years.

I am speculating but, basically, I think it is recognised that we didn't quite know how to deal with this sensitive data among donors around that particular time. And so I'm speculating that that may also have contributed to the paucity and poor quality of the record keeping in regard to these particular episodes at that time. But it is a speculation, although not based on idle musing.

**MS SCOTT:** I've come to the end of my questions. We'll need

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records in later years.

Can you tell us what it was that you found and why you came to that view?

**A.** I think it would be more a case of what I suspect, rather than found. You're right, this was a very difficult exercise. The state of the records was disgraceful because I think these were ones which I referred to had been farmed out to a decommissioned mental hospital near Basingstoke, called Park Prewett, and those records were contaminated with bird droppings through a leaky roof and, indeed, some of the -- I didn't do it myself but some of the people who went there felt that they were themselves suffering -- susceptible to health hazards from the state of those records.

So a few hundred records, I think, had to be destroyed or were inaccessible on that basis. So that indicates a sort of standard of care at that particular time, under the priority that historical records were thought to have. That's one aspect.

As far as the confidentiality is concerned, again, this was the era, as I say 1983/1984, crucial years, not just in Edinburgh but in the rest of the country, in how on earth we were to inform potential donors about the risks of -- about us not wanting to have any blood that

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to take a further break so Core Participants can send in any further questions that they would like me to ask Dr Boulton.

**SIR BRIAN LANGSTAFF:** Yes. Do you have any sense as to how long you might need?

**MS SCOTT:** Well, I've had some questions in from the break before, the earlier break, but I'm conscious we've covered quite a lot of ground with Dr Boulton, and so it's certainly going to be more than 20 minutes. Could I say -- I think it's probably going to be -- could I say until 4.45?

**SIR BRIAN LANGSTAFF:** Yes. Well, let's say not before 4.45.

**MS SCOTT:** Yes.

**SIR BRIAN LANGSTAFF:** Using that formulation, Dr Boulton, to allow for the fact that it might be a little later, we'll just have to take our guidance from Ms Scott, but if we're ready for 4.45, then we may well be able to start then.

**A.** I'll be ready at 4.45. Thank you.

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

(4.23 pm)

(A short break)

(4.44 pm)

**SIR BRIAN LANGSTAFF:** Yes, Ms Scott.

**MS SCOTT:** Dr Boulton, I've got a number of questions from

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1 Core Participants, so I think we'll be going slightly  
2 all over the place, but the first question is in  
3 relation to the evidence you gave this morning about  
4 your time in Liverpool, and you were describing how, for  
5 children, it was -- your practice was to give them  
6 cryoprecipitate and then at some point, as they got  
7 older, concentrate, and the question is at what age  
8 would you typically make the decision to move from  
9 cryoprecipitate to concentrate on the basis of age?

10 A. I am not sure that there was a very consistent policy  
11 there, but I suspect that it would be when they became  
12 teenagers. So somewhere between the age of 13 and 17,  
13 depending upon all sorts of things, like their -- the  
14 frequency of their bleeds, actually how big they were --  
15 as much as anything else, it was their size. So that --  
16 and indeed, some of the boys, by the age of 13, having  
17 been well treated, would be quite [audio disruption].  
18 So consequently, you had to take it on a case-by-case  
19 basis. But I think it would be around about then.

20 But I have to say I have no clear memory of  
21 operating that policy specifically. My answer is based  
22 to some extent on suppositions and probabilities, rather  
23 than actually remembering a precise set of  
24 circumstances.

25 Q. In your evidence this morning, you said that the amount

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1 details in ways that would be inappropriate these days.  
2 So in a sense, that was relying on a concept of  
3 confidentiality that no one would ever see what we'd  
4 written. Nowadays, a completely misplaced concept, but  
5 that was fairly common at that time. And as we grew  
6 more experienced and became more aware of the really  
7 important nature of patient/professional relationships,  
8 I think we changed.

9 In Edinburgh, I think there, it wasn't for me so  
10 much a record of patients, because it was more  
11 a question of confidentiality of communications around  
12 staff. And that was a real problem, because -- I mean,  
13 I know that some of my colleagues, I mean, were required  
14 to sign the Official Secrets Act concerning their  
15 discussions in Committees. And yet they've all been  
16 revealed. So it's actually -- that was a real hamper to  
17 communications.

18 So that part of my answer was probably  
19 more directed towards the degree of professional  
20 confidentiality and the way that interfered with  
21 transmission of -- the communications about policies,  
22 et cetera. There was a lot of secrecy about at that  
23 time -- which I think was unnecessary -- possibly  
24 because those who were talking felt vulnerable, but  
25 these days I rather hope that attitudes have changed,

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1 of confidential material which was inappropriately  
2 confidential and hampered communications was quite  
3 profound. Now, you've given us some evidence this  
4 afternoon about what you found and what you concluded  
5 from looking at records in Wessex. Was that also the  
6 case in Liverpool and Edinburgh?

7 A. Is that about donor characteristics?

8 Q. Well, I think you, in a -- I can't remember the question  
9 that I asked you, but as part of your response, you said  
10 either these words or words to this effect: the amount  
11 of confidential material which was inappropriately  
12 confidential and hampered communication was quite  
13 profound.

14 A. Yes.

15 Q. And as I say, you've dealt with that in relation to  
16 Wessex but is there something you can assist us with,  
17 whether you found that also to be the case in Liverpool  
18 and Edinburgh?

19 A. Well, in -- Liverpool and Edinburgh were a very  
20 different set of circumstances. I don't ...

21 Liverpool, 40 years ago, confidentiality, the  
22 concept among medical practitioners, including myself,  
23 was perhaps less sophisticated than it is now. And to  
24 a certain extent my shame, I will be party to the common  
25 medical practice of making personal records of patient

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1 and the concept of openness and accountability is at  
2 least acknowledged more, although sadly, judging by  
3 official public records on other circumstances, the  
4 degree of redactions when people ask for the Freedom of  
5 Information inquiries is still -- there's a lot of  
6 obfuscation at that level.

7 So my feeling is that confidentiality often went  
8 too far and hampered communications, both with patients,  
9 who should have been handled better, with donors, who  
10 could have had clearer information about what was  
11 required of them, and then within the professional --  
12 professions that were involved in the whole provision of  
13 blood service. So that's my answer to that, my rather  
14 long answer to that particular question.

15 Q. You referred to cryoprecipitate being made, in your time  
16 as a houseman, from plasma collected from the naval base  
17 in Portsmouth in the late 1960s. Can you recall what  
18 knowledge there was or what consideration was given at  
19 that time to the risk of viral hepatitis being  
20 transmitted by military personal at the naval base? And  
21 of course bearing in mind that this was pre-hepatitis B  
22 screening.

23 A. But still known to be associated with transmitting  
24 hepatitis. My answer to that question is there would  
25 have been no regard taken to that particular aspect.

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1 In fact, Dr O'Brien, who was the consultant in charge,  
2 a very eminent haematologist, part of the team that  
3 discovered Christmas disease in Oxford in 1952, was  
4 a very effective operator, and he would have had no  
5 hesitation, under the circumstances of this particular  
6 patient, in pulling strings with his contacts in the  
7 navy, getting onto the boats, and having a lot of  
8 exercise in producing literally hundreds of donations.

9 The effect on the staff in the lab, I learnt  
10 afterwards, was profound, particularly in the end it all  
11 turned out to be -- the patient died fairly soon. So  
12 a lot of hard work for a particular episode, but in  
13 terms of things like transmutant -- transmitted  
14 infections, no, that was the last thing on Dr O'Brien's  
15 mind. And I have to say that it wasn't very prominent  
16 in my mind either, because this was a very significantly  
17 ill person who I thought was unlikely to survive anyway.

18 Q. When you were in Liverpool, did you monitor the white  
19 cells of your patients, ie the CD4 and CD8 counts and  
20 ratios?

21 A. No.

22 Q. Were you involved in white cell testing on a haemophilia  
23 patients, ie CD4 and CD8 counts and ratios, while you  
24 were in Edinburgh?

25 A. No.

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1 Festival, for example, may have been able to donate  
2 blood?

3 A. You're absolutely right. I should have said people  
4 donating in Britain. So we would not have excluded  
5 tourists, that was one of the concerns we had about the  
6 Edinburgh Festival, the possibility that American  
7 visitors, in their spirit of goodwill, would turn up at  
8 a donor session offering to give blood and they would  
9 not have been turned down, unless we actually identified  
10 a specific feature.

11 Q. Sorry, Dr Boulton, I'm just getting in another question,  
12 so let me just -- thank you.

13 Do you know anything -- do you have any awareness  
14 of blood being collected at the US naval base in  
15 Holy Loch in the 1980s?

16 A. There were donations from military and naval  
17 institutions collected in Edinburgh at that particular  
18 time, I wasn't actually responsible for those  
19 organisations, but I think on looking back there was  
20 some sessions at those. Those would have been included  
21 as sort of public session and so, consequently, I could  
22 not exclude the possibility of that happening. But  
23 I wasn't directly involved.

24 Q. So presumably those sessions would have been taking  
25 donations from US naval --

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1 Q. In relation to the infection with AIDS in Edinburgh,  
2 what investigations were done into how the products  
3 those patients received had come to be infected by  
4 a donor in Scotland?

5 A. There would have been extensive -- there were extensive  
6 records of the donors who attended particular sessions.  
7 Those donors could be identified with each batch of  
8 Factor VIII concentrate that was produced by PFC. So it  
9 was indeed possible, at least in theory, to trace  
10 everybody who -- to identify, or at least have some  
11 identifying features, of everybody who gave.

12 It was not possible to be 100 per cent certain on  
13 following up those donors, that those identifications  
14 would reach the intended donor. They may have moved  
15 away, they may indeed have died, or something else might  
16 have happened, and we wouldn't have known about that.

17 So the system was very sophisticated, very  
18 intensive but by no means expected to be 100 per cent  
19 foolproof, and I think that the donor or donors who are  
20 implicated in that -- who would have contaminated that  
21 batch were never actually identified.

22 Q. You described NHS factor concentrates as being derived  
23 only from the blood of British people, and I've been  
24 asked to ask you whether or not that's, in fact,  
25 correct. Is it the case that tourists at the Edinburgh

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1 A. Yes, what I don't know is how long that continued into  
2 the 1980s.

3 Q. Just in relation to the position at Wessex, at the time  
4 that hepatitis C testing was instituted, did you re-call  
5 blood or blood products that had already been issued  
6 prior to 1 September? So they would have been untested,  
7 sent out to the hospitals prior to the 1 September. Did  
8 you re-call those to get them tested or destroy them?

9 A. I'm not quite sure that I understand the question but is  
10 it that, okay, the tests were introduced on 14 October  
11 for HIV. Blood collected before that date, which was  
12 still in date, was that tested for HIV before it was  
13 distributed?

14 And I'm pretty sure the answer to that is they  
15 were tested so that after 14 October, no blood in the  
16 blood bank of Edinburgh Royal Infirmary had been -- had  
17 not been tested for HIV. I'm fairly sure that's the  
18 situation.

19 Q. So this is a question in relation to Wessex, and --

20 A. Oh sorry, Wessex.

21 Q. -- and to HCV testing. So the question is, for the  
22 blood and blood products that had been issued from  
23 Wessex prior to 1 September 1991, ie untested --

24 A. -- HCV, yes.

25 Q. -- HCV -- would those have been re-called or could

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1 untested blood have been issued and used from hospitals  
2 post-1 September 1991?

3 A. I cannot actually remember if there was a re-call at  
4 that particular time, and that's why I think I couldn't  
5 exclude the possibility of untested blood being issued  
6 at that time. But I think that's what I said at the  
7 time, so I'm not sure. It's a possibility, distinctly,  
8 that some blood may have been issued that was not --  
9 that had not been tested for HCV, but I can't be certain  
10 of that.

11 Q. We've heard some centres re-called all the blood and  
12 blood products that were sitting in their hospitals, and  
13 so -- that was untested, re-called it and either tested  
14 it or destroyed it; did Wessex do that?

15 A. I cannot recall if that's what happened at Wessex.

16 Q. In relation to products in Wessex that had been made and  
17 were untested prior to 1 September '91, frozen  
18 components that have a long shelf life, were they tested  
19 before they were released?

20 A. That's a very good question about the testing, both for  
21 the HIV and the HCV, because the frozen stuff would have  
22 been still there a year or so after they donated. So  
23 there could be stuff that was collected in  
24 September 1990 that was still in our freezers. And, to  
25 be honest, I cannot recall how those donations were

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1 that point of view the programme achieved its aims. It  
2 may not have achieved the aims of actually banning the  
3 import of American products, but nevertheless ...

4 So that programme was actually very informative to  
5 quite a lot of the people that I was dealing with in  
6 Liverpool.

7 Q. Did you tell your patients directly about the relative  
8 risks of cryoprecipitate versus concentrate?

9 A. Um ... I do not recall specific conversations to that  
10 effect. I think it's highly likely that I would have  
11 done, to explain to those on home programmes why  
12 cryoprecipitate was preferred. But I honestly cannot  
13 say the -- how much of detail I went into with the  
14 patients of that level.

15 I apologise for my lack of memory on that one.  
16 It's an important question, but I can't answer it in any  
17 more detail than I think I probably did.

18 Q. And it may be that this is -- the answer to this  
19 question is the same but I've been asked to ask it, so,  
20 again, did you discuss the relative merits of pool sizes  
21 and the impact on infection risk with your patients?

22 A. Again, that featured in the World in Action programme.  
23 So if that question was asked, I would have answered  
24 about the greater risk potentially from the larger  
25 pooled products, but again, I don't recall specific

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1 handled. So I can't give a satisfactory answer to that  
2 question.

3 I think it could -- it may be possible to check  
4 from colleagues who have retired, who I know are still  
5 around, what their recollection of that particular  
6 experience was, and the other person who might have  
7 an insight is Dr Andrew Herborn, if he's contactable,  
8 and we could do our best to try to contact him.

9 Q. This is returning now to your time in Liverpool. You  
10 said that you thought patients preferred NHS  
11 concentrates because they knew of the risk -- they knew  
12 that the risks were -- that it was a less risky product  
13 than the commercial concentrate. What's the factual  
14 basis for your belief that patients preferred NHS  
15 concentrate for that reason? Did your patients tell you  
16 that or was that an assumption on your part?

17 A. I think some patients would have mentioned it, possibly  
18 in passing.

19 Don't forget that the World in Action programme  
20 of 1970 -- whenever that was, was Granada, and lots of  
21 people in Liverpool would have heard it, so consequently  
22 there was an awareness, certainly among the haemophilic  
23 community in the Liverpool, of that particular  
24 programme, and it did cause them to ask all sorts of  
25 questions about the nature of the products. So from

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1 conversations to that effect.

2 Q. Now you told us that you would tell patients if you  
3 thought that they had contracted non-A, non-B. Would  
4 you also tell them that the illness was due to the  
5 products that had been provided to them for their  
6 medical treatment?

7 A. Yes, I think I would have done. And that also -- also  
8 is for hepatitis B, as I think I said, so our patients  
9 who contracted hepatitis B, I think they or their  
10 parents would have been informed this would have come  
11 from the product which they were given.

12 Q. And the last question I'm going to ask you is, did you  
13 also -- for those patients that you thought had  
14 contracted non-A, non-B, did you also explain the  
15 potential long-term consequences of liver cancer,  
16 cirrhosis and so on?

17 A. I don't think I would have done. I was not particularly  
18 aware of those risks -- I was of hepatitis -- of the  
19 cancer, but not of -- the cancer from hepatitis B  
20 contamination, but I wasn't -- I don't think anybody was  
21 really aware of the long-term consequences of  
22 hepatitis C until Eric Preston published his paper in  
23 1978, and I can't recall any specific questions from the  
24 haemophilia community with regards to that. So I don't  
25 think I would have told them about the long-term risk of

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1 them getting a product contaminated with non-A, non-B.

2 **MS SCOTT:** Sir, those are the questions that I'm going to  
3 ask from the Core Participants.

4 **Questions from SIR BRIAN LANGSTAFF**

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

6 Just one question which comes out of the question  
7 you had early on in this session about confidentiality  
8 and what you said earlier about a description of  
9 a mother as "histrionic", you would accept, would you,  
10 that, a character assessment is not part of the proper  
11 function of a doctor whose job is to treat a patient  
12 medically?

13 **A.** I would agree.

14 **SIR BRIAN LANGSTAFF:** But that must then mean that comments  
15 about how nice a person is or how lively, et cetera, are  
16 unlikely to be of any clinical significance and should  
17 be omitted? Would you be happy with that?

18 **A.** That is correct. That is correct from the -- yes, that  
19 I would say. But, on the other hand, there is such  
20 a thing as developing human relationships and so one  
21 isn't necessarily effective in doing that if one adopts  
22 too objective an approach. But certainly in  
23 documentation, any judgementalism of that nature is  
24 inappropriate, and I actually think that that particular  
25 comment was unjustified and inappropriate.

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1 the whole, so long as it's not overdone and so long as  
2 it's also honest, it is a justifiable approach.

3 **SIR BRIAN LANGSTAFF:** Well, thank you. Thank you for that.

4 That's all that I ask.

5 Ms Scott?

6 **MS SCOTT:** Sir, Dr Boulton's legal representatives don't  
7 have any questions so it just falls to ask Dr Boulton  
8 whether or not he would like to add anything to his  
9 evidence.

10 **A.** Yes, thank you, I would. And I've got it written down,  
11 so I will be reading it out.

12 I'm profoundly sorry and deeply regret that my  
13 professional activities as a doctor during the period  
14 covered by the Inquiry led to the deaths and sufferings  
15 of so many people. In the late 1970s, I was responsible  
16 for the care of haemophiliacs in Merseyside and  
17 prescribed vials of commercially prepared Factor VIII  
18 concentrate, many of which happened to be contaminated  
19 with viruses and led to the development of hepatitis or  
20 AIDS, and sometimes both.

21 Within 10 years or so, many of these people had  
22 died, while others had to cope with the severe morbidity  
23 of chronic infection. AIDS was unknown at that time but  
24 almost certainly some batches of the commercial products  
25 given in the late 1970s were contaminated with AIDS

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1 So we learn as we go along.

2 **SIR BRIAN LANGSTAFF:** Well, you've made that perfectly  
3 clear, and I applaud you for it. The thrust of the  
4 question really is the number of letters which many will  
5 have seen from doctors which say nice things about  
6 a patient but they're not to the patients, they're not  
7 forming a relationship with the patient by doing so.  
8 They are really beside the point when it comes to  
9 medical treatment; is there really any place for them?

10 **A.** Well, I think there is, if it's not meant in a -- that  
11 sort of critical, judgmental way. I mean, doctors  
12 particularly -- or anyone who has face-to-face contact  
13 with people on that sort of medico-social basis, and who  
14 is describing, in a professional context, their  
15 experience with that, is entitled to put a human face  
16 onto the nature of their communications. And that, to  
17 be totally objective, could actually appear to be  
18 heartless and, in itself, therefore have regrettable  
19 consequences.

20 So, philosophically, I think we are dealing with  
21 people who have feelings, whether they're our  
22 co-professionals and, in particular, whether they're the  
23 people we have some responsibility for their care. So,  
24 consequently, putting that human face on our  
25 communications is, I think, an understandable and, on

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1 viruses originating from plasma bought by American  
2 fractionators.

3 On the other hand, potential contamination with  
4 viruses causing hepatitis was well recognised by  
5 professionals including myself, and not just in  
6 commercial products but also from donations to the UK  
7 Blood Transfusion Services. Although from the early  
8 1970s, screening tests were applied to UK blood  
9 donations to prevent the transfusions of blood  
10 contaminated with what was thought to be the most common  
11 source of serum hepatitis (that's hepatitis B), it is  
12 recognised that these tests were unlikely to offer  
13 complete protection, even from hepatitis B, and,  
14 furthermore, that other hepatitis-related viruses,  
15 especially non-A, non-B, could not be detected even when  
16 present even NHS blood.

17 Nevertheless, the professional consensus was that  
18 such infections were usually mild, often asymptomatic,  
19 and short lived, so that the possibility of adverse  
20 consequences were often downplayed when advising the  
21 patients and their parents.

22 I should have done my best to ensure that everyone  
23 who received blood and blood products understood that  
24 there were risks of transfusion-transmitted infections  
25 in the products they were using. Although the degree of

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those risks was unknown.

I was keen to extend the home therapy programme for the haemophiliacs in Merseyside and this was welcomed by the haemophilia community, especially the mothers of affected boys. Mothers, many mothers, on learning that they had carried the defective genes to their sons, felt guilty although such carriage was actually a form of lottery. Nevertheless, many were keen to be trained by me so that they could deal with the consequences of their parentage, and see the palpable relief of pain which would follow their administrations of Factor VIII or Factor IX to their young children. In no way can they be held responsible for the later sufferings of their children.

After I left Liverpool in January 1980, I never saw those people again. Although I note from some of the testimonies that the service to haemophiliacs in Merseyside may not have improved very much, if at all, until substantial developments occurred there under later haemophilia directors. The haemophilia community on Merseyside were great people, and I miss them. But it was proper to let my immediate successors take over from me completely.

I have felt since that I sort of deserted them in never having, for example, to conduct the personal and

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difficult conversations, although I also recognise the part that I played in this tragic saga when I was at Edinburgh, and pay tribute to my Scottish colleagues who tried so hard to improve the testings for transmissible infections, to increase donor awareness, and hence to improve patient safety, as well as their pioneering efforts to inactivate the viruses contaminating the plasma while retaining the biological clotting activity.

The consequences of the contamination of Scottish Factor VIII concentrates revealed in November 1984 were permanent and will never leave the affected patients, their families, myself, my Edinburgh BTS colleagues and the Scottish Haemophilia Directors, and other people who administered the treatments.

I am therefore very pleased that this Inquiry is taking place and hope that those people and their families, who suffered and survived, and the families of those who died, obtain full recognition of their sufferings.

I extend this, of course, to any recipient of UK blood who has suffered from the contamination of that blood. I want no excuses but hope that everyone gets a clear explanation enabling them to develop an adequate sense of closure. Thank you.

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**SIR BRIAN LANGSTAFF:** Well, thank you. What you've given us today has been really most informative, it really has and you haven't sought to make excuses, quite the opposite, in many cases. Perhaps living up to your name, you've been frank.

**A.** (Laughs)

**SIR BRIAN LANGSTAFF:** I hope you'll forgive me for that. But it is particularly useful, I think, for us to see somebody who has had experience from, as it were, both sides of the fence, both in the Transfusion Service but also as a treating clinician, and has had the experience of doing it both in Liverpool and in Edinburgh, and in dealing with blood supplies both in Edinburgh and in Wessex.

So you have the ability to give a comparison to us, which few others have, and I just want to thank you for that.

Now, I'll turn to Ms Scott and ask her what we have in store for us next week.

**MS SCOTT:** Well, sir, we sit again on Tuesday, 8 February. We start at 10.00 with a presentation about Wessex before Dr Boulton arrived in 1990, so the early years of Wessex, which will take us up until 12.00. And then we have the oral evidence, remotely, of Dr Huw Lloyd. He is abroad, and so he -- the plan is for his evidence to

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begin at 1.

**SIR BRIAN LANGSTAFF:** Yes, he's in Canada, I think.

**MS SCOTT:** Yes.

**SIR BRIAN LANGSTAFF:** So we will have -- we start him at 1.00.

**MS SCOTT:** Yes.

**SIR BRIAN LANGSTAFF:** Very well. 10.00, then, on Monday (sic). Thank you again.

**MS SCOTT:** On Tuesday, sir.

**SIR BRIAN LANGSTAFF:** On Tuesday, deary me! It's getting too late in the day, isn't it. But thank you for your staying power too, Dr Boulton.

So until Tuesday, 10.00, goodnight.

(5.17 pm)

(Adjourned until 10.00 am on Tuesday, 8 February 2022)

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(60) go... - hepatitis

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(73) shrugged - straightforward



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<b>W</b> <b>writing</b> [2] 67/20 72/25 <b>written</b> [5] 5/9 156/1 158/16 171/4 183/10 <b>wrong</b> [9] 31/20 55/7 56/14 59/6 85/11 122/24 154/22 155/9 163/9 <b>wrote</b> [9] 35/8 35/11 98/25 99/2 116/13 124/24 148/24 156/5 159/3	143/21 143/25 147/11 150/13 159/2 163/14 163/14 163/16 163/17 168/4 168/12 168/13 168/24 170/14 176/1 176/24 180/7 181/18 183/10 188/2 188/3 188/6 <b>yesterday</b> [2] 79/13 79/15 <b>yet</b> [6] 48/19 119/6 120/6 133/4 143/18 171/15 <b>York</b> [1] 150/15 <b>you</b> [469] <b>you'd</b> [3] 59/17 88/5 155/18 <b>you'll</b> [2] 160/8 187/7 <b>you're</b> [25] 1/9 1/11 1/16 6/14 18/22 34/1 45/8 48/16 53/13 82/3 93/24 94/4 94/9 94/21 96/22 103/14 103/14 106/13 106/14 114/6 125/14 152/10 156/18 166/5 175/3 <b>you've</b> [38] 4/2 8/2 8/2 13/4 21/10 22/3 22/14 24/5 40/15 46/15 48/17 54/5 58/7 58/24 71/11 71/13 82/4 84/4 85/11 86/9 90/12 90/17 100/15 103/18 112/11 115/5 119/1 119/11 134/4 138/13 141/12 143/2 143/10 170/3 170/15 182/2 187/1 187/5 <b>young</b> [9] 13/20 14/7 14/8 33/13 56/4 56/9 61/14 120/25 185/13 <b>your</b> [111] 1/11 1/18 1/22 2/14 3/21 5/12 5/15 7/12 7/12 8/3 9/21 9/22 10/21 12/3 12/8 13/2 15/8 22/22 24/21 25/5 25/5 31/20 31/25 36/5 39/16 45/4 45/6 48/17 49/3 51/20 51/21 53/8 55/9 59/8 59/14 59/20 59/24 61/24 62/12 62/12 66/18 66/18 66/19 67/10 71/1 73/7 73/17 79/19 81/14 83/25 84/4 84/5 84/5 90/13 93/20 94/4 94/12 94/15 100/5 100/16 101/10 101/17 104/18 105/22 107/13 112/13 112/16 112/19 114/2 114/3 114/9 114/13	114/22 115/2 124/19 128/16 129/1 130/22 134/10 141/8 141/21 143/4 143/13 144/4 146/2 149/21 152/1 152/16 155/16 156/7 156/11 156/18 162/16 164/5 164/12 165/2 165/20 169/4 169/5 169/25 170/9 172/15 173/19 178/9 178/14 178/15 178/16 179/7 179/21 187/4 188/11 <b>yourself</b> [2] 1/14 63/3 <b>YouTube</b> [1] 1/19			
<b>Y</b> <b>yeah</b> [9] 6/10 30/7 38/10 68/23 129/2 154/25 155/20 162/11 167/12 <b>year</b> [34] 8/10 18/25 20/13 21/9 23/9 26/10 26/11 26/12 28/23 33/6 33/7 38/12 38/13 43/5 47/6 91/15 91/15 92/18 94/15 99/10 100/2 110/3 110/3 113/7 115/12 134/17 134/20 139/20 140/16 154/18 154/20 155/11 159/18 177/22 <b>years</b> [27] 10/17 11/11 27/1 27/2 29/24 44/10 49/22 64/24 73/8 79/16 80/13 85/16 86/18 111/25 122/11 122/12 134/15 140/1 140/11 146/7 157/19 166/1 166/22 167/16 170/21 183/21 187/22 <b>years'</b> [1] 149/16 <b>yes</b> [89] 1/7 1/7 1/15 3/24 4/1 4/1 4/16 5/6 5/8 5/8 5/11 6/5 6/6 9/23 20/10 22/17 22/24 23/10 24/11 24/21 25/10 26/3 31/23 31/24 34/20 34/20 46/5 48/12 49/1 50/12 50/21 50/21 51/24 52/12 53/14 57/1 59/16 59/17 61/1 81/19 83/19 85/6 87/11 88/11 88/19 90/6 91/3 93/13 93/14 93/21 94/6 94/19 95/16 98/10 99/22 106/17 115/4 116/17 117/21 119/17 119/17 123/16 125/15 129/2 134/24 141/7 143/11		<b>Z</b> <b>Z8</b> [12] 125/17 125/20 126/9 126/10 128/20 128/22 129/14 129/19 130/1 130/3 130/24 132/18			